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

IN THE MATTER OF: **CASE NO. A-2025-0272**

Synergy Primary Care and Wellness **License No. 02-2888100**
4895 Monroe St. #203
Toledo, Ohio 43623

September 10, 2025

Dear Synergy Primary Care and Wellness:

You are hereby notified, in accordance with Section 119.07 of the Ohio Revised Code (ORC), the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Synergy Primary Care and Wellness' 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 Synergy Primary Care and Wellness' 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 Synergy Primary and Wellness' license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.54 and 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Ohio Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or $1,000 if the acts committed have not been classified as an offense by the ORC.

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

3. 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. Synergy Primary Care and Wellness, located at 4895 Monroe St. #203, Toledo, Ohio 43623, is a licensed TDDD under license number 02-2888100 and lists Bushra Ali, M.D. [Ohio Medical Board license number 35.093947CTR] as the Responsible Person and owner.

ALLEGATIONS

1. On or about August 20, 2025, the Board conducted an inspection at Synergy Primary Care and Wellness, ("Synergy"), a prescriber clinic licensed by the Board (TDDD 02-2888100), which is advertised as "Synergy Health and Wellness". Responsible person and owner Dr. Bushra Ali was present during the inspection. During the inspection, the following violations were identified:

    a. The practice possessed illegal dangerous drugs purchased from an unknown source for administration to patients. Specifically, four vials of medication labeled as Botox 100 unit from AbbVie with Turkish language labeling were discovered.

        i. All vial caps had the name Allergan and 100u printed on them. The vials did not contain an NDC number.

        ii. Two vials were sealed and contained a small amount of white residue in the vial and appeared nearly empty.

        iii. Two vials had been opened and reconstituted by Dr. Ali. Dr. Ali stated she could not recall what the vial contents looked like prior to reconstitution.

        iv. Dr. Ali admitted to purchasing the drugs from an aesthetic practice on Facebook, and she refused to reveal the name of the person/business she purchased from.

    b. The practice compounded patient-specific weight loss drugs into single dose syringes and distributed them to other patients. The single dose vials were also used to administer drugs to multiple patients.

2. The inspection conducted on August 20, 2025, resulted in seven warnings requiring written responses and one warning for violations including the following:

    a. Purchased dangerous drugs from unlicensed sources.

        i. The clinic had not conducted an annual query to confirm organizations they purchase drugs from are licensed with the Ohio Board of Pharmacy.

ii. The clinic purchased Botox with foreign language labeling from a source on Facebook.

1. Semaglutide and Tirzepatide were purchased from Monarch Sciences/GLP-1 Sciences, 2901 W. Coast Highway, Newport Beach, CA, which is an unlicensed location.

b. Synergy was acting as a pick-up station but did not meet the requirements of a pick-up station.

i. Multiple patient-specific medications were shipped to the clinic but there is no record of these medications being distributed to the patients to whom they were prescribed.

ii. Synergy did not meet the requirements of a pick-up station as there was no clear and convincing evidence that delivery of the prescription to the patient would result in danger to the public health or safety or result in danger to the patient, as required by rule to act as a pick-up station.

c. Patient-specific prescriptions were used as office stock.

i. The clinic had multiple patient-specific medications in the active drug stock and several vials compounded by 503A pharmacies that lacked a patient label. Drug stock on hand including compounds of semaglutide, tirzepatide, methylcobalamin, NAD+, and Vitamin D were purchased patient specific from 503a compounding pharmacies, however the drugs were removed from the 503a packaging and used by the prescriber as clinic drug stock for all patients.

ii. Dr. Ali admitted to using patient-specific compounded vials of semaglutide and tirzepatide to compound single dose syringes which she then personally furnished to her patients to take home for self-administration.

1. Syringes were not labeled.

2. Syringes were not used within 6 hours of compounding, and they were not prepared compliant with USP 797 to be personally furnished.

