

Mike DeWine, Governor Jim Tressel, Lt. Governor Steven W. Schierholt, Executive Director

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

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Steven W. Schierholt, Esq., Executive Dir. Date: 8/22/2025

-MUST HAVE BOARD SEAL TO BE OFFICIAL

IN THE MATTER OF:

CASE NO. A-2025-0252

License No. 02-62001117

Wellness Flow Columbus dba Elmntl 300 Marconi Blvd., Ste 306

Columbus, OH 43215

August 22, 2025

Dear Elmntl:

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

JURISDICTION

- 1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Sections 4729.54 and 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Ohio Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the ORC.
- 2. Pursuant to Section 4729.571(A)(1) of the ORC and the rules adopted thereunder, the Board has the authority to suspend a terminal distributor's license without a hearing if it determines that there is clear and convincing evidence of a danger of immediate and serious harm to others due to the method used by the terminal distributor to possess or distribute dangerous drugs.

77 S. High Street, 17th Floor Columbus, OH 43215 U.S.A. Phone: 614 | 466 4143 Fax: 614 | 752 4836



- 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. Wellness Flow Columbus dba Elmntl ("Elmntl"), located at 300 Marconi Blvd., Ste. 306, Columbus, OH 43215, is a licensed TDDD under license number 02-62001117 and lists Addison Reede Tarr, D.O., [Ohio Medical Board license number 34.009509] as the Responsible Person and Sean Carroo as the owner/CEO.

ALLEGATIONS

- 1. On or about June 2025, Board agents conducted an undercover order of retatrutide, from Elmntl, located at 300 Marconi Blvd., Ste. 306, Columbus, OH. Retatrutide is a dangerous drug that lacks USP/NF monograph, is not a drug substance that is a component of an approved drug, and does not appear on the approved 503A bulk drug substances list.
 - a. The retatrutide was available for purchase via Elmntl's website for \$400 per vial. As part of the ordering process, a patient consultation was conducted by Elmntl CEO Sean Carroo, a non-healthcare professional.
 - b. Board agents subsequently received a package by mail containing a vial labeled GLP-1 R, a vial of bacteriostatic water, syringes, a hypodermic needle, alcohol pads, and information cards with "reconstitution and injection instructions." The vial containing the GLP-1 R contained a white powder and was labeled from Alpha BioMed, which is an entity that is not a licensed wholesale drug distributor, outsourcing facility, compounding pharmacy, or drug manufacturer in the United States and does not have Food and Drug Administration (FDA) manufacturer registration.
- 2. On or about August 5, 2025, the Board conducted an inspection at Elmntl. During the inspection, Elmntl CEO Sean Carroo and Sachin Gupta, an employee who works in marketing, were present.
 - a. The inspection confirmed Elmntl was purchasing drugs from an unlicensed drug distributor. Carroo produced a FedEx labeled bubble mailer, recently delivered from Alpha BioMed, containing the following illegal drugs:
 - i. One vial NAD+ 1000mg, for injection;
 - ii. Two vials BPC 157/TB500 10mg/10mg, for injection;
 - iii. One vial CJC 1295/Ipamorelin 5 mg/5 mg, for injection
 - iv. One vial IGF1-LR3 1 mg, for injection.

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- v. NOTE: these drugs are not approved by the U.S. Food and Drug Administration (FDA) and are not permitted to be compounded because they lack USP/NF monograph, are not a component of an approved drug, and do not appear on the 503A bulk drug substances list.
- b. The inspection resulted in warnings requiring written responses for violations including the following:
 - i. Several expired dosage forms were present in the clinic's drug storage area and unapproved compounded drugs labeled "physician use only" were present.
 - ii. Dangerous drugs were purchased from entities not licensed in Ohio and the clinic was not conducting license verification
 - iii. Several open multi-dose vials were not labeled with open date or beyond use date.
 - iv. The clinic had moved from 15 Price Ave., Columbus, Ohio to 300 Marconi Blvd., Columbus, Ohio, and had failed to timely submit a Change of Address notification to the Board.
- c. During the August 5, 2025 inspection, Board personnel spoke with Elmntl CEO Sean Carroo. He stated that Elmntl's current business model includes a telehealth consultation with a patient, ordering medications from AlphaBioMed, receiving the medications at Elmntl, packaging the medication and supplies, and shipping to the patient.

POTENTIAL VIOLATIONS OF LAW

- 1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.52(A) of the ORC, Prohibited acts, each, a misdemeanor of the fourth degree, each punishable by a maximum penalty of \$2,000 if committed by an organization: The following acts and causing them are prohibited:
 - a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded, ORC Section 3715.52(A)(1); and/or
 - b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC Section 3715.52(A)(2); and/or
 - c. The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, ORC Section 3715.52(A)(3); and/or
 - d. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 3715.61 or 3715.65 of the Revised Code, ORC Section 3715.52(A)(4).

