-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: 8/6/2025
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

ORDER OF THE OHIO BOARD OF PHARMACY
Case Number A-2025-0143

In The Matter Of:

Pure Bliss Aesthetics and MediSpa
860 W. Emmitt Avenue, Suite 3,
Waverly, OH 45690
License No. 02-60003125

INTRODUCTION

The Matter of Pure Bliss Aesthetics and MediSpa came for hearing on August 4, 2025, before the following members of the Ohio Board of Pharmacy (Board): Jeff Huston, RPh, *Presiding*; Jason George, RPh, Vice President; Trina Buettner, RPh; Mindy Ferris, RPh; Leonard Hubert, *Public Member*; T.J. Grimm, RPh; Rich Miller, RPh; and Christine Pfaff, RPh.

Anthony Buchta, Sr., RPh; Absent.

The Board issued a Notice of Opportunity for Hearing ("Notice") to Pure Bliss Aesthetics and MediSpa on May 22, 2025, via electronic mail, confirmation of receipt requested. Respondent received the Notice on May 22, 2025. Pursuant to Ohio Revised Code (ORC) Section 119.07, Pure Bliss Aesthetics and MediSpa had a right to a hearing if requested within 30 days of mailing. Pure Bliss Aesthetics and MediSpa failed to do so.

The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Leslie Arnold

Respondent's Witnesses:

1. None

State's Exhibits:

1. Notice Letter
2. Inspection Report – 5/9/2025
3. Licensee Response

4. Text Messages 1
5. Text Messages 2
6. Evidence Photos Taken 4/13/2025 (Sealed)
7. List of Medications Seized
8. Evidence Photos Taken by Tewanger 5/9/2025 (Sealed)
9. Evidence Photos Taken by Cologie 5/9/2025 (Sealed)
10. Inspection Report 12/4/2024

FINDINGS OF FACT

After hearing the testimony, observing the demeanor of the witnesses, considering the evidence, and weighing the credibility of each, the Board finds the following to be fact:

1. From on or about April 1, 2025, to on or about May 9, 2025, Board agent(s) conducted undercover order(s), pickup(s), and purchase(s) of tirzepatide, a dangerous drug, from Pure Bliss, located at 860 W. Emmitt Avenue, Waverly, Ohio. The transaction(s) occurred without an evaluation by a prescriber and/or a prescription. A vial(s) was/were provided by non-licensed personnel of Pure Bliss to the agent(s) labeled "TirzeLean 2.5" without a prescription for $120 cash each. Syringes and verbal and written mixing/dosing instructions, which specifically instructed the agent(s) on reconstitution, dosing, and administration of the dangerous drug were provided by non-licensed personnel of Pure Bliss. The tirzepatide was later found to be non-Federal Drug Administration (FDA) approved and to have been purchased from unlicensed entities.

2. On or about May 9, 2025, the Board conducted an inspection at Pure Bliss, located at located at 860 W. Emmitt Avenue, Waverly, Ohio. The following issues were found during the inspection:

    a. No evidence of Pure Bliss conducting an annual wholesale query was found at the time of the inspection.

    b. An expired dangerous drug was found in the refrigerator with active drug stock.

    c. Dangerous drugs are being personally furnished/sold to patients without a valid prescription from a provider.

    d. Hypodermics and dangerous drugs were stored in a room which did not have a lock on the door.

    e. Pure Bliss manually documents the temperature of the refrigerator. There is no documentation of temperature on the days the clinic is closed. A policy regarding refrigeration excursions or storage of food in the refrigerator could not be produced at the time of the inspection.

    f. Two vials of dangerous drugs stored in the refrigerator were not labeled properly. One vial was punctured with no expiration date written on the vial. One vial was punctured with an open date of May 7, 2025, and an expiration date of October 13, 2025.

g. No records of dangerous drugs received, administered, personally furnished, disposed of, sold, or transferred could be produced at the time of inspection. The records were not readily retrievable.

