IN THE MATTER OF: **CASE NO. A-2025-0269**

Aesthetics By Kayla **License No. 02-64000607**
c/o Kayla Shane, APRN
3496 Snouffer Road, Ste 14
Columbus, Ohio 43235

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Aesthetics By Kayla for the purpose of resolving all issues between the parties relating to the Board investigation of Aesthetics By Kayla's possession of non-FDA approved drugs obtained from an unlicensed entity. Together, the Board and Aesthetics By Kayla 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. Aesthetics By Kayla is a licensed Terminal Distributor of Dangerous Drugs under license number 02-64000607, located at 3496 Snouffer Road, Ste 14, Columbus, Ohio and lists Kayla Shane, APRN, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Aesthetics By Kayla, Terminal Distributor of Dangerous Drugs license number 02-64000607, related to Aesthetics By Kayla's possession of non-FDA approved drugs obtained from an unlicensed entity.

2. On or about September 10, 2025, the Board sent a Notice of Opportunity for Hearing to Aesthetics By Kayla, 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 September 11, 2025, Aesthetics By Kayla timely requested an administrative hearing. This matter was settled via this Agreement in lieu of an administrative hearing.

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. Aesthetics By Kayla admits the allegations stated in the Summary Suspension/Notice of Opportunity for Hearing letter dated September 10, 2025; however, 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 Aesthetics By Kayla's TDDD, license number 02-64000607, and reinstate the license upon the effective date of this Agreement.

4. Aesthetics By Kayla agrees to pay to the Board a monetary penalty the amount of $25,000. $20,000 of this monetary penalty shall be stayed upon the following conditions:

    a. Aesthetics By Kayla pays $5,000 to the Board no later than twelve (12) months from the effective date of this Agreement; and

    b. Aesthetics By Kayla does not have any additional violations of rule or law, as listed in Term 8 of this Agreement, for no less than twelve (12) months from the effective date of this Agreement.

    c. The remaining balance will be due immediately if Aesthetics By Kayla does not meet conditions 4(a) and 4(b), as outlined above.

    d. This monetary penalty will be attached to the license record for Aesthetics By Kayla. To pay this fine, a representative for Aesthetic Essentials must login to www.elicense.ohio.gov and process the items in the cart.

5. The Board hereby imposes a written reprimand on Aesthetics By Kayla's TDDD license, number 02-64000607.

6. Aesthetics By Kayla agrees that the current Responsible Person must complete the Board sponsored Responsible Person 101 Roundtable (1 hour) and six hours of approved continuing education (0.6 CEUs) in the topics of drug storage and handling, regulatory compliance and/or law/ethics. The Roundtable and 0.6 CEUs must be completed within six months from the effective date of this Agreement. Copies of completed CEUs must be e-mailed to legal@pharmacy.ohio.gov.

7. Aesthetics By Kayla 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. Aesthetics By Kayla 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 Aesthetics By Kayla 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 Aesthetics By Kayla by the Board and will NOT discharge Aesthetics By Kayla from any obligation under the terms of this Agreement.

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

10. Aesthetics By Kayla 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 Aesthetics By Kayla will operate.

12. Aesthetics By Kayla 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.

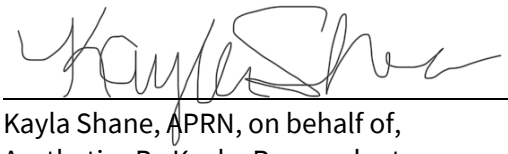
16. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain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

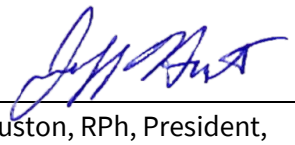


Kayla Shane, APRN, on behalf of,
Aesthetics By Kayla, Respondent

10/02/2025
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature



10.02.2025

Jeff Huston, RPh, President,
Ohio Board of Pharmacy

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: 9/10/2025
-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 NOS. A-2025-0269**

Aesthetics By Kayla
c/o Kayla Shane
3496 Snouffer Road, Ste 14
Columbus, Ohio 43235

License No. 02-64000607

September 10, 2025

Dear Aesthetics By Kayla:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Aesthetics By Kayla'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 Aesthetics By Kayla's method used to possess or distribute dangerous drugs, and the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor. As such, the Board summarily suspends Aesthetics By Kayla's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code (ORC) 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. Additionally, Section 4729.57 of the 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. Pursuant to Section 4729.571(A)(2) 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 of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor.

