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Steven W. Schierholt, Esq., Executive Dir.
Date: 1/13/2026
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ORDER OF THE OHIO BOARD OF PHARMACY
Case Number A-2025-0176

In The Matter Of:
Enbody
16808 Chagrin Blvd.
Cleveland, Ohio 44120
Revoked License No. 02-60002832

INTRODUCTION

On June 17, 2025, the Ohio Board of Pharmacy (Board) issued a Notice of Opportunity for Hearing/Summary Suspension (Notice) to Enbody (Respondent) via registered email to Enbody's Responsible Person, Tiffinne Perkins, at Enbody's email of record with the Board. The Certified Record of Opening confirmed the Notice was delivered and opened, and Enbody's Responsible Person timely requested a hearing through her attorney. Further, Enbody's statutory agent, Universal Registered Agents, Inc., was served with the Notice and Scheduling Order for the hearing. On January 6, 2026, this matter came before the following members of the Board: Jeff Huston, RPh, *Presiding*; Jason George, RPh, *Vice President*; Anthony Buchta, Sr., RPh; Trina Buettner, RPh; T.J. Grimm, RPh; Mindy Ferris, RPh; Rich Miller, RPh; Thomas Whiston, RPh; and Leonard Hubert, *Public Member*.

A representative from Enbody was not present and Enbody was not represented by counsel. The State of Ohio was represented by Henry Appel, Assistant Attorney General.

SUMMARY OF EVIDENCE

State's Witnesses:

1. Katie Stabi, RPh – Board Compliance Specialist

Respondent's Witnesses:

1. None

State's Exhibits:

1. Notice Letter
2. Request for Hearing
3. Request for Continuance
4. First Scheduling Order
5. Current Scheduling Order

6. Clarification of Ownership
7. Articles of Incorporation
8. Statutory Agent
9. Renewal Application
10. Inspection Report June 2025
11. Impound Report
12. Receipt Log of Medications
13. Certificates of Analysis
14. Chinese Certificates of Analysis
15. Log of Appointments (under seal)
16. Photos of Vials
17. Advertisement on New Day Cleveland

Respondent's Exhibits:

A. None

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. On or about June 5, 2025 a Board Agent and a Board Specialist (Board inspectors) conducted an inspection at Enbody, located at 16808 Chagrin Blvd., Cleveland, Ohio. The Responsible Person, Tiffinne Perkins, APRN, was present. APRN Perkins stated the clinic also employs Epiphany Perkins, Office Manager; Consuela Albright, APRN [Ohio Board of Nursing license number APRN.CNP.020856]; and often has nursing students on rotation.

2. **The inspection revealed Enbody was in possession of illegal drugs. These drugs were purchased from illegitimate entities that are not licensed wholesale drug distributors or drug manufacturers in the United States and do not have Food and Drug Administration (FDA) manufacturer registration. These drugs are counterfeit and/or "For Research Use Only" and these drugs are <u>not</u> FDA-approved medications. The following 413 vials of illegal drugs were found:**

    a. 79 vials labeled by APRN Perkins as, "Tirzepatide 20 mg T013 Received Date: 05/05/2025".

        i. The vials were in 8 boxes. The top box label was in a foreign language (suspected to be Chinese) and stated "Product: Beauty Peptide" with a suspected label quantity of "10".

        ii. Each individual vial was unlabeled and contained a white powder.

iii. Enbody's recordkeeping system stated these vials were from Jiangsu Jitai Peptide; received 5/1/25 and sent for testing on 5/1/25.

1. Perkins stated she sends products to ARL Bio Pharma, Inc for testing.

2. The ARL Bio Pharma Certificate of Analysis Perkins obtained documents the potency result of tirzepatide 22.3315 mg/2 mL.

b. "Tvigoura" in a sealed package labeled in a foreign language (suspected to be Chinese); "received 6/1/2025" was handwritten on the package.

i. APRN Perkins stated there were 100 vials of tirzepatide in the package and it is from Jiangsu Jitai Peptide.

c. 49 vials with APRN Perkins' self-made label stating "S007 Received date 02/27/2025".

i. There were vials in 5 boxes. Each individual vial was unlabeled and contained white powder.

ii. Enbody's recordkeeping system stated these vials were from Jiangsu Jitai Peptide; received 2/27/25 and contained semaglutide 11 mg/2 mL.

iii. An ARL Bio Pharma Certificate of Analysis was not provided.