h. Fifty-four (54) vials of tirzepatide, labeled as "TirzeLean," with "For Research Only" were found during the inspection at Pure Bliss. The vials included the following:

   i. Twenty-four (24) vials labeled TirzeLean 2.5- For Research Only.

   ii. Nineteen (19) vials labeled TirzeLean 5- For Research Only.

   iii. Five (5) vials labeled TirzeLean 7.5- For Research Only.

   iv. Three (3) vials labeled TirzeLean 10- For Research Only.

   v. One (1) vial labeled TirzeLean 12.5- For Research Only.

   vi. Two (2) vials labeled TirzeLean 15- For Research Only.

i. Multiple other dangerous drugs were found at Pure Bliss. They included the following vials:

   i. Fifty-seven (57) vials of bacteriostatic water, Rx Only (NDC:0409-3977-01).

   ii. Two (2) vials labeled LIPO-C 10Ml.

   iii. One (1) sealed bottle SLU-PP-332 250 mcg (100 tablet bottle).

3. On or about May 9, 2025, Board agents spoke on the phone with the owner of Pure Bliss, Haley Schackart (Borders). She made the following statements:

   a. Haley Schackart (Borders) admitted to purchasing tirzepatide online without conducting a wholesale license verification check of the supplier.

   b. Haley Schackart (Borders) admitted knowing the tirzepatide came from China.

   c. Haley Schackart (Borders) stated she had been selling the tirzepatide from China to customers for approximately one year.

   d. Haley Schackart (Borders) stated she had the tirzepatide shipped to her house instead of Pure Bliss.

   e. Haley Schackart (Borders) stated she would remove the existing label on the drug vials and would replace them with a label identifying the vial as "TirzeLean" prior to selling them to customers. She stated she did this on advice from the supplier due to "patent" concerns and in an effort to keep the customer from ordering directly and cutting her out.

f. Haley Schackart (Borders) stated she ordered the bacteriostatic water from the same suppliers as she ordered the tirzepatide.

4. On or about May 9, 2025, Board agents spoke on the phone with the Responsible Person of Pure Bliss, Alice Frazier, Doctor of Osteopathic Medicine. She made the following statements:

   a. Dr. Frazier stated she was aware Pure Bliss was selling tirzepatide to patients without them being evaluated by a prescriber and being issued a prescription.

   b. Dr. Frazier stated she thought it was okay for Pure Bliss to sell tirzepatide without a prescription since it could be purchased online by anyone and it had not been reconstituted prior to being sold.

CONCLUSIONS 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. 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

[1] ORC Section 3715.63 states: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:
1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or
2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or
3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or
4. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary, ORC Section 3715.63(A)(5); and/or
5. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

[2] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:
a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or
3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms

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

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

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

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, 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.

3. 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.

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(G) of the ORC, effective October 3, 2023, No licensed terminal distributor of dangerous drugs shall engage in the retail sale or other distribution of dangerous drugs or investigational drugs or products or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor.

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.

6. 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:

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that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

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

   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

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, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as effective April 25, 2022:

   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

   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).

8. Such conduct as set forth in the 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:

   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

   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

   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).

9. Such conduct as set forth in the 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:

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

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

    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

    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

    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

    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).

10. Such conduct as set forth in the 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:

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

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

    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

    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

    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

    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

g. Commission of an act that constitutes a disqualifying offense, regardless of the jurisdiction in which the act was committed, OAC Rule 4729:5-4-01(B)(14); and

h. 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

i. 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).

11. 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:

    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.

        i. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:5-3-06(B).

12. Such conduct as set forth in the 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).

13. Such conduct as set forth in the 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:

    a. During non-business hours, hypodermics 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, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections, OAC Rule 4729:5-19-03(H); and

    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

c. All records relating to the receipt, administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access, OAC Rule 4729:5-19-03(J); and

d. 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

   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

   iii. The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs, OAC Rule 4729:5-19-03(K)(3); and

e. 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

f. 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); and

g. Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(O).

14. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective February 4, 2021:

   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

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

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

      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

   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

d. 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, OAC Rule 4729:5-19-04(D); and

e. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration, and either:

   i. For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug, OAC Rule 4729:5-19-04(E)(1)(a); and

   ii. Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-19-04(E)(2); and

   iii. Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the

requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification, OAC Rule 4729:5-19-04(E)(3); and

f. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F); and

g. 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.

   i. A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board, OAC Rule 4729:5-19-04(J)(1); and

   ii. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-04(J)(2).

DECISION OF THE BOARD

Pursuant to Section 4757.571(A)(1) of the Ohio Revised Code, the Ohio Board of Pharmacy hereby lifts the Summary Suspension Order issued to Pure Bliss Aesthetics and MediSpa on May 22, 2025.

Pursuant to Section 4729.57 of the Ohio Revised Code and Ohio Administrative Code Rule 4729:5-1-01(U), and after consideration of the record as a whole, the Ohio Board of Pharmacy adjudicates the matter of Pure Bliss Aesthetics and MediSpa as follows:

On the basis of the Findings of Fact and Section (1) through (14) of the Conclusions of Law, taken collectively or as individual violations, the Ohio Board of Pharmacy hereby revokes permanently the Terminal Distributor of Dangerous Drugs (TDDD) license, No. 02-60003125, held by Pure Bliss Aesthetics and MediSpa, effective the date of this Order.

The Board finds Pure Bliss Aesthetics and MediSpa and/or its owner Haley Schackart (Borders) may not reapply for a Terminal Distributor of Dangerous Drugs License over which the Board has jurisdiction.

Pursuant to 4729.57 of the Ohio Revised Code, the State of Ohio Board of Pharmacy imposes a monetary penalty in the amount of $90,000.00. This fine will be attached to the license record for Pure Bliss Aesthetics and MediSpa and must be paid no later than 180 days from the effective date of this Order. To pay this fine a representative of Pure Bliss Aesthetics and MediSpa must log in to www.elicense.ohio.gov and process the items in the cart.

Further, the Board hereby grants the State's Motion to Seal the Record in this matter including, but not limited to, all confidential patient health information contained in the record, specifically State's exhibits: 6, 8, and 9.

Jason George moved for Findings of Fact; Mindy Ferris seconded the motion. Motion passed (Yes-7/No-0).

Jason George moved for Conclusions of Law; Mindy Ferris seconded the motion. Motion passed (Yes-7/No-0).

Jason George moved for Action of the Board; Mindy Ferris seconded the motion. Motion passed (Yes-7/No-0).

SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin county. Such notices of appeal shall be filed within fifteen (15) days after the service of the notice of the Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE STATE BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **August 6, 2025**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/jak/jrn

-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: 5/22/2025
-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-2025-0143**

Pure Bliss Aesthetics and MediSpa **License No. 02-60003125**
c/o Haley Schackart (Borders)
860W. Emmitt Avenue, Suite 3
Waverly, Ohio 45690

May 22, 2025

Dear Pure Blis Aesthetics and MediSpa and Haley Schackart (Borders):

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Pure Bliss Aesthetics and MediSpa's (Pure Bliss) 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 Pure Bliss' method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Pure Bliss' 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. Pure Bliss Aesthetics and MediSpa, located at 860 W. Emmitt Avenue, Suite 3, Waverly, Ohio, is a licensed TDDD under license number 02-60003125 and lists Dr. Alice Frazier, DO, [Medical Board of Ohio license number 34.005990] as the Responsible Person. Haley Schackart (Borders) is listed as the owner.