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¹ ORC Section 3715.63 – When drug or device is adulterated.

² ORC Section 3715.64 – Misbranded drug or device.

- 2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of section 3715.65(A) of the ORC, Application for new drug required, each a misdemeanor of the fourth degree, each punishable by a maximum penalty of \$2,000 if committed by an organization:
 - a. No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless an application with respect to the drug has become effective under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.
- 3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Rule 4729:5-3-06 of the OAC, as effective July 1, 2024, Storage of adulterated drugs, each violation punishable by a maximum penalty of \$1,000:
 - a. To prevent their use, adulterated drugs, as defined in agency 4729 of the Administrative Code, shall be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding and administration, OAC 4729:5-3-06; and/or
 - Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons, OAC 4729:5-3-06(A); and/or
 - ii. Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in agency 4729 of the Administrative Code, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons, OAC Rule 4729:5-3-06(B).
- 4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(F) of the ORC, effective April 9, 2025, Selling, purchasing, distributing, or delivering dangerous or investigational drugs No licensed terminal distributor of dangerous drugs or person that is exempt from licensure under section 4729.541 of the Revised Code shall purchase dangerous drugs or investigational drugs or products from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, punishable by a maximum penalty of \$5,000 if committed by an organization.
- 5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, Verification of license prior to transactions Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the roster established pursuant to section 4729.59 of the Revised Code to confirm the seller is licensed to engage in the sale or distribution of dangerous drugs at wholesale, each violation punishable by a maximum penalty of \$1,000 if committed by an organization.
- 6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-04 of the OAC, as effective March 1, 2019, Verification of licensure prior to sale or purchase, each violation punishable by a maximum penalty of \$1,000:

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- a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the board's online roster (available on the board's website: www.pharmacy.ohio.gov) to confirm any of the following:
 - i. The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or
 - ii. The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2); and/or
- b. If no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of section 4729.51 of the Revised Code, OAC Rule 4729:5-3-04(B).
- 7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-03 of the OAC, as effective February 4, 2021, Security, control and storage of dangerous drugs, each violation punishable by a maximum penalty of \$1,000:
 - a. The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license and the terminal distributor of dangerous drugs, OAC Rule 4729:5-19-03(A); and/or
 - b. Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyonduse date shall be deemed adulterated, OAC Rule 4729:5-19-03(L); and/or
 - c. Adulterated drugs, including expired drugs, shall be stored in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(M); and/or
 - d. Disposal of non-controlled dangerous drugs shall be conducted in accordance with rule 4729:5-3-06 of the Administrative Code, OAC Rule 4729:5-19-03(0).
- 8. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, as effective March 1, 2020, General security requirements, each violation punishable by a maximum penalty of \$1,000:
 - a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure supervision and control of dangerous drugs, as required in division (B) of section 4729.55 of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

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- 9. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-19-04 of the OAC, Record Keeping, as effective March 1, 2020, each violation punishable by a maximum penalty of \$1,000:
 - a. A clinic or prescriber office shall keep a record of all dangerous drugs received, administered, personally furnished, disposed, sold or transferred, OAC Rule 4729:5-19- 04(A); and/or
 - b. Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received, the name and address of the seller, the name and address of the recipient, and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement, OAC Rule 4729:5-19-04(B); and/or
 - c. Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed, the date of disposal, the method of disposal, and the identification of the licensed health care professional that performed the disposal, OAC Rule 4729:5-19-04(F).
 - d. All records maintained in accordance with this rule and rule 4729:5-19-03 of the Administrative Code shall be readily retrievable and shall be kept on-site for a period of three years, OAC Rule 4729:5-19-04(J).
- 10. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible person terminal distributor, as effective April 25, 2022, each punishable by a maximum penalty of \$1,000:
 - a. The responsible person to whom the terminal distributor of dangerous drugs license has been issued and all licensed health professionals on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs, OAC Rule 4729:5-2-01(E)(4); and/or
 - A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site, OAC Rule 4729:5-2-01(E)(5); and/or
 - c. 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).
- 11. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-03 of the OAC, Change in description of a terminal distributor of dangerous drugs, as effective October 1, 2024, each punishable by a maximum penalty of \$1,000:

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- a. Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires an application and required fee. The application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address, OAC Rule 4729:5-2-03(A).
- 12. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective April 4, 2023, each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or
 - b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or
 - c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or
 - d. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); and/or
 - e. Any other cause for which the board may impose discipline as set forth in rules adopted under section 4729.26 of the Revised Code, ORC Section 4729.57(B)(10).
- 13. 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. 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
 - e. 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
 - f. 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).

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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

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

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