d. 44 vials with APRN Perkins' self-made label stating "Semaglutide 20 mg S006 Received Date: 03/26/2025"

i. There were vials in 5 boxes. Each individual vial was unlabeled and contained white powder.

ii. Enbody's recordkeeping system stated these vials were from Shaanxi Zebrango Ind Co Ltd and were sent for testing on 11/20/24.

iii. The ARL Bio Pharma Certificate of Analysis Perkins obtained documents the potency result of semaglutide 11.4271 mg/2 mL.

e. 18 vials labeled as "R001".

i. The vials were in two boxes; one box had a label made by APRN Perkins that stated, "Retatrutide 11mg/ml R001 Received 01/31/2025".

ii. Each individual vial was unlabeled and contained white powder.

iii. Each box of vials has a different color cap.

iv. The ARL Bio Pharma Certificate of Analysis Perkins obtained documents the potency result of retatrutide 9.6687 mg / 2 mL with the date tested of 12/13/24.

f. 90 vials as “S10 10 mg/vial 10 vials/box for research use only” and APRN Perkins’ self-made label stating “S008”.

   i. The vials were in 9 boxes. Each individual vial was unlabeled and contained white powder.

   ii. Enbody’s recordkeeping system stated these vials were from Shaanxi Zebrango Ind Co Ltd and were received on 3/27/25.

g. 10 vials with APRN Perkins’ self-made label stating “Liraglutide 5 mg”. The box had no other label.

   i. There vials were in one box. Each individual vial was unlabeled and contained white powder.

h. 9 vials of “NAD500”. The vials were in one box; the box had no other label.

   i. Each individual vial is unlabeled and contains a white powder.

   ii. Enbody’s recordkeeping system stated these vials were from Jiangsu Jitai Peptide and were received on 2/27/25.

i. 1 bottle containing powder with APRN Perkins’ handwritten label stating “1 g oral sema”.

   i. APRN Perkins stated it was oral semaglutide that she ordered in error.

j. 6 vials labeled with Perkins’ self-made label “Cargrillintide Received date: 02/27/2025”.

   i. The vials were in one box. Each individual vial was unlabeled and contained white powder.

   ii. Enbody’s recordkeeping system stated these vials were from Jiangsu Jitai Peptide and were received on 2/27/25.

   iii. APRN Perkins’ assigned lot stated “C010” and the date sent for testing was crossed off. Perkins did not get these vials tested.

k. 7 vials of Bacteriostatic Water.

   i. APRN Perkins stated she ordered these vials from Amazon Office, but could not find her purchase receipt when requested.

      1. The vials were purportedly manufactured by HEPIUS- an unlicensed entity- and do not contain an NDC number.

      2. APRN Perkins stopped using the vials because patients said, “it burned”.

3. The inspection conducted on June 5, 2025, resulted in 6 warnings requiring written responses, including but not limited to:

a. Purchases of dangerous drugs from unlicensed entities.

    i. Enbody purchased dangerous drugs direct from multiple unlicensed manufacturers in China and from the Amazon website.

        1. APRN Perkins stated the HEPIUS Bacteriostatic water was purchased from Amazon (not through the Amazon Pharmacy); however, she was unable to find the purchase history when requested to look for it.

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

b. Enbody was acting as a pick-up station.

    i. Compounded B12 and D3 purchased from a 503A pharmacy were observed. They were prescribed under an employee name but used for other Enbody patients.

    ii. Most drugs on site did not meet the requirement of a pick-up station and this entity was not authorized to act as a pickup 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. Refrigerators used for storage of drugs and devices did not record temperatures daily.

    i. The refrigerator had a thermometer. APRN Perkins stated Enbody maintains a manual log, but it was not available during the inspection. Enbody is only open Wednesday – Saturday and it is unknown how often monitoring of the temperature occurs.

d. Adulterated Drugs.

    i. Observed For Research Use Only Products and Counterfeit Drugs, which were comingled with the additional drug stock.

e. Records of in-office drug administration were not compliant.

    i. Not all drug administrations were documented in Enbody's electronic health record, Charm.

        1. Four vials of cargrillintide were unaccounted for; APRN Perkins stated an employee injected them.

        2. One retatrutide vial was unaccounted for; APRN Perkins stated an employee most likely injected it.

    ii. Note: cargrillintide and retatrutide are <u>not</u>-FDA approved drugs and not allowed to be purchased or administered in the United States.

f. Personally furnished pre-drawn syringes of dangerous drugs

i. APRN Perkins stated she has occasionally provided pre-drawn syringes of peptides to patients when they were unable to come to the clinic for injections.

ii. Records of personally furnishing were not compliant. There were no readily retrievable records of administration and personally furnishing drugs.