ALLEGATIONS

1. From on or about April 1, 2025, to on or about May 9, 2025, Board agent(s) conducted undercover order(s), pickup(s), and purchase(s) of tirzepatide, a dangerous drug, from Pure Bliss, located at 860 W. Emmitt Avenue, Waverly, Ohio. The transaction(s) occurred without an evaluation by a prescriber and/or a prescription. A vial(s) was/were provided by non-licensed personnel of Pure Bliss to the agent(s) labeled "TirzeLean 2.5" without a prescription for $120 cash each. Syringes and verbal and written mixing/dosing instructions, which specifically instructed the agent(s) on reconstitution, dosing, and administration of the dangerous drug were provided by non-licensed personnel of Pure Bliss. The tirzepatide was later found to be non-Federal Drug Administration (FDA) approved and to have been purchased from unlicensed entities.

2. On or about May 9, 2025, the Board conducted an inspection at Pure Bliss, located at located at 860 W. Emmitt Avenue, Waverly, Ohio. The following issues were found during the inspection:

    a. No evidence of Pure Bliss conducting an annual wholesale query was found at the time of the inspection.

    b. An expired dangerous drug was found in the refrigerator with active drug stock.

    c. Dangerous drugs are being personally furnished/sold to patients without a valid prescription from a provider.

    d. Hypodermics and dangerous drugs were stored in a room which did not have a lock on the door.

    e. Pure Bliss manually documents the temperature of the refrigerator. There is no documentation of temperature on the days the clinic is closed. A policy regarding refrigeration excursions or storage of food in the refrigerator could not be produced at the time of the inspection.

    f. Two vials of dangerous drugs stored in the refrigerator were not labeled properly. One vial was punctured with no expiration date written on the vial. One vial was punctured with an open date of May 7, 2025, and an expiration date of October 13, 2025.

    g. No records of dangerous drugs received, administered, personally furnished, disposed of, sold, or transferred could be produced at the time of inspection. The records were not readily retrievable.

h. Fifty-four (54) vials of tirzepatide, labeled as “TirzeLean,” with “For Research Only” were found during the inspection at Pure Bliss. The vials included the following:

   i. Twenty-four (24) vials labeled TirzeLean 2.5- For Research Only.

   ii. Nineteen (19) vials labeled TirzeLean 5- For Research Only.

   iii. Five (5) vials labeled TirzeLean 7.5- For Research Only.

   iv. Three (3) vials labeled TirzeLean 10- For Research Only.

   v. One (1) vial labeled TirzeLean 12.5- For Research Only.

   vi. Two (2) vials labeled TirzeLean 15- For Research Only.

i. Multiple other dangerous drugs were found at Pure Bliss. They included the following vials:

   i. Fifty-seven (57) vials of bacteriostatic water, Rx Only (NDC:0409-3977-01).

   ii. Two (2) vials labeled LIPO-C 10Ml.

   iii. One (1) sealed bottle SLU-PP-332 250 mcg (100 tablet bottle).

3. On or about May 9, 2025, Board agents spoke on the phone with the owner of Pure Bliss, Haley Schackart (Borders). She made the following statements:

   a. Haley Schackart (Borders) admitted to purchasing tirzepatide online without conducting a wholesale license verification check of the supplier.

   b. Haley Schackart (Borders) admitted knowing the tirzepatide came from China.

   c. Haley Schackart (Borders) stated she had been selling the tirzepatide from China to customers for approximately one year.

   d. Haley Schackart (Borders) stated she had the tirzepatide shipped to her house instead of Pure Bliss.

   e. Haley Schackart (Borders) stated she would remove the existing label on the drug vials and would replace them with a label identifying the vial as “TirzeLean” prior to selling them to customers. She stated she did this on advice from the supplier due to “patent” concerns and in an effort to keep the customer from ordering directly and cutting her out.

   f. Haley Schackart (Borders) stated she ordered the bacteriostatic water from the same suppliers as she ordered the tirzepatide.

4. On or about May 9, 2025, Board agents spoke on the phone with the Responsible Person of Pure Bliss, Alice Frazier, Doctor of Osteopathic Medicine. She made the following statements:

    a. Dr. Frazier stated she was aware Pure Bliss was selling tirzepatide to patients without them being evaluated by a prescriber and being issued a prescription.

    b. Dr. Frazier stated she thought it was okay for Pure Bliss to sell tirzepatide without a prescription since it could be purchased online by anyone and it had not been reconstituted prior to being sold.

