



IN THE MATTER OF:

**CASE NOS. A-2022-0070
A-2023-0450**

Akron Pharmacy dba Mac Pharmacy

c/o Sheriff Mankaryous, RPh
879 E. Exchange Street
Akron, OH 44306

License No. 02-2271700

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Akron Pharmacy dba Mac Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of non-sterile compounding issues, unregistered individuals working as technicians, and record keeping issues. Together, the Board and Akron Pharmacy dba Mac Pharmacy are referred to hereinafter as "the parties."

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 Section 4729.54 of the Ohio Revised Code.
2. Akron Pharmacy dba Mac Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2271700.

FACTS

1. The Board initiated an investigation of Akron Pharmacy dba Mac Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-2293300, related to Akron Pharmacy dba Mac Pharmacy's non-sterile compounding issues, unregistered individuals working as technicians, and record keeping issues.
2. On or about January 24, 2024, the Board sent a Notice of Opportunity for Hearing to Akron Pharmacy dba Mac Pharmacy, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.
3. On or about February 22, 2024, Akron Pharmacy dba Mac Pharmacy timely requested an administrative hearing, which was subsequently scheduled for December 10, 2024.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Akron Pharmacy dba Mac Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated January 24, 2024; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Akron Pharmacy dba Mac Pharmacy agrees to pay to the Board a monetary penalty the amount of \$1,000. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to www.license.ohio.gov and process the items in your cart.
4. The Board hereby imposes a written reprimand on Akron Pharmacy dba Mac Pharmacy's TDDD license, number 02-2271700.
5. Akron Pharmacy dba Mac Pharmacy agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
6. Akron Pharmacy dba Mac Pharmacy agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Akron Pharmacy dba Mac Pharmacy of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Akron Pharmacy dba Mac Pharmacy by the Board and will NOT discharge Akron Pharmacy dba Mac Pharmacy from any obligation under the terms of this Agreement.
7. Akron Pharmacy dba Mac Pharmacy agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. Akron Pharmacy dba Mac Pharmacy understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Akron Pharmacy dba Mac Pharmacy will operate.
10. Akron Pharmacy dba Mac Pharmacy explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.
11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.
12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.
14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.
15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

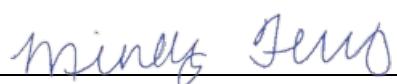
Approved by:



Sherif Mankaryous, RPh, on behalf of,
Akron Pharmacy dba Mac Pharmacy, Respondent

11/6/2024

Date of Signature



Mindy Ferris, RPh, President,
Ohio Board of Pharmacy

11.08.2024

Date of Signature



**STATE OF
OHIO**
BOARD OF PHARMACY

-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.

Stan W. Schierholt

Steven W. Schierholt, Esq., Executive Dir.

Date: Jan 24, 2024

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

**NOTICE OF OPPORTUNITY FOR HEARING
FOR TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE**

IN THE MATTER OF:

CASE Nos. A-2022-0070

A-2023-0450

Akron Pharmacy dba Mac Pharmacy
c/o Sherif Mankaryous, RPh
879 E. Exchange Street
Akron, OH 44306

License No. 02-2271700

January 24, 2024

Dear Sherif Mankaryous, RPh and Akron Pharmacy dba Mac Pharmacy:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code, the State of Ohio Board of Pharmacy (Board) proposes to take disciplinary action against your license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Section 4729.57.

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 Section 4729.54 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. Akron Pharmacy dba Mac Pharmacy (Mac Pharmacy) is a Licensed TDDD under License No. 02-2271700, which lists the Responsible Person as Sherif Mankaryous, RPh.

ALLEGATIONS

1. On or about November 17, 2021, a Board inspection revealed significant non-sterile compounding violations, which resulted in Mac Pharmacy, located at 879 E. Exchange Street, Akron, Ohio, entering into an agreement with the Board to cease all non-sterile compounding until the pharmacy was found by the Board to be compliant with United States Pharmacopeia Chapter 795 (USP 795), ORC 4729, and chapter 4729:7 of the Ohio Administrative Code (OAC). The violations consisted of the following:
 - a. The pharmacy's policy and procedure manual was not all-inclusive and was not reviewed or updated regularly.