4. The following records were provided to Board inspectors:

   a. ARL Bio Pharma, Inc reports for semaglutide lots and tirzepatide lots.

   b. A few certificates of analysis obtained by APRN Perkins from the manufacturers.

      i. Some were in a foreign language

      ii. One certificate stated, “sermaglutide”

      iii. Two stated “it is only supplied as chemical product”.

   c. Enbody’s schedule from March 4, 2025 to June 5, 2025 was provided as the administration record. The following was documented on the schedule:

      i. Visit type: semaglutide 872 and tirzepatide 436

      ii. 156 patient names

      iii. Of the 1,308 visit types, 965 had the status “confirmed.”

      iv. Asia Jackson, Epiphany Perkins, and Staff Nurses were listed as providers.

         1. Note: Asia Jackson and Epiphany Perkins are not licensed healthcare professionals, per APRN Perkins.

5. During the June 5, 2025 inspection, APRN Tiffinne Perkins, Responsible Person of Enbody, was interviewed by Board inspectors. The following was stated by APRN Perkins:

   a. APRN Perkins opened Encore in 2023. Patients come in to receive peptides administered at the medical spa. Perkins has also sent doses home (a maximum of 4 syringes at a time) when patients go on vacation or can’t come in for a couple weeks.

   b. She created her own titration schedule of semaglutide and tirzepatide.

   c. She uses the sterile vials (found at the medical spa) for reconstitution of the drug powder. She uses bacteriostatic saline. Note: an unapproved drug “bacteriostatic water” was observed by Board inspectors.

d. Jiangsu Jitai is her primary drug manufacturer. She stated she found them by doing a lot of research. She went to the FDA website and found a list of FDA-registered vendors; she buys directly from the manufacturer.

    i. Note: Jiangsu Jitai is not recognized as a legitimate drug distributor. It is not a licensed wholesale drug distributor or drug manufacturer in the United States and it does not have FDA manufacturer registration.

e. When asked for invoices or records that come in the drug packages, APRN Perkins stated packing slips are not sent.

f. APRN Perkins showed Board inspectors a sealed package of Tvigoura that recently arrived, as an example.

    i. When asked what is in the package, APRN Perkins explained it was tirzepatide and "All you have to do is take a picture and ask someone to translate it [the package] for you."

    ii. She stated the packages come from China.

    iii. She has every batch tested at ARL.

g. APRN Perkins does not have a registered study or a new drug application.

h. She stated cargrillintide is currently under study; she does not use that drug for patients.

    i. When asked about the four missing vials, she stated a staff member used them. The staff member is not her patient and did not document it in a patient chart. The patient is not a licensed healthcare profession.

    ii. APRN Perkins did not prescribe cargrillintide to Epiphany. She stated Epiphany used the drugs without her permission.

i. When asked about the two missing vials of "R001", suspected to be retatrutide, APRN Perkins stated, "somebody probably used them without my permission or took them." Then she recalled she sent one off for testing, therefore only one vial is missing.

j. When told non-FDA approved drugs cannot be used, APRN Perkins stated lots of non-FDA approved drugs are used, and incorrectly claimed that testosterone is not FDA-approved.

    i. Note: testosterone is an FDA-approved drug; it can be used off label.

k. APRN Perkins stated she was trained by a PharmD from Revelation Pharma. She took a course in USP <795> compounding. When APRN Perkins was informed she is actually performing sterile compounding, which must comply with USP <797> and not non-sterile compounding, which is USP <795>, APRN Perkins stated the PharmD told her it's USP<795> and it's not sterile because it's as clean as possible.

i. Note: No documentation was provided during the inspection to support APRN Perkins received this training.

l. Despite compounding substances to be injected into patients, APRN Perkins incorrectly answered "yes, non-sterile drugs" when asked on the Board's renewal application if Enbody compounds.

i. Note: Enbody performs sterile compounding.

m. Enbody's recordkeeping system was observed to include a "peptide tracker."

i. Manufacturers on the tracker included: Xi'an Frazier Biotech (no FDA registration listed), Jiangsu Jitai Peptide Industry Science and Technology LTD (FDA registration listed 3004986788), Guanyuan Chemical (no FDA registration listed), Shaanxi Zebrango Ind. Co., LTD (FDA registration listed 15636708030)