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: A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:
1. It consists, in whole or in part, of any filthy, putrid, or decomposed substance, ORC Section 3715.63(A)(1); and/or
2. It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, ORC Section 3715.63(A)(2); and/or
3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health, ORC Section 3715.63(A)(3); and/or
4. It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary, ORC Section 3715.63(A)(5); and/or
5. It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess, ORC Section 3715.63(A)(6).

[2] ORC Section 3715.64 states: A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:
1. Its labeling is false or misleading in any particular, ORC Section 3715.64(A)(1); and/or
2. It is in package form and does not bear a label containing both of the following:
a. In clearly legible form, the name and place of business of the manufacturer, packer, or distributor, ORC Section 3715.64(A)(2)(a); and/or
3. Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms

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, constitutes a violation of section 2925.09(A) of the ORC, Unapproved drugs, No person shall administer, dispense, distribute, manufacture, possess, sell, or use any drug, other than a controlled substance, that is not approved by the United States food and drug administration, or the United States department of agriculture, a felony of the fifth degree, each violation punishable by a maximum penalty of $2,500 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 4729.51(G) of the ORC, effective October 3, 2023, No licensed terminal distributor of dangerous drugs shall engage in the retail sale or other distribution of dangerous drugs or investigational drugs or products or maintain possession, custody, or control of dangerous drugs or investigational drugs or products for any purpose other than the distributor's personal use or consumption, at any establishment or place other than that or those described in the license issued by the state board of pharmacy to such terminal distributor, each violation is a

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that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, ORC Section 3715.64(A)(5); and/or
4. It is an imitation of another drug, ORC Section 3715.64(A)(10)(b); and/or
5. It is offered for sale under the name of another drug, ORC Section 3715.64(A)(10)(c).

misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

6. 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.

7. 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, 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).

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 the 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).

10. Such conduct as set forth in the 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 the 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 disqualifying offense, regardless of the jurisdiction in which the act was committed, OAC Rule 4729:5-4-01(B)(14); and/or

h. 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

i. 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 4729:5-3-06 of the OAC, as effective July 1, 2024, 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.

        i. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:5-3-06(B).

13. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(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).

14. Such conduct as set forth in the 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. During non-business hours, hypodermics 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, hypodermics shall not be stored in areas where members of the public are not supervised by individuals authorized to administer injections, OAC Rule 4729:5-19-03(H); 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 records relating to the receipt, administration, distribution, personal furnishing and sale of dangerous drugs shall be maintained under appropriate supervision and control to restrict unauthorized access, OAC Rule 4729:5-19-03(J); and/or

    d. 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

iii. The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs, OAC Rule 4729:5-19-03(K)(3); and/or

e. 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

f. 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); and/or

g. Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(O).

15. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective February 4, 2021, 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. 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, OAC Rule 4729:5-19-04(D); and/or

e. Records of administration shall contain the name, strength, dosage form, and quantity of the dangerous drugs administered, the name and date of birth of the person to whom or for whose use the dangerous drugs were administered, the date of administration, and either:

   i. For non-controlled substance dangerous drugs: the identification of the health care professional administering the drug, OAC Rule 4729:5-19-04(E)(1)(a); and/or

   ii. Records of dangerous drugs administered which become a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph, OAC Rule 4729:5-19-04(E)(2); and/or

   iii. Records of dangerous drugs administered by a health care professional, acting within the professional's scope of practice, who is not a prescriber shall include documentation of an order issued by a prescriber or protocol authorizing the administration of the drug. An order that is a permanent part of the patient's medical record shall be deemed to meet the requirements of this paragraph. Orders for the administration of controlled substances shall be documented using positive identification, OAC Rule 4729:5-19-04(E)(3); and/or

f. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F); and/or

g. 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.

   i. A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board, OAC Rule 4729:5-19-04(J)(1); and/or

   ii. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-04(J)(2).

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/jak/kll