77 South High Street, 17th Floor, Columbus, Ohio 43215

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- b. The pharmacy did not have a training program containing an annual review of USP 795 and compounding policies and procedures.
- c. The pharmacy did not have a documented or completed facility training program for personnel performing compounding work or who check compounding.
- d. The pharmacy did not have a training program in place for demonstrating competencies in compounding, equipment usage, product evaluation, packaging, storage, handling, dispensing, and hazardous drug procedures.
- e. The pharmacy did not have a training program in place for hazardous drug use including storage, handling, and disposal.
- f. The pharmacy had greater than 15 expired products/chemical in active stock for compounding dating from a few days expired to a year expired.
- g. Cleaning products were repackaged; however, the labels were incomplete and there was no record of repackaging.
- h. Compounded prescriptions prepared in anticipation of a prescription drug order were not labeled completely as required in the Ohio Administrative Code.
- i. The compounding area was observed to be unclean.
- j. Facility did not monitor temperature and humidity of compounding area.
- k. Equipment used in compounding was not capable of measuring quantities as instructed by formulas and pharmacy did not document what was measured.
- l. Quantities measured for compounding were not documented.
- m. Facility did not have records of scale calibration.
- n. Scales and other equipment were not calibrated annually.
- o. Cleaning/maintenance records were not maintained for equipment used in compounding.
- p. Facility did not maintain complete Master Formulas.
- q. Facility did not maintain Positive ID of compounding technician.
- r. Staff member who compounded was an unregistered technician.
- s. Beyond-use-dates were not assigned in accordance with USP 795 guidelines.
- t. Facility did not have supported testing to extend beyond-use dates.

2. On or about November 17, 2021, a Board inspection at Mac Pharmacy found multiple violations of Ohio Pharmacy laws and rules. The following violations were found:
 - a. Two unregistered individuals were performing the duties of a pharmacy technician.
 - b. There were discrepancies in the annual controlled substance inventory. There were 70 discrepancies found out of 186 National Drug Codes (NDCs) counted.
 - c. Schedule II controlled substances were not stored in a securely locked, substantially constructed cabinet or safe.
3. Mac Pharmacy was found to have four unregistered individuals that had been performing the duties of a pharmacy technician. They are the following individuals:
 - a. Lucarie Dorsey worked 143 hours between 10/18/2021 and 11/15/2021 as an unregistered technician.
 - b. Samantha Hertzog worked 17 hours between 11/15/2021 and 11/17/2021 as an unregistered technician.
 - c. Michael Michael worked 276 hours between 9/1/2021 and 11/16/2021 as an unregistered technician and compounded non-sterile dangerous drugs.
 - d. Joel Bacola worked 104 hours between 11/5/2021 and 11/23/2021 as an unregistered technician.
4. On or about December 21, 2021, representatives from the Board reinspected Mac Pharmacy. The following violations were found:
 - a. The pharmacy had an unlocked cabinet with Schedule II-controlled substances.
 - b. Multiple expired medications were found in active drug stock.
 - c. Return to stock potassium chloride tablets were observed not following return-to-stock rules.
 - d. Multiple bottles were observed on active drug shelves with no label or incorrect labelling.
 - e. Customized patient medication packages were observed not containing all requirements for labelling- date of dispensing, federal cautions and quantity dispensed were missing.
5. As a result of remediation efforts by Mac Pharmacy, the Board, on or about December 21, 2021, authorized Mac Pharmacy to resume non-sterile compounding.
6. On or about November 1, 2023, a Board inspection was conducted at Mac Pharmacy, located at 879 E. Exchange Street, Akron, Ohio. The following violations were found:
 - a. The pharmacy did not have accurate and completed annual inventory of controlled substances for 2022 and 2023 on site.

- b. Return to stock bottles were not labeled correctly or not labeled at all.
- c. Multiple expired medications were observed within the active drug stock.
- d. Multiple expired Active Pharmaceutical Ingredients/compounding products were found in the active compounding stock.
- e. The compounding area appeared clean, but no documentation of cleaning was observed since April 2023.
- f. The system to document temperature and humidity was not functioning. Battery was replaced during the inspection. No data was documented since November 2022.
- g. The pharmacy was only documenting some of the actual measurements on compounding records. Observed one compounding record with no Beyond-Use Date. Observed compounding records with no documented lot numbers or expiration dates for products used or with documented expiration dates of expired products. Observed compounding records with no duplicate label.