1. Note: None of these entities have registrations or identifiers on the FDA database (https://dps.fda.gov/decrs). These are all non-FDA registered entities and do not possess licenses to manufacturer or distribute drugs in the United States.

ii. The records did not provide a quantity of how much drug was purchased.

n. APRN Perkins stated she does not receive any packing slips or invoices with the products.

o. APRN Perkins stated "nothing" is required to set up an account with a manufacturer. The [drugs] are on a website and there is a list of products available; they ship directly to her.

p. APRN Perkins stated she asked them [the manufacturers] the other day if they are still FDA registered "because they are really cracking down here in the U.S.".

q. Many of the manufactures provided her with a certificate of analysis; many of these are in a foreign language and English.

r. When asked about the product labeled "for research only," APRN Perkins said Jiangsu Jitai Peptide does not add that label. Shaanxi Zebrango Ind Co Ltd just started adding that label. When she talked on the phone to a rep in China, she told the rep "don't do that" because "we're not allowed to use for research peptides."

s. APRN Perkins asked why the Board is taking all the drugs. A Board inspector explained to her that they are not approved drugs, and they are not from an approved source. APRN Perkins stated, "I understand why you took the ones with the Chinese language on it. But do you think you have a reason to take the other ones that are properly labeled?"

t. When asked why she injected something that said for research use only, APRN Perkins stated "…it was for medical use for a patient. And it said for research. So I took that research peptide and I had it sent to a… to a lab to have it tested. So I'm just trying to understand why it's illegal".

CONCLUSIONS OF LAW

1. Such conduct as set forth in the Findings of Fact, constitutes a violation of section 3715.52 of the ORC, prohibited acts, each, a misdemeanor of the fourth degree. 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

    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 Findings of Fact, 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.

3. Such conduct as set forth in the Findings of Fact, constitutes a violation of section 2925.09(A) of the ORC, 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, each a felony of the fifth degree.

4. Such conduct as set forth in the Findings of Fact, 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.

5. Such conduct as set forth in the Findings of Fact, 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.

[1] ORC Section 3715.63: When a drug or device is adulterated
[2] ORC Section 3715.64: When a drug or device is misbranded

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

    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 Findings of Fact 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.

8. Such conduct as set forth in the Findings of Fact 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).

9. Such conduct as set forth in Findings of Fact 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).

10. Such conduct as set forth in Findings of Fact 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

    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 Findings of Fact 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/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

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

12. Such conduct as set forth in the Findings of Fact constitutes a violation of the following sections of Rule 4729:7-3-03 of the OAC, as effective March 31, 2021:

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

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

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

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

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

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

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

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

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

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

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

d. A prescriber may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-03(F); and

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

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and

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

i. Verify the accuracy of:

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

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

13. Such conduct as set forth in the Findings of Fact constitutes a violation of the following sections of Rule 4729:7-3-06 of the OAC, as effective March 31, 2021:

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

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

ii. All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

1. Complies with the requirements of this rule, OAC Rule 4729:7-3-06(A)(2)(a); and

2. All paper records shall be scanned in full color via technology designed to capture information and reproduce it in an electronic medium presentable and usable to an end user, OAC Rule 4729:7-3-06(A)(2)(b); and

3. Contains security features, such as unique user names and passwords, to prevent unauthorized access, OAC Rule 4729:7-3-06(A)(2)(c); and

4. Contains daily back-up functionality to protect against record loss, OAC Rule 4729:7-3-06(A)(2)(d); and

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

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

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

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

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

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

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

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

8. The positive identification of either of the following:

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

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

b. Records of disposal of compounded drugs, 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, the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:7-3-06(B); and

c. All records maintained in accordance with this rule 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 4729:7-3-06(E)(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 4729:7-3-06(E)(2).

14. Such conduct as set forth in the Findings of Fact constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024: 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.

15. Such conduct as set forth in Findings of Fact, 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: 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).

16. Such conduct as set forth in Findings of Fact constitutes a violation of the following sections of Rule 4729:5-19-02 of the OAC, as effective March 1, 2020:

a. Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification, OAC Rule 4729:5-19-02(E)(1); and

b. Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or

require any additional monetary compensation for the dangerous drug, OAC Rule 4729:5-19-02(K).

17. Such conduct as set forth in Findings of Fact, 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. 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

    b. 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

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

18. Such conduct as set forth in Findings of Fact constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, as effective March 1, 2020:

    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. 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).

19. Such conduct as set forth in Findings of Fact constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, as effective December 1, 2020: 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 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)(1).

