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

IN THE MATTER OF:

Optimal Balance Pharmacy, LLC
c/o Jason Ka Hei Chen, RPh
2204 Cypress Creek Pkwy Ste F
Houston, TX 77090

CASE NO. A-2026-0338

License No. 02-42001006

-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 9/29/2026
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

September 29, 2026

Dear Mr. Ka Hei Chen and Optimal Balance Pharmacy, LLC:

You are notified, in accordance with Section 119.07 of the Revised Code, the Ohio Board of Pharmacy (Board) hereby SUMMARILY SUSPENDS Optimal Balance Pharmacy LLC'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 Optimal Balance Pharmacy LLC's method used to possess or distribute dangerous drugs. As such, the Board summarily suspends Optimal Balance Pharmacy LLC'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. Further, pursuant to Section 4729.55(E), the Board shall refuse to issue a future license to an applicant for a TDDD if the applicant, or any agent (including any owner or responsible person) or employee of the applicant, has been found to have violated any of the specified laws identified therein or any rule of the board, absent proof of adequate safeguards assuring prevention of a recurrence of the violation. 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. Optimal Balance Pharmacy LLC, located at 2204 Cypress Creek Pkwy Ste F, Houston, TX, is a licensed TDDD under license number 02-42001006. Jason Ka Hei Chen, RPh, Ohio License No. 03-446546, is listed as the Responsible Person.

ALLEGATIONS

1. From on or about August 20, 2025, to August 25, 2026, Optimal Balance Pharmacy LLC (Optimal Balance Pharmacy), located at 2204 Cypress Creek Pkwy Ste F, Houston, TX, shipped 617 unapproved compounded drugs to Ohio patients.

2. On August 20, 2026, a Board Specialist sent a records request for prescription dispensing records for drugs shipped into Ohio between August 19, 2025, and August 19, 2026, and records related to a recent glutathione recall that was self-reported to the Board. An extension was requested and granted by the Board through August 31, 2026. After multiple requests by the Board, the records were received on September 15, 2026.

3. The records show that from on or about August 20, 2025, to August 25, 2026, the pharmacy dispensed 3,569 prescriptions to Ohio. Of these dispensings, the pharmacy dispensed 617 compounded prescriptions using drugs that were ineligible for compounding because they lack a United States Pharmacopeia – National Formulary (USP/NF) monograph, are not drug substances that are components of approved drugs, and do not appear on the Food and Drug Administration (FDA) approved 503A bulk drug substances list (Category 1 list). Additionally, at least 62 dispensings could be classified as Biological Product, which requires an approved Biologics License Application (BLA) to compound. Optimal Balance Pharmacy does not have an active approved BLA.

    a. The list of the 617 prescriptions dispensed to Ohio patients during this time is set forth in Attachment A, attached hereto and incorporated as though fully set forth herein.

    b. Optimal Balance Pharmacy obtained an Ohio-issued TDDD license on or about November 3, 2025. Records show that 8 of the 3,569 prescriptions were dispensed to Ohio patients between August 20, 2025 to October 13, 2025, prior to Optimal Balance Pharmacy obtaining a license.

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

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

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

2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 3715.65(A) of the ORC, effective April 15, 2005, 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, each violation is a misdemeanor of the fourth degree, each violation punishable by a maximum penalty of $2,000 if committed by an organization.

3. Such conduct as set forth in the Allegations Section, if proven, 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, each constitutes a violation of the following sections of Rule 4729:5-8-03 of the OAC, Compliance, as effective June 30, 2025, each violation punishable by a maximum penalty of $1,000:

a. A nonresident terminal distributor of dangerous drug shall comply with all the statutory requirements of the state of Ohio set forth in Chapters 4729., 3719., 3715., and 2925. of the Revised Code for all drugs sold, dispensed or personally furnished into this state, unless the licensee can demonstrate that such compliance would cause the nonresident terminal distributor of dangerous drugs to violate either the statutory or regulatory requirements of the state in which it is located or federal statutory or regulatory requirements, OAC Rule 4729:5-8-03(E); and/or

b. A nonresident terminal distributor of dangerous drugs shall operate in compliance with all applicable laws, regulations and standards set forth by the United States food and drug administration and the United States drug enforcement administration, OAC Rule 4729:5-8-03(H); and/or

c. A nonresident terminal distributor of dangerous drugs shall supply, within three business days of a request, all information needed by the board of pharmacy to carry out its

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

responsibilities as a licensing, regulatory, and drug law enforcement agency of the state of Ohio, OAC Rule 4729:5-8-03(J); and/or

d. A nonresident terminal distributor of dangerous drugs shall supply, within three business days of a request, all information needed by the board of pharmacy and any local, state, or federal agency to carry out its responsibilities in enforcing the federal and state laws governing the distribution of drugs in the state of Ohio, OAC Rule 4729:5-8-03(K).

5. Such conduct as set forth in the Allegations Section, if proven, 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 shall be responsible for the practice of the profession of pharmacy, 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(A)(2); and/or

   b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3); and/or

   c. 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

   d. 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).

6. 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. 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).

7. Such conduct as set forth in Allegations Section, if proven, 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. 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

   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).

8. Such conduct as set forth in Allegations Section, if proven, 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).

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 <u>not</u> 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/rlj

Encl: Attachment A