POTENTIAL VIOLATIONS OF LAW

- 1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57 of the ORC, effective September 29, 2017 and 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 TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7).
- 2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, effective March 31, 2021 and October 3, 2023, TDDD license requirements:
 - a. Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC 4729.55(D); and/or

- b. If the applicant, or any agent or employee of the applicant, has been found guilty of violating section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., or 4729. of the Revised Code, or any rule of the board, adequate safeguards are assured to prevent the recurrence of the violation, ORC 4729.55(E).
- 3. Such conduct as set forth in paragraphs (1)(r), (2)(a), (3)(a), (3)(b), (3)(c), and (3)(d) of the Allegations Section, if proven, constitutes a violation of the of Section 4729.95(C) of the ORC, effective April 6, 2018, no terminal distributor of dangerous drugs shall knowingly allow any person employed or otherwise under the control of the person who owns, manages, or conducts the terminal distributor to violate division (A) of this section (allow an unregistered person to perform the activities listed in 4729.91 of the ORC), each violation punishable by a maximum penalty of \$1,000.
- 4. Such conduct as set forth in the Allegations Section, inclusive, if proven, constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible Person of a Terminal Distributor, as effective March 1, 2019 and 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).
- 5. Such conduct as set forth in paragraphs (6)(a), (6)(b), (6)(c), (6)(d), (6)(e), (6)(f), and (6)(g) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective April 25, 2022, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:
 - 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. 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
 - d. 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).
- 6. Such conduct as set forth in paragraphs (1)(a) – (1)(t) inclusive, (2)(a), (2)(b), (2)(c), (3)(a), (3)(b), (3)(c), (3)(d), (4)(a), (4)(b), (4)(c), (4)(d), and (4)(e) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- 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. 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
- d. 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)(25).

7. Such conduct as set forth in paragraphs (1)(f), (4)(b), (6)(c), and (6)(d) of the Allegations Section, if proved, each constitutes a violation of Rule 4729:5-3-06, Storage of adulterated drugs, effective March 1, 2019, 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, each violation is punishable by a maximum penalty of \$1,000.

8. Such conduct as set forth in paragraphs (2)(b) and (6)(a) of the Allegations Section, if proved, each constitutes a violation of Rule 4729:5-3-07(A), Controlled substance inventory requirements, effective March 1, 2019, All category III terminal distributor licensees shall complete a controlled substance inventory in accordance with 21 CFR 1304.11 (9/9/2014), each violation is punishable by a maximum penalty of \$1,000.

9. Such conduct as set forth in paragraphs (2)(c) and (4)(a) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, General Security Requirements, as effective March 1, 2020, All terminal distributors of dangerous drugs shall provide effective controls and procedures to do the following, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
- b. Ensure supervision and control of dangerous drugs, as required in division (B) of section [4729.55](#) of the Revised Code, and adequate safeguards to ensure that dangerous drugs are being distributed in accordance with all state and federal laws, as required in section [4729.55](#) of the Revised Code, OAC Rule 4729:5-3-14(A)(2).

10. Such conduct as set forth in paragraphs (1)(g), (1)(n), (4)(c), and (6)(b) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-17(D) of the OAC, Drugs repackaged or relabeled by a pharmacy, Labels of drugs repackaged by and stored within a pharmacy prior to being dispensed shall contain, but not be limited to, the following, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. Name of drug, strength, and dosage form, OAC Rule 4729:5-5-17(D)(1); and/or
- b. National drug code or universal product code, if applicable, which may be embedded in a bar code or quick response (QR) code on the label, OAC Rule 4729:5-5-17(D)(2); and/or

- c. The identification of the repackager by name or by the final seven digits of the terminal distributor of dangerous drugs license number, OAC Rule 4729:5-5-17(D)(3); and/or
- d. Pharmacy control number, OAC Rule 4729:5-5-17(D)(4); and/or
- e. The beyond-use date of the repackaged drug in accordance with the guidance listed in paragraph (C) of this rule, OAC Rule 4729:5-5-17(D)(5).

11. Such conduct as set forth in paragraphs (1)(a) – (1)(t) inclusive, (6)(e), (6)(f), and (6)(g) of the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:7-2-03(A) of the OAC, Drugs compounded in a pharmacy, effective July 1, 2021, for all non-sterile compounded drug preparations, the pharmacy shall comply with United States pharmacopeia chapter <795>, each violation punishable by a maximum penalty of \$1,000.