DECISION OF THE BOARD

Pursuant to Section 4729.57 of the Ohio Revised Code and Ohio Administrative Code 4729:5-1-01(U), and after consideration of the record as a whole, the findings of fact and violations of law, the pattern of violations and judgment shown by Enbody, the Board hereby adjudicates the matter of Enbody as follows:

> **On the basis of the Findings of Fact and Sections (1) through (19) 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. 02-60002832, held by Enbody, effective the date of this Order.**

The Board finds Enbody 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 $300,000.00 on the revoked license. This fine will be attached to the license record for Enbody and must be paid no later than 180 days from the effective date of this Order. To pay this fine a representative of Enbody 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 portions of the Record in this matter including, but not limited to, all confidential patient health information contained in the record, specifically State's Exhibit 15.

Mr. Grimm moved for Findings of Fact; Mr. George seconded the motion. Motion passed (Yes-8/No-0).

Mr. Grimm moved for Conclusions of Law; Mr. George seconded the motion. Motion passed (Yes-8/No-0).

Mr. Grimm moved for Action of the Board; Mr. George seconded the motion. Motion passed (Yes-8/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: **January 13, 2026**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/alg/jrn

CMRRR: 7003 0500 0002 4314 8454

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

-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: 6/17/2025
-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-2025-0176**

Enbody **License No. 02-60002832**
c/o Tiffinne Perkins
16808 Chagrin Blvd.
Shaker Heights, Ohio 44120

June 17, 2025

Dear Enbody:

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

Furthermore, the Board finds that based upon the facts set forth in the Allegations Section, there is clear and convincing evidence of a danger of immediate and serious harm to others due to Enbody's method used to possess or distribute dangerous drugs, and the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor. As such, the Board summarily suspends Enbody's license as a Terminal Distributor of Dangerous Drugs.

JURISDICTION

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

2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that

there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs.

3. Pursuant to Section 4729.571(A)(2) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method of prescribing dangerous drugs used by a licensed health professional authorized to prescribe drugs who holds a terminal distributor license or practices in the employ of or under contract with a terminal distributor.

4. Enbody, located at 16808 Chagrin Blvd., Cleveland, Ohio, is a licensed TDDD under license number 02-60002832 and lists Tiffinne Perkins, APRN, [Ohio Board of Nursing license number APRN.CNP.0031476] as the Responsible Person.

ALLEGATIONS

1. On or about June 5, 2025 a Board Agent and a Board Specialist (Board inspectors) conducted an inspection at Enbody, located at 16808 Chagrin Blvd., Cleveland, Ohio. The Responsible Person, Tiffinne Perkins, APRN, was present. APRN Perkins stated the clinic also employs Epiphany Perkins, Office Manager; Consuela Albright, APRN [Ohio Board of Nursing license number APRN.CNP.020856]; and often has nursing students on rotation.

2. **The inspection revealed Enbody was in possession of illegal drugs. These drugs were purchased from illegitimate entities that are not licensed wholesale drug distributors or drug manufacturers in the United States and do not have Food and Drug Administration (FDA) manufacturer registration. These drugs are counterfeit and/or "For Research Use Only" and these drugs are <u>not</u> FDA-approved medications. The following 413 vials of illegal drugs were found:**

    a. 79 vials labeled by APRN Perkins as, "Tirzepatide 20 mg T013 Received Date: 05/05/2025".

        i. The vials were in 8 boxes. The top box label was in a foreign language (suspected to be Chinese) and stated "Product: Beauty Peptide" with a suspected label quantity of "10".

        ii. Each individual vial was unlabeled and contained a white powder.

        iii. Enbody's recordkeeping system stated these vials were from Jiangsu Jitai Peptide; received 5/1/25 and sent for testing on 5/1/25.

            1. Perkins stated she sends products to ARL Bio Pharma, Inc for testing.

            2. The ARL Bio Pharma Certificate of Analysis Perkins obtained documents the potency result of tirzepatide 22.3315 mg/2 mL.

    b. "Tvigoura" in a sealed package labeled in a foreign language (suspected to be Chinese); "received 6/1/2025" was handwritten on the package.

i. APRN Perkins stated there were 100 vials of tirzepatide in the package and it is from Jiangsu Jitai Peptide.

c. 49 vials with APRN Perkins' self-made label stating "S007 Received date 02/27/2025".

i. There were vials in 5 boxes. Each individual vial was unlabeled and contained white powder.