4. Aesthetics By Kayla, located at 3496 Snouffer Road, Ste 14, Columbus, Ohio, is a licensed TDDD under license number 02-64000607 and lists Kayla Shane, NP, [Ohio Board of Nursing license number APRN.CNP.0028812] as the Responsible Person.

ALLEGATIONS

1. On or about September 4, 2025 a Board Specialist (Board inspector) conducted an inspection at Aesthetics By Kayla, located at 3496 Snouffer Road, Ste 14, Columbus, Ohio. The Responsible Person, Kayla Shane, NP, was present.

2. The inspection revealed Aesthetics By Kayla was in possession of illegal drugs purchased from PureRx. PureRx 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. Drugs purchased from PureRx are misbranded and adulterated. The following drugs purchased from PureRx were observed:

    a. Four unopened vials of "GLP-1 S injection," 10 mg/vial, labeled "For use as directed by Physician Only".

        i. Note: These vials contained white powder and purported to be Semaglutide.

    b. Two unopened vials of "GLP-1 T injection," 30 mg/vial, labeled "For use as directed by Physician Only".

        i. Note: These vials contained white powder and purported to be Tirzepatide.

    c. One opened and reconstituted vial of "GLP-1 S injection," 10 mg/vial, labeled "For use as directed by Physician Only".

    d. One opened and reconstituted vial of "GLP-1 T injection," 30 mg/vial, labeled "For use as directed by Physician Only".

3. Records provided to the Board indicated that between November 21, 2024 and August 29, 2025 a total of 34 vials of GLP-1 S, purporting to be semaglutide, and 35 vials of GLP-1 T, purporting to be tirzepatide, were purchased from PureRx by Aesthetics by Kayla.

4. The inspection conducted on September 4, 2025, resulted in eight warnings requiring written responses, including but not limited to:

    a. Non-controlled dangerous drugs and/or hypodermics were not maintained under appropriate supervision and control.

        i. Observed a drop ceiling with walls that did not extend to the true ceiling.

        ii. Dangerous drugs and hypodermics were displayed on shelves in the patient treatment suite.

    b. Purchased dangerous drugs from unlicensed entity.

        i. Observed vials of “GLP-1 S injection” and “GLP-1 T injection” labeled as “For use as directed by Physician Only” purchased from PureRx, an entity not licensed in any state (see above). These vials were misbranded and adulterated.

        ii. Records were obtained that showed drugs purchased from PureRx; purchases from PureRx occurred from November 2024 to August 2025.

        iii. The clinic did not complete a query of the board's online roster prior to purchase of dangerous drugs at wholesale.

    c. Multi-dose vials were not properly labeled.

        i. Multi-dose vials were not labeled with the date opened and/or the beyond use date (BUD).

    d. Adulterated drugs were comingled in the active drug stock.

        i. Observed several expired drug vials present within the active drug stock (medication cabinet).

        ii. Adulterated drugs from PureRx were comingled with active drug stock (refrigerator and medication cabinet).

    e. Personally furnished drugs were not properly documented.

        i. Personally furnished drugs were labeled but records of personal furnishing were not compliant. There were no readily retrievable records of personally furnished drugs.

        ii. The clinic provided pre-drawn syringes of drug to patients so they could inject themself at home instead of going to the clinic for injections.

    f. Immediate use, sterile non-hazardous prescriber compounding was not compliant.

i. Observed neurotoxins in the refrigerator but the clinic was unable to provide compounding records for neurotoxins.

ii. GLP-1 drugs were compounded and future doses were drawn into syringes for patient distribution. This is not permitted because it is considered repackaging.

g. 503A pharmacy drugs dispensed to Portrait Health were observed.

i. Observed three preparations of Lidocaine/Tetracaine compounded Topical Cream, dispensed by Welcare Pharmacy, San Marcos, CA (a 503A pharmacy and not Ohio licensed) to "Portrait Health."

ii. Drugs compounded by a 503A pharmacy must be patient specific and may not be dispensed to an entity for use on/for multiple patients.

iii. 503A pharmacies must be licensed in Ohio; Welcare Pharmacy is not licensed in Ohio.

h. The clinic maintains a Category III TDDD license but a controlled substance inventory was not completed as required.