12. Such conduct as set forth in paragraphs (1)(r) and (3)(c) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-2-03(F) of the OAC, Drugs compounded in a pharmacy, Only the following may engage in compounding at a pharmacy, as effective July 1, 2021, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. A pharmacist, OAC Rule 4729:7-2-03(F)(1); and/or
- b. A pharmacy intern under the personal supervision of a pharmacist, OAC Rule 4729:7-2-03(F)(2); and/or
- c. A certified pharmacy technician or pharmacy technician trainee under the personal supervision of a pharmacist, OAC Rule 4729:7-2-03(F)(3); and/or
- d. A registered pharmacy technician under the personal supervision of a pharmacist, but only with respect to non-sterile drug compounding, OAC Rule 4729:7-2-03(F)(4).

13. Such conduct as set forth in paragraphs (1)(a) – (1)(t) inclusive, (6)(e), (6)(f), and (6)(g) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-2-03(H) of the OAC, Drugs compounded in a pharmacy, For all compounded drug preparations, a pharmacist shall be responsible for the following, as effective July 1, 2021, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. All compounding records pursuant to rule [4729:7-2-04](#) of the Administrative Code, OAC Rule 4729:7-2-03(H)(1); and/or
- b. The proper maintenance, cleanliness, and use of all equipment used in compounding, OAC Rule 4729:7-2-03(H)(2).

14. Such conduct as set forth in paragraphs (1)(s), (4)(d), (4)(e), (6)(b), and (6)(g) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:7-2-03(L) of the OAC, Drugs compounded in a pharmacy, Labels for a compounded drug that is prepared in anticipation of a patient-

specific prescription shall also contain the following, as effective July 1, 2021, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. The name, strength, and quantity of each active ingredient used in the compounded drug preparation, OAC Rule 4729:7-2-03(L)(1); and/or
- b. Pharmacy control number, OAC Rule 4729:7-2-03(L)(2); and/or
- c. The assigned beyond-use date, OAC Rule 4729:7-2-03(L)(3); and/or
- d. The identification of the repackager or outsourcing facility by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier, OAC Rule 4729:7-2-03(L)(4); and/or
- e. The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label, OAC Rule 4729:7-2-03(L)(5).

15. Such conduct as set forth in paragraph (3)(c) of the Allegations Section, if proved, each constitutes a violation of Rule 4729:7-2-4(A)(11)(a), Record Keeping. In addition to the pharmacy record keeping requirements of agency 4729 of the Administrative Code, a pharmacy shall maintain records of all drugs compounded that include the positive identification of the pharmacy personnel responsible for preparing the compounded drug preparation, effective, July 1, 2021, each violation is punishable by a maximum penalty of \$1,000.

16. Such conduct as set forth in paragraphs (4)(b) and (6)(c) of the Allegations Section, if proven, constitutes a violation of the following divisions of Section 3715.52 of the ORC, constituting a misdemeanor of the fourth degree, each punishable by a maximum fine of \$2,000, if committed by an organization:

- a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded, ORC 3715.52(A)(1); and/or
- b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC 3715.52(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 State of Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

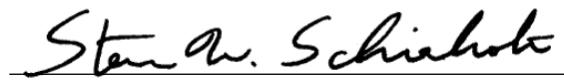
IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will not be accepted). **YOUR REQUEST MUST BE RECEIVED 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 State of 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 STATE BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll



-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

Steven W. Schierholt, Esq., Executive Dir.

Date: Sep 18, 2024

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

BEFORE THE OHIO BOARD OF PHARMACY

In the Matter of : **Case No. A-2020-0760**
Akron Pharmacy d.b.a. :
MAC Pharmacy :
c/o Sherif Mankaryous, RPh : **License No. 02-2271700**
879 E. Exchange Street :
Akron, Ohio 44306 :
: **Respondent.** :

FINAL ORDER OF THE OHIO BOARD OF PHARMACY

Akron Pharmacy d.b.a. MAC Pharmacy (“Respondent”) was issued a license as a terminal distributor of dangerous drugs by the Ohio Board of Pharmacy, under license number 02-2271700. The Board issued a Notice of Opportunity for Hearing (“Notice”) to Respondent via certified mail, return receipt requested, to Respondent’s address of record, on February 23, 2022. Respondent received the Notice on March 1, 2022. Pursuant to Ohio Revised Code (ORC) Section 119.07, Respondent had a right to a hearing if requested within 30 days of service of the Notice. Respondent failed to do so. Accordingly, no hearing was held, and the matter was brought before the Board on July 9, 2024, for final adjudication pursuant to ORC 119.07, and 4729.57(E).