ii. Enbody's recordkeeping system stated these vials were from Jiangsu Jitai Peptide; received 2/27/25 and contained semaglutide 11 mg/2 mL.

iii. An ARL Bio Pharma Certificate of Analysis was not provided.

d. 44 vials with APRN Perkins' self-made label stating "Semaglutide 20 mg S006 Received Date: 03/26/2025"

i. There were vials in 5 boxes. Each individual vial was unlabeled and contained white powder.

ii. Enbody's recordkeeping system stated these vials were from Shaanxi Zebrango Ind Co Ltd and were sent for testing on 11/20/24.

iii. The ARL Bio Pharma Certificate of Analysis Perkins obtained documents the potency result of semaglutide 11.4271 mg/2 mL.

e. 18 vials labeled as "R001".

i. The vials were in two boxes; one box had a label made by APRN Perkins that stated, "Retatrutide 11mg/ml R001 Received 01/31/2025".

ii. Each individual vial was unlabeled and contained white powder.

iii. Each box of vials has a different color cap.

iv. The ARL Bio Pharma Certificate of Analysis Perkins obtained documents the potency result of retatrutide 9.6687 mg / 2 mL with the date tested of 12/13/24.

f. 90 vials as "S10 10 mg/vial 10 vials/box for research use only" and APRN Perkins' self-made label stating "S008".

i. The vials were in 9 boxes. Each individual vial was unlabeled and contained white powder.

ii. Enbody's recordkeeping system stated these vials were from Shaanxi Zebrango Ind Co Ltd and were received on 3/27/25.

g. 10 vials with APRN Perkins' self-made label stating "Liraglutide 5 mg". The box had no other label.

i. There vials were in one box. Each individual vial was unlabeled and contained white powder.

h. 9 vials of "NAD500". The vials were in one box; the box had no other label.

i. Each individual vial is unlabeled and contains a white powder.

ii. Enbody's recordkeeping system stated these vials were from Jiangsu Jitai Peptide and were received on 2/27/25.

i. 1 bottle containing powder with APRN Perkins' handwritten label stating "1 g oral sema".

i. APRN Perkins stated it was oral semaglutide that she ordered in error.

j. 6 vials labeled with Perkins' self-made label "Cargrillintide Received date: 02/27/2025".

i. The vials were in one box. Each individual vial was unlabeled and contained white powder.

ii. Enbody's recordkeeping system stated these vials were from Jiangsu Jitai Peptide and were received on 2/27/25.

iii. APRN Perkins' assigned lot stated "C010" and the date sent for testing was crossed off. Perkins did not get these vials tested.

k. 7 vials of Bacteriostatic Water.

i. APRN Perkins stated she ordered these vials from Amazon Office, but could not find her purchase receipt when requested.

1. The vials were purportedly manufactured by HEPIUS- an unlicensed entity- and do not contain an NDC number.

2. APRN Perkins stopped using the vials because patients said, "it burned".

3. The inspection conducted on June 5, 2025, resulted in 6 warnings requiring written responses, including but not limited to:

a. Purchases of dangerous drugs from unlicensed entities.

    i. Enbody purchased dangerous drugs direct from multiple unlicensed manufacturers in China and from the Amazon website.

        1. APRN Perkins stated the HEPIUS Bacteriostatic water was purchased from Amazon (not through the Amazon Pharmacy); however, she was unable to find the purchase history when requested to look for it.

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

b. Enbody was acting as a pick-up station.

    i. Compounded B12 and D3 purchased from a 503A pharmacy were observed. They were prescribed under an employee name but used for other Enbody patients.

    ii. Most drugs on site did not meet the requirement of a pick-up station and this entity was not authorized to act as a pickup 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. Refrigerators used for storage of drugs and devices did not record temperatures daily.

    i. The refrigerator had a thermometer. APRN Perkins stated Enbody maintains a manual log, but it was not available during the inspection. Enbody is only open Wednesday – Saturday and it is unknown how often monitoring of the temperature occurs.

d. Adulterated Drugs.

    i. Observed For Research Use Only Products and Counterfeit Drugs, which were comingled with the additional drug stock.

e. Records of in-office drug administration were not compliant.

    i. Not all drug administrations were documented in Enbody’s electronic health record, Charm.

