IN THE MATTER OF: **CASE NO. A-2025-0350**

Blue Sky Med Spa
c/o Dr. Maura Manning
480 S. 3rd St.
Columbus, OH 43215-5702

License No. 02-62001097

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Blue Sky Med Spa (Blue Sky) for the purpose of resolving all issues between the parties relating to the Board investigation of Blue Sky's possession and administration of unapproved dangerous drugs obtained from an unlicensed source, and drug storage, compounding, and recordkeeping violations. Together, the Board and Blue Sky are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.

2. Blue Sky is a licensed Terminal Distributor of Dangerous Drugs under license number 02-62001097.

FACTS

1. The Board initiated an investigation of Blue Sky, Terminal Distributor of Dangerous Drugs license number 02-62001097, related to Blue Sky's possession and administration of unapproved dangerous drugs obtained from an unlicensed source, and drug storage, compounding, and recordkeeping violations.

2. On or about November 5, 2025, the Board sent a Summary Suspension/Notice of Opportunity for Hearing to Blue Sky, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

3. On or about November 10, 2025, Blue Sky, through co-owner Dr. Maura Manning, timely requested an administrative hearing, which was subsequently scheduled for February 2, 2026.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.

2. Blue Sky admits the allegations stated in the Summary Suspension/Notice of Opportunity for Hearing letter dated November 5, 2025, and the Board finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.

3. The Board will lift the summary suspension imposed on Blue Sky's TDDD license number 02-62001097 and reinstate the license immediately upon the effective date of this Agreement.

4. Blue Sky agrees to pay to the Board a monetary penalty in the amount of $25,000. This fine will be attached to your license record and must be paid no later than one year from the effective date of this Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in the cart of the Responsible Person.

5. The Board hereby imposes a written reprimand on Blue Sky's TDDD license, number 02-62001097.

6. Blue Sky agrees that the Responsible Person will (1) attend and successfully complete the Board sponsored Responsible Person 101 Roundtable (one hour) and (2) obtain six hours professional continuing education, to be pre-approved by the Board and which may not also be used for license renewal, and must be in the following topic areas: drug storage and handling, regulatory compliance and/or law/ethics. The continuing education must be completed within six months from the effective date of this Agreement. Copies of completed CEs must be e-mailed to legal@pharmacy.ohio.gov.

7. Blue Sky agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.

8. Blue Sky agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Blue Sky of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement

action related to any licenses granted to Blue Sky by the Board and will NOT discharge Blue Sky from any obligation under the terms of this Agreement.

9. Blue Sky agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

10. Blue Sky understands that it has the right to be represented by counsel for review and execution of this agreement.

11. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Blue Sky will operate.

12. Blue Sky explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.

13. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.

14. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.

15. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.

16. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.

17. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

Dr. Maura Manning

Dr. Maura Manning, on behalf of,
Blue Sky Med Spa, Respondent

01/08/2026
Date of Signature

Todd Newkirk, Attorney for Respondent

1/8/26
Date of Signature

Jeff Huston

Jeff Huston, RPh, President,
Ohio Board of Pharmacy

01.08.2026
Date of Signature

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 11/5/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

SUMMARY SUSPENSION/NOTICE OF OPPORTUNITY FOR HEARING
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE

IN THE MATTER OF: **CASE NO. A-2025-0350**

Blue Sky Med Spa **License No. 02-62001097**
c/o Dr. Maura Manning
480 S. 3rd St.
Columbus, OH 43215-5702

November 5, 2025

Dear Blue Sky Med Spa and Dr. Maura Manning:

You are hereby notified, in accordance with Section 119.07 of the Ohio Revised Code (ORC), the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Blue Sky Med Spa's license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Sections 4729.57 and 4729.571 of the Ohio Revised Code.