WHEREFORE, after review of the administrative record, the Board finds that Respondent was legally served with the Notice and informed of the allegations contained therein and the rights afforded pursuant to ORC Chapter 119.

WHEREFORE, after review of the administrative record and pursuant to ORC 4729.57(A) and Ohio Administrative Code (OAC) 4729:5-4-01(A), the Board finds and concludes that Respondent engaged in conduct set forth in ORC 4729.57(B), ORC 4729.55, ORC 4729.95(C), OAC 4729:5-4-01(B), OAC 4729:5-2-01, and all violations of law as described in the Notice. Based on the findings contained herein, the Board ORDERS as follows:

1. The Board hereby imposes a written reprimand on Respondent’s terminal distributor of dangerous drugs license no. 02-2271700.
2. The Board hereby imposes a fine in the amount of \$250.00. This fine will be attached to the license record and must be paid no later than 180 days from the effective date of this Order. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.
3. This Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which Respondent currently holds a professional license, as required by any such state or jurisdiction, including to the Board on renewal applications or applications for a new license or registration.

Service of this Order shall be perfected in accordance with the requirements of ORC Chapter 119.

Rich Miller, RPh, moved for the findings and decision of the Board. T.J. Grimm, RPh, seconded the motion. Motion passed (Yes-6/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 Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE OHIO BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **September 18, 2024**

By:

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/alg/kll





**STATE OF
OHIO**
BOARD OF PHARMACY

-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

Steven W. Schierholt, Esq., Executive Dir.
Date: Feb 23, 2022

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

**NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST
TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSEE**

IN THE MATTER OF:

Case No. A-2020-0760

501-3923

Akron Pharmacy D.B.A. MAC Pharmacy
c/o Sherif Mankaryous, RPh
879 E. Exchange Street
Akron, Ohio 44306

License No. 02-2271700

February 23, 2022

Dear Akron Pharmacy D.B.A. MAC Pharmacy and Mr. Mankaryous:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Terminal Distributor of Dangerous Drugs under authority of Section (TDDD) 4729.57 of the Revised Code.

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 section 4729.54 of the Ohio Revised Code 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 Revised Code.
2. Akron Pharmacy D.B.A. MAC Pharmacy (MAC Pharmacy) has an active TDDD license with the Board under license number 02-2271700, which lists Sherif Mankaryous, RPh, as the Responsible Person.

ALLEGATIONS

1. On or about October 27, 2020, an inspection of MAC Pharmacy, located at 879 E. Exchange Street, Akron, Ohio, revealed a pharmacy employee was performing pharmacy technician duties without obtaining proper registration with the Board. The inspection revealed the following:
 - a. Joel Bacola had been working as a pharmacy technician at MAC Pharmacy from on or about May 2020 to October 27, 2020, without Board-issued registration. During the inspection, he was

77 South High Street, 17th Floor, Columbus, Ohio 43215

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observed performing duties of a pharmacy technician, including pulling stock bottles from the shelves and counting medications. He was issued registration as a pharmacy technician trainee on or about November 5, 2020.

2. On or about November 9, 2020, MAC Pharmacy's Responsible Person, Sheriff Mankaryous, RPh, spoke with an agent of the Board. He stated that he did not know Joel Bacola was not registered as a technician. Joel Bacola was asked to become registered after all his training.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct, as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.95(C) of the ORC, No terminal distributor of dangerous drugs shall knowingly allow any person employed or otherwise under the control of the person who owns, manages, or conducts the terminal distributor to violate division (A) which states: No person who is not a pharmacist, pharmacy intern, registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee shall knowingly engage in any of the activities listed in section 4729.91 of the Revised Code in a location licensed as a terminal distributor of dangerous drugs, a misdemeanor of the second degree, punishable by a maximum penalty of \$4,000.
2. Such conduct, as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000: Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC 4729.55(D).
3. Such conduct, as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57 of the ORC, 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. Ceasing to satisfy the qualifications of a TDDD set forth in 4729.55 of the Revised Code, ORC Section 4729.57(B)(7); 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).
4. 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, effective March 1, 2019, each punishable by a maximum penalty of \$500:
 - a. 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

- b. 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
- 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).

5. Such conduct, as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:
 - 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. 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).

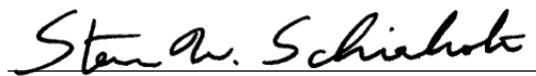
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of 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 MAILING 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 corporation, 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 mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

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 STATE BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director

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