        1. Four vials of cargrillintide were unaccounted for; APRN Perkins stated an employee injected them.

        2. One retatrutide vial was unaccounted for; APRN Perkins stated an employee most likely injected it.

ii. Note: cargrillintide and retatrutide are not-FDA approved drugs and not allowed to be purchased or administered in the United States.

f. Personally furnished pre-drawn syringes of dangerous drugs

i. APRN Perkins stated she has occasionally provided pre-drawn syringes of peptides to patients when they were unable to come to the clinic for injections.

ii. Records of personally furnishing were not compliant. There were no readily retrievable records of administration and personally furnishing drugs.

4. The following records were provided to Board inspectors:

a. ARL Bio Pharma, Inc reports for semaglutide lots and tirzepatide lots.

b. A few certificates of analysis obtained by APRN Perkins from the manufacturers.

i. Some were in a foreign language

ii. One certificate stated, “sermaglutide”

iii. Two stated “it is only supplied as chemical product”.

c. Enbody’s schedule from March 4, 2025 to June 5, 2025 was provided as the administration record. The following was documented on the schedule:

i. Visit type: semaglutide 872 and tirzepatide 436

ii. 156 patient names

iii. Of the 1,308 visit types, 965 had the status “confirmed.”

iv. Asia Jackson, Epiphany Perkins, and Staff Nurses were listed as providers.

1. Note: Asia Jackson and Epiphany Perkins are not licensed healthcare professionals, per APRN Perkins.

5. During the June 5, 2025 inspection, APRN Tiffinne Perkins, Responsible Person of Enbody, was interviewed by Board inspectors. The following was stated by APRN Perkins:

a. APRN Perkins opened Encore in 2023. Patients come in to receive peptides administered at the medical spa. Perkins has also sent doses home (a maximum of 4 syringes at a time) when patients go on vacation or can’t come in for a couple weeks.

b. She created her own titration schedule of semaglutide and tirzepatide.

c. She uses the sterile vials (found at the medical spa) for reconstitution of the drug powder. She uses bacteriostatic saline. Note: an unapproved drug "bacteriostatic water" was observed by Board inspectors.

d. Jiangsu Jitai is her primary drug manufacturer. She stated she found them by doing a lot of research. She went to the FDA website and found a list of FDA-registered vendors; she buys directly from the manufacturer.

    i. Note: Jiangsu Jitai is not recognized as a legitimate drug distributor. It is not a licensed wholesale drug distributor or drug manufacturer in the United States and it does not have FDA manufacturer registration.

e. When asked for invoices or records that come in the drug packages, APRN Perkins stated packing slips are not sent.

f. APRN Perkins showed Board inspectors a sealed package of Tvigoura that recently arrived, as an example.

    i. When asked what is in the package, APRN Perkins explained it was tirzepatide and "All you have to do is take a picture and ask someone to translate it [the package] for you."

    ii. She stated the packages come from China.

    iii. She has every batch tested at ARL.

g. APRN Perkins does not have a registered study or a new drug application.

h. She stated cargrillintide is currently under study; she does not use that drug for patients.

    i. When asked about the four missing vials, she stated a staff member used them. The staff member is not her patient and did not document it in a patient chart. The patient is not a licensed healthcare profession.

    ii. APRN Perkins did not prescribe cargrillintide to Epiphany. She stated Epiphany used the drugs without her permission.

i. When asked about the two missing vials of "R001", suspected to be retatrutide, APRN Perkins stated, "somebody probably used them without my permission or took them." Then she recalled she sent one off for testing, therefore only one vial is missing.

j. When told non-FDA approved drugs cannot be used, APRN Perkins stated lots of non-FDA approved drugs are used, and incorrectly claimed that testosterone is not FDA-approved.

i. Note: testosterone is an FDA-approved drug; it can be used off label.

k. APRN Perkins stated she was trained by a PharmD from Revelation Pharma. She took a course in USP <795> compounding. When APRN Perkins was informed she is actually performing sterile compounding, which must comply with USP <797> and not non-sterile compounding, which is USP <795>, APRN Perkins stated the PharmD told her it's USP<795> and it's not sterile because it's as clean as possible.

i. Note: No documentation was provided during the inspection to support APRN Perkins received this training.

l. Despite compounding substances to be injected into patients, APRN Perkins incorrectly answered "yes, non-sterile drugs" when asked on the Board's renewal application if Enbody compounds.

i. Note: Enbody performs sterile compounding.

m. Enbody's recordkeeping system was observed to include a "peptide tracker."

i. Manufacturers on the tracker included: Xi'an Frazier Biotech (no FDA registration listed), Jiangsu Jitai Peptide Industry Science and Technology LTD (FDA registration listed 3004986788), Guanyuan Chemical (no FDA registration listed), Shaanxi Zebrango Ind. Co., LTD (FDA registration listed 15636708030)