Furthermore, the Board finds that based upon the facts set forth in the Allegations Section, there is clear and convincing evidence of a danger of immediate and serious harm to others due to Blue Sky Med Spa's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Blue Sky Med Spa's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.54 and 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Further, pursuant to Section 4729.55(E), the Board shall refuse to issue a future license to an applicant for a TDDD if the applicant, or any agent (including any owner or responsible person) or employee of the applicant, has been found to have violated any of the specified laws identified therein or any rule of the board, absent proof of adequate safeguards assuring prevention of a recurrence of the violation. Additionally, Section 4729.57 of the Ohio Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or $1,000 if the acts committed have not been classified as an offense by the ORC.

2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs

3. Blue Sky Med Spa, located at 480 3rd St., Columbus, Ohio 43215-5702, is a licensed TDDD under license number 02-62001097, co-owned by Monna Manning and Dr. Maura Manning [Ohio Medical Board license number 35.077714] who is listed as the Responsible Person.

ALLEGATIONS

1. On or about October 8, 2025, the Board conducted an inspection at Blue Sky Med Spa, a prescriber clinic licensed by the Board (TDDD 02-62001097). Responsible person and co-owner Dr. Maura Manning and co-owner Monna Manning were present during the inspection.

2. During the inspection, the following adulterated dangerous drugs intended for injection were located in the active drug stock. The drugs were purchased from Alpha BioMed, which is an entity that is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration:

    a. Two (2) unopened vials containing white powder, labeled GLP-1 S 20mg/vial "Physician Use Only" (purported semaglutide);

    b. Four (4) unopened vials containing white powder, labeled GLP-1 S 10mg/vial "Physician Use Only" (purported semaglutide);

    c. Three (3) unopened vials containing white powder, labeled GLP-1 R 24mg/vial "Physician Use Only" (purported retatrutide). NOTE: Retatrutide is a dangerous drug that lacks USP/NF monograph, is not a drug substance that is a component of an approved drug, and does not appear on the approved 503A bulk drug substances list.

    d. Four (4) unopened vials containing white powder, labeled 2X Blend CJC-1295 No DAC/Ipamorelin 5mg/5mg/vial "Physician Use Only". NOTE: these drugs are not approved by the FDA and are not permitted to be compounded because they lack USP/NF monograph, are not components of an approved drug, and do not appear on the 503A bulk drug substances list. They currently only appear on the FDA's Substances Nominated for the 503A Bulk Drug Substances List in Category 2.

3. Purchase records showed that from May 22, 2025, to September 30, 2025, the clinic purchased from Alpha BioMed a total of forty-nine (49) vials of adulterated dangerous drugs intended for injection:

    a. 2X Blend CJC-1295 No DAC (5mg)/Ipamorelin (5mg) – 8 vials

b. GHK-Cu (100mg) – 2 vials

c. Reta GLP-3 (24mg) – 4 vials

d. Sema GLP-1 (20mg) – 4 vials

e. GLP-1 S (20mg) – 9 vials

f. GLP-1 S (10mg) – 4 vials

g. GLP-1 R (24mg) – 16 vials

h. GLOW GHK-CU (45mg)/BPC-157 (10mg)/TB500 (10mg) – 2 vials. NOTE: GLOW is not an FDA-approved drug.

4. Clinic administration records show the following:

   a. Administration records for GLP-1 S identify seventy (70) administrations to seven (7) separate patients from June 6, 2025, through October 8, 2025.

   b. Administration records for GLP-3 identify a total of forty (40) self-administrations to Dr. Maura Manning and Monna Manning from May 26, 2025, through October 6, 2025.

   c. Administration records for CJC/IPA 5/5 identify a total of one hundred (100) self-administrations to Dr. Maura manning and Monna Manning from May 26, 2025 through July 30, 2025.

   d. Administration records for GLOW 65 identify a total of sixty (60) self-administrations to Dr. Maura Manning and Monna Manning from September 3, 2025, through October 2, 2025.