3. There were no compounding records or distribution records for this process.

d. Drug storage and security.

i. Non-patient specific testosterone was stored in a cabinet in the prescriber office. Non-prescribers had access to testosterone when prescriber was not on site.

ii. There was no temperature monitoring of the refrigerated drug stock.

iii. Food was observed in the drug storage refrigerator.

iv. There are no records of drug destruction. The clinic would place expired or adulterated drugs in sharps containers for destruction.

e. Multi-dose vials were not properly labeled.

i. The clinic does not date multi-dose vials (MDVs) upon initial puncture. All open, reconstituted, or punctured drug vials were not dated with a date opened or 28-day beyond use date (BUD).

ii. Several single-dose vials (SDVs) were observed opened/used and placed in the refrigerator to use again on other patients. Multiple puncture marks were observed in some single dose vials.

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

i. Expired drugs were observed in active drug stock (oldest expiration 12/2024).

ii. Multiple adulterated drugs (MDV without a puncture date and SDV used as MDV) were observed in active drug stock.

iii. One compounded drug, Methylcobalamin from Hollandale Pharmacy (TDDD 0242000232) did not contain any information for BUD once reconstituted. The drug did not state if the vials were single dose or multiple dose vials and were used as multiple dose by the prescriber.

g. Requested records have not been provided.

i. A request for records was included in the August 20, 2025, inspection report, #18, which included three years of the following records to be provided to the Board within three business days, pursuant to the Ohio Administrative Code, including:

1. Invoices for purchase of all drugs from Brooksville Pharmacy, Monarch Sciences, and GLP-1 Sciences.

2. Any and all information regarding the purchase of Botox from the aesthetic group found on Facebook.

ii. An additional request for records was submitted to the clinic on August 27, 2025, which included three years of the following records to be provided to the Board within three business days (by Tuesday, September 2, 2025), pursuant to the Ohio Administrative Code, including:

1. Invoices/Receipts for all purchases related to wellness/aesthetic practice: Botox, GLP-1, peptides, B12, IV Vitamin Drip, hormone therapy replacement, etc.

2. Administration records for all patients of wellness/aesthetic practice including Botox, GLP-1, peptides, B12, IV Vitamin Drip, hormone therapy replacement, etc.

iii. As of the date of the issuance of this Notice letter, Synergy has failed to submit all records as requested. Regarding the Botox purchased from Facebook, the clinic asserts Dr. Ali deleted her Facebook account and is unable to provide details from the aesthetic group.

POTENTIAL VIOLATIONS OF LAW

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

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

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

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

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.65(A) of the ORC, Application for new drug required, each a misdemeanor of the fourth degree, each punishable by a maximum penalty of $2,000 if committed by an organization:

   a. No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

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 April 9, 2025, Selling, purchasing, distributing, or delivering dangerous or investigational drugs – No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or

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

wholesale distributor, punishable by a maximum penalty of $5,000 if committed by an organization.

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

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

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

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

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

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

6. 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.

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

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

b. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons, OAC Rule 4729:5-3-06(A); and/or

c. 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 . . .. 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).

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

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

b. Except as provided in paragraphs (F) and (G) of this rule, controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe to deter and detect unauthorized access, OAC Rule 4729:5-19-03(B); and/or

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

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

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

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

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

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

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

f. 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).

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

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

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

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

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

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

       i. For temperature logs, either:

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

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

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

d. 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).

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, OAC Rule 4729:5-19-04(J).

11. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, Prescription pick-up station, as effective December 1, 2020, each violation punishable by a maximum penalty of $1,000: The state board of pharmacy may restrict a site from acting as a pick-up station if it has clear and convincing evidence that the activities of the pick-up station present the following:

    a. Danger to the public health or safety, OAC Rule 4729:5-5-14(C)(1); or

    b. Danger to the patient, OAC Rule 4729:5-5-14(C)(2).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

d. 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, constitutes a violation of the following sections of Rule 4729:7-3-04 of the OAC, as effective April 2, 2021, Immediate-use, sterile non-hazardous drugs compounded by a prescriber, each violation punishable by a maximum penalty of $1,000:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16. 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. 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

    f. 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).

17. 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).

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/zas/jrn

cc: Melinda Snyder, State Medical Board of Ohio, at: melinda.snyder@med.ohio.gov