1. Note: None of these entities have registrations or identifiers on the FDA database (https://dps.fda.gov/decrs). These are all non-FDA registered entities and do not possess licenses to manufacturer or distribute drugs in the United States.

ii. The records did not provide a quantity of how much drug was purchased.

n. APRN Perkins stated she does not receive any packing slips or invoices with the products.

o. APRN Perkins stated "nothing" is required to set up an account with a manufacturer. The [drugs] are on a website and there is a list of products available; they ship directly to her.

p. APRN Perkins stated she asked them [the manufacturers] the other day if they are still FDA registered "because they are really cracking down here in the U.S.".

q. Many of the manufactures provided her with a certificate of analysis; many of these are in a foreign language and English.

r. When asked about the product labeled "for research only," APRN Perkins said Jiangsu Jitai Peptide does not add that label. Shaanxi Zebrango Ind Co Ltd just started adding that label.

When she talked on the phone to a rep in China, she told the rep "don't do that" because "we're not allowed to use for research peptides."

s. APRN Perkins asked why the Board is taking all the drugs. A Board inspector explained to her that they are not approved drugs, and they are not from an approved source. APRN Perkins stated, "I understand why you took the ones with the Chinese language on it. But do you think you have a reason to take the other ones that are properly labeled?"

t. When asked why she injected something that said for research use only, APRN Perkins stated "…it was for medical use for a patient. And it said for research. So I took that research peptide and I had it sent to a… to a lab to have it tested. So I'm just trying to understand why it's illegal".

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

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

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

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

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

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective September 29, 2017 and April 6, 2017, No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, each violation is a misdemeanor of the first degree, each violation punishable by a maximum penalty of $5,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 2925.09(A) of the ORC, 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, each a felony of the fifth degree, punishable by a maximum penalty of $7,500 if committed by an organization.

4. 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.

5. 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

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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 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).

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, 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.

9. 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).

10. 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).

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

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

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

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

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

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

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

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

12. 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).

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

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

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

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

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

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

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

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

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

iv. Ensuring 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 may designate an appropriately trained agent to prepare compounded drug preparations, OAC Rule 4729:7-3-03(F); and/or

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

i. Inspect and approve the compounding process, OAC Rule 4729:7-3-03(G)(1); and

ii. Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered, OAC Rule 4729:7-3-03(G)(2); and/or

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

i. Verify the accuracy of:

1. Drug name, OAC Rule 4729:7-3-03(I)(3)(a); and/or

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

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

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

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

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

ii. All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

1. Complies with the requirements of this rule, OAC Rule 4729:7-3-06(A)(2)(a); and

2. All paper records shall be scanned in full color via technology designed to capture information and reproduce it in an electronic medium presentable and usable to an end user, OAC Rule 4729:7-3-06(A)(2)(b); and

3. Contains security features, such as unique user names and passwords, to prevent unauthorized access, OAC Rule 4729:7-3-06(A)(2)(c); and

4. Contains daily back-up functionality to protect against record loss, OAC Rule 4729:7-3-06(A)(2)(d); and

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

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

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

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

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

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

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

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

8. The positive identification of either of the following:

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

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

b. Records of disposal of compounded drugs, 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, the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:7-3-06(B); and/or

c. All records maintained in accordance with this rule 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 4729:7-3-06(E)(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 4729:7-3-06(E)(2).

15. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, each violation punishable by a maximum penalty of $1,000: To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding, and administration.

16. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000: All terminal distributors of dangerous drugs shall provide effective controls and procedures to: Ensure supervision and control of dangerous

drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

17. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-02 of the OAC, as effective March 1, 2020, each violation punishable by a maximum penalty of $1,000:

    a. Except as provided in paragraph (E)(2) of this rule, only a prescriber shall personally furnish a drug. The act of personally furnishing shall be documented using positive identification, OAC Rule 4729:5-19-02(E)(1); and/or

    b. Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug, OAC Rule 4729:5-19-02(K).

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

    a. 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

    b. 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

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

19. 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, 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. 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).

20. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-14 of the OAC, 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 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)(1).

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

IF YOU DESIRE A HEARING, such request shall either be mailed to the Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (**please note faxes will not be accepted**). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143

and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

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

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

BY ORDER OF THE OHIO BOARD OF PHARMACY

Steven W. Schierholt, Esq., Executive Director

SWS/alg/jrn

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