5. Multiple warnings requiring written responses were issued for violations, including the following:

   a. The clinic possessed adulterated dangerous drugs purchased from an unlicensed source. See Allegation #2.

   b. The clinic had not conducted a query to confirm organizations they purchase drugs from are licensed with the Ohio Board of Pharmacy. See Allegation #2.

   c. Dangerous drugs, specifically prescription only tretinoin creams, were stored on open shelves in the waiting room, accessible to patients.

   d. The clinic did not maintain a temperature log for the drug storage refrigerator.

e. Multi-dose vials were not properly labeled. The clinic's active drug stock contained numerous open multi-dose vials, none of which were labeled with an open date or beyond use date.

f. Immediate use compounds for IV hydration sometimes include more than 3 drugs.

6. During the October 8, 2025, inspection, Board personnel spoke with co-owners Dr. Maura Manning and Monna Manning, who reported the following information:

a. The facility purchased the vials from Alpha BioMed through their online ordering portal.

b. "GLP-1 S" refers to semaglutide and "GLP-1 R" refers to retatrutide.

c. The last purchase was made on September 30, 2025.

d. Dr. Manning states she was unaware of Alpa BioMed's licensure status with the Board.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.52(A) of the ORC, Prohibited acts, each, a misdemeanor of the fourth degree, each punishable by a maximum penalty of $2,000 if committed by an organization: The following acts and causing them are prohibited:

a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated[1] or misbranded,[2] ORC Section 3715.52(A)(1); and/or

b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or

c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3).

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective April 9, 2025, Selling, purchasing, distributing, or delivering dangerous or investigational drugs – No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, punishable by a maximum penalty of $5,000 if committed by an organization.

[1] ORC Section 3715.63 – When drug or device is adulterated.
[2] ORC Section 3715.64 – Misbranded drug or device.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, Verification of license prior to transactions – Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, Verification of licensure prior to sale or purchase, each violation punishable by a maximum penalty of $1,000:

    a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:

        i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or

        ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and/or

    b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).

5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-06 of the OAC, as effective March 1, 2019, Storage of adulterated drugs, each violation punishable by a maximum penalty of $1,000:

    a. To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, OAC Rule 4729:5-3-06.

6. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021, Security, control and storage of dangerous drugs, each violation punishable by a maximum penalty of $1,000:

    a. The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-03(A); and/or

    b. During non-business hours, non-controlled dangerous drugs shall be stored in an area secured by a physical barrier with suitable locks, which may include a substantially

constructed cabinet, locked room, or secured facility. During normal business hours, non-controlled dangerous drugs shall not be stored in areas where members of the public are not supervised by individuals authorized to administer such drugs, OAC Rule 4729:5-19-03(I); and/or

c. All areas where dangerous drugs and devices are stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

   i. Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

      1. Temperature logs with, at a minimum, daily observations, OAC Rule 4729:5-19-03(K)(1)(a); or

      2. A temperature monitoring system capable of detecting and alerting staff of a temperature excursion, OAC Rule 4729:5-19-03(K)(1)(b); and/or

   ii. The terminal distributor shall develop and implement policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs, OAC Rule 4729:5-19- 03(K)(2); and/or

d. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and/or

e. Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(M).

7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, General security requirements, each violation punishable by a maximum penalty of $1,000:

   a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

8. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, Record Keeping, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19-04(A); and/or

b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and/or

c. Records of temperature control monitoring described in paragraph (K)(1) of rule 4729:5-19-03 of the Administrative Code shall include any of the following:

   i. For temperature logs, either:

      1. The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(a); and/or

      2. For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded, OAC Rule 4729:5-19-04(C)(1)(b); and/or

   ii. For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion, OAC Rule 4729:5-19-04(C)(2); and/or

d. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years, OAC Rule 4729:5-19-04(J).

9. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, Non-Hazardous Drugs Compounded by a Prescriber, each violation punishable by a maximum penalty of $1,000:

   a. Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(B); and/or

   b. For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

      i. Rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-03(C)(1); or

      ii. United States pharmacopeia chapter <797>, OAC Rule 4729:7-3-03(C)(2); and/or

c. The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-03(E)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-03(E)(2); and/or

iii. Compliance with Title 21 U.S. Code section 353a (November 27, 2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-03(E)(3); and/or

iv. Ensuring documented training and competency of compounding personnel, OAC Rule 4729:7-3-03(E)(4); and/or

v. Ensuring environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and/or

vi. Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished, OAC Rule 4729:7-3-03(E)(6); and/or

vii. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-03(E)(7); and/or

viii. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-3-03(E)(8); and/or

ix. Ensuring aseptic technique for the preparation of all sterile compounded drugs, OAC Rule 4729:7-3-03(E)(9).

10. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, Immediate-use, sterile non-hazardous drugs compounded by a prescriber, each violation punishable by a maximum penalty of $1,000:

a. The responsible person of a facility where a prescriber is engaged in the compounding of immediate-use, sterile non-hazardous dangerous drug preparations in accordance with paragraph (B) of this rule shall be responsible for all the following:

i. Developing and implementing appropriate compounding procedures, OAC Rule 4729:7-3-04(A)(1); and/or

ii. Overseeing facility compliance with this rule, OAC Rule 4729:7-3-04(A)(2); and/or

iii. Compliance with Title 21 U.S.C. section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules, OAC Rule 4729:7-3-04(A)(3); and/or

iv. Ensuring that compounded drug preparations maintain quality and sterility until administered, OAC Rule 4729:7-3-04(A)(5); and/or

v. Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(A)(6); and/or

b. Immediate-use, sterile compounded drug preparations are exempt from the requirements in rule 4729:7-3-03 of the Administrative Code if all the following criteria are met:

i. The beyond-use date for an immediate-use compounded drug preparation is as follows:

1. Except as provided in paragraph (B)(4)(b) of this rule, no later than six-hours following preparation of the drug, OAC Rule 4729:7-3-04(B)(4)(a); and/or

ii. Unless administered immediately, the compounded drug preparation shall bear a label listing all the following:

1. Except for preparations compounded in accordance with paragraph (G)(2) of this rule, patient identification information, including the patient's first and last name, OAC Rule 4729:7-3-04(B)(6)(a); and/or

2. The name and quantity of each ingredient, OAC Rule 4729:7-3-04(B)(6)(b); and/or

3. The beyond-use date and time prepared, OAC Rule 4729:7-3-04(B)(6)(c); and/or

4. The name or initials of the person who prepared the compounded drug preparation, OAC Rule 4729:7-3-04(B)(6)(d); and/or

iii. Immediate-use compounded drug preparations are for administration only and shall not be personally furnished by a prescriber, OAC Rule 4729:7-3-04(B)(7); and/or

c. Unless administered within one-hour of preparation, sterile compounded drug preparations for immediate-use shall be prepared in a designated clean medication area that is not adjacent to areas where potentially contaminated or hazardous items are placed. Such an area shall be limited to compounding personnel and shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Cleaning and disinfection agents must be selected and used with careful consideration of compatibility, effectiveness, and inappropriate or toxic residues. Cleaning and disinfecting shall occur before compounding is performed. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile seventy per cent isopropyl alcohol, which is allowed to dry before compounding begins, OAC Rule 4729:7-3-04(C); and/or

d. Preparations that are deemed category two, medium-risk level, or high-risk level compounded drug preparations as defined in United States pharmacopeia chapter <797> shall not be prepared as immediate-use, OAC Rule 4729:7-3-04(D); and/or

e. Preparations that do not meet all the requirements listed in paragraph (B) of this rule shall comply with the requirements in rule 4729:7-3-03 of the Administrative Code, OAC Rule 4729:7-3-04(E); and/or

f. Records of drug compounding shall be maintained pursuant to rule 4729:7-3-06 of the Administrative Code, OAC Rule 4729:7-3-04(H); and/or

g. For all compounded drugs prepared pursuant to this rule, a prescriber shall:

    i. Inspect and approve the compounding process, OAC Rule 4729:7-3-04(L)(1); and/or

    ii. Except as provided in paragraph (M) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-04(L)(2); and/or

h. The requirements of paragraph (M)(2) of this rule do not apply to either of the following:

    i. A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(1); or

    ii. A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (N) of this rule, OAC Rule 4729:7-3-04(M)(2); and/or

i. All the following are required to administer a compounded drug preparation in accordance with paragraphs (M)(1) and (M)(2) of this rule:

    i. Verify the accuracy of:

