



IN THE MATTER OF:

CASE NO. A-2020-0473

Okuley's Pharmacy & Home Medical, Inc.
c/o Lauren Bosch, RPh
1201 E. Second Street
Defiance, OH 43512

License No. 02-1184400

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Okuley's Pharmacy & Home Medical, Inc. for the purpose of resolving all issues between the parties relating to the Board investigation of a technician performing pharmacy duties without a pharmacist present. Together, the Board and Okuley's Pharmacy & Home Medical, Inc. 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. Okuley's Pharmacy & Home Medical, Inc. is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1184400.

FACTS

1. The Board initiated an investigation of Okuley's Pharmacy & Home Medical, Inc., Terminal Distributor of Dangerous Drugs license number 02-1184400, related to a technician performing pharmacy duties without a pharmacist present.
2. On or about March 29, 2022 the Board sent a Notice of Opportunity for Hearing to Okuley's Pharmacy & Home Medical, Inc., 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.

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3. On or about May 5, 2022, Okuley's Pharmacy & Home Medical, Inc., through counsel, Zachary Swisher, requested an administrative hearing, which was subsequently scheduled for March 8, 2023.

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:

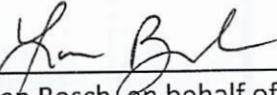
1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Okuley's Pharmacy & Home Medical, Inc. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 29, 2022; however, the Board has evidence 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. Okuley's Pharmacy & Home Medical, Inc. agrees to pay to the Board a monetary penalty the amount of \$2,000.00 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 Okuley's Pharmacy & Home Medical, Inc.'s TDDD license, number 02-1184400.
5. Okuley's Pharmacy & Home Medical, Inc. 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. Okuley's Pharmacy & Home Medical, Inc. 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 Okuley's Pharmacy & Home Medical, Inc. 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 Okuley's Pharmacy & Home Medical, Inc. by the Board and will NOT discharge Okuley's Pharmacy & Home Medical, Inc. from any obligation under the terms of this Agreement.

7. Okuley's Pharmacy & Home Medical, Inc. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. Okuley's Pharmacy & Home Medical, Inc. 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 Okuley's Pharmacy & Home Medical, Inc. will operate.
10. Okuley's Pharmacy & Home Medical, Inc. 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]