5. During the September 4, 2025 inspection, Kayla Shane, NP, the owner and Responsible Person of Aesthetics by Kayla, was interviewed by the Board inspector. The following was stated:

a. She has a business partnership with a company called "Portrait Health" and utilizes their ordering portal to obtain drugs.

b. "GLP-1 S" refers to semaglutide and "GLP-1 T" refers to tirzepatide. She affixes the 2D barcodes to the labels when they arrive at the clinic.

c. Some patients prefer to receive their injections in the clinic. Other patients prefer to have the syringes drawn from the vial and administer the injections themselves at home.

d. She was unaware of PureRx's licensure status with the Board.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.52 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

[1] ORC Section 3715.63 states when a drug or device is adulterated
[2] ORC Section 3715.64 states when a drug or device is misbranded

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); and/or

d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4); and/or

e. The dissemination of any false advertisement, ORC Section 3715.52(A)(5).

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 September 29, 2017 and April 6, 2017, 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, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 3715.68(A) of the ORC, An advertisement of food, drug, device, or cosmetic is false if it is false or misleading in any particular, 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 Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, 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, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, 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.

6. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, 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).

7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 4729.291(A) of the ORC, Drugs personally furnished by prescriber- Except when provided under section 4731.97 of the Revised Code, when a licensed health professional authorized to prescribe drugs personally furnishes drugs to a patient pursuant to division (B) of section 4729.29 of the Revised Code, the prescriber shall ensure that the drugs are labeled and packaged in accordance with state and federal drug laws and any rules and regulations adopted pursuant to those laws. Records of purchase and disposition of all drugs personally furnished to patients shall be maintained by the prescriber in accordance with state and federal drug statutes and any rules adopted pursuant to those statutes, each violation punishable by a maximum penalty of $1,000 if committed by an organization.

8. 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, as effective April 25, 2022, each violation 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).

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

10. 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and/or

    e. Falsely or fraudulently promoting to the public a dangerous drug, except that nothing in this division prohibits a terminal distributor of dangerous drugs from furnishing information concerning a dangerous drug to a health care provider or another licensed terminal distributor; ORC Section 4729.57(B)(6); and/or

    f. 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

    g. 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).

11. 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); and/or

e. 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

f. 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

g. 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

h. 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).

12. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021, 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 environmental control of the compounding areas, OAC Rule 4729:7-3-03(E)(5); and/or

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

vi. 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

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

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

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

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and/or
2. Drug strength and dosage form, OAC Rule 4729:7-3-03(I)(3)(b); and/or
3. Drug volume, OAC Rule 4729:7-3-03(I)(3)(c); and/or
4. Rate of administration, OAC Rule 4729:7-3-03(I)(3)(d); and/or
5. Route of administration, OAC Rule 4729:7-3-03(I)(3)(e); and/or
6. Expiration dates/times, OAC Rule 4729:7-3-03(I)(3)(f); and/or
7. Appearance and physical integrity of the drugs, OAC Rule 4729:7-3-03(I)(3)(g); and/or

ii. Indicate in the compounding record verification was completed, OAC Rule 4729:7-3-03(I)(4); and/or

e. A prescriber shall not compound drug preparations unless a specific patient need exists. Compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited, OAC Rule 4729:7-3-03(J).

13. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, each violation punishable by a maximum penalty of $1,000: 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.

14. 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, each violation punishable by a maximum penalty of $1,000: 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).

15. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-02 of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification, OAC Rule 4729:5-19-02(E)(1).

16. 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, 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. 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

    c. 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).

17. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of Rule 4729:5-19-04(D) of the OAC, as effective February 4, 2021, each violation punishable by a maximum penalty of $1,000: Records of personally furnishing shall contain the name, strength, dosage form, and quantity of the dangerous drugs personally furnished, the name, address and date of birth of the person to whom or for whose use the dangerous drugs were personally furnished, the positive identification of the prescriber personally furnishing the drug, the date the drug is personally furnished and, if applicable, the date the drug is received by the patient or patient's caregiver.

18. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-07 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of $1,000:

    a. Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014), OAC 4729:3-07(A); and/or

    b. In the event a terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory, OAC 4729:3-07(F).

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 not 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/alg/jrn

cc: David Geiger, Ohio Board of Nursing, at: david.geiger@nursing.ohio.gov