        1. Drug name, OAC Rule 4729:7-3-04(N)(3)(a); and

        2. Drug strength and dosage form, OAC Rule 4729:7-3-04(N)(3)(b); and

        3. Drug volume, OAC Rule 4729:7-3-04(N)(3)(c); and

        4. Rate of administration, OAC Rule 4729:7-3-04(N)(3)(d); and

        5. Route of administration, OAC Rule 4729:7-3-04(N)(3)(e); and

6. Expiration dates/times, OAC Rule 4729:7-3-04(N)(3)(f); and

7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-04(N)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-04(N)(4).

11. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-3-06 of the OAC, as effective March 31, 2021, Record Keeping, each violation punishable by a maximum penalty of $1,000:

a. The responsible person shall maintain the following records relating to the compounding of dangerous drugs:

i. All drug orders and records, including logs, relating to the compounding of drugs. Such drug orders and records may be retained by any process providing an exact duplicate of the original order or prescription, OAC Rule 4729:7-3-06(A)(1); and/or

ii. Records of each drug compounded shall, at a minimum, include all the following:

1. The full name of the patient, unless compounded in accordance with paragraph (G)(2) of rule 4729:7-3-04 of the Administrative Code, OAC Rule 4729:7-3-06(A)(3)(a); and/or

2. Name, strength, and dosage form of the compounded drug, OAC Rule 4729:7-3-06(A)(3)(b); and/or

3. Name and quantity of each ingredient, OAC Rule 4729:7-3-06(A)(3)(c); and/or

4. If a controlled substance, the disposition of unused drug(s) and amount, OAC Rule 4729:7-3-06(A)(3)(d); and/or

5. Date and time of preparation, OAC Rule 4729:7-3-06(A)(3)(e); and/or

6. Beyond-use date of the compounded drug, OAC Rule 4729:7-3-06(A)(3)(f); and/or

7. The positive identification of the personnel responsible for compounding the drug, OAC Rule 4729:7-3-06(A)(3)(g); and/or

8. The positive identification of either of the following:

a. Person or persons performing medication validation prior to the compounded drug being administered, OAC Rule 4729:7-3-06(A)(3)(h)(i); and/or

b. The prescriber personally furnishing the compounded drug, OAC Rule 4729:7-3-06(A)(3)(h)(ii).

12. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible person – terminal distributor, as effective April 25, 2022, each punishable by a maximum penalty of $1,000:

    a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or

    b. The responsible person shall be responsible for ensuring the terminal distributor of dangerous drugs requirements are met, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(E)(6).

13. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, as effective October 3, 2023, TDDD license requirements, each violation punishable by a maximum penalty of $1,000:

    a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or

    b. A… licensed health professional authorized to prescribe drugs… will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or

    c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C).

14. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023, each violation punishable by a maximum penalty of $1,000:

    a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or

    b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or

    c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or

d. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or

e. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).

15. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of $1,000:

    a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or

    b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or

    c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, OAC Rule 4729:5-4-01(B)(4); and/or

    d. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this rule prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor, OAC Rule 4729:5-4-01(B)(6); and/or

    e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, OAC Rule 4729:5-4-01(B)(7); and/or

    f. Commission of an act that constitutes a misdemeanor that is related to, or committed in, the person's professional practice, OAC Rule 4729:5-4-01(B)(18); and/or

    g. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(23).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will <u>not</u> be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and

examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the Ohio Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE OHIO BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/zas/jrn

cc: Kimberly Anderson, Ohio Medical Board, at Kimberly.Anderson@med.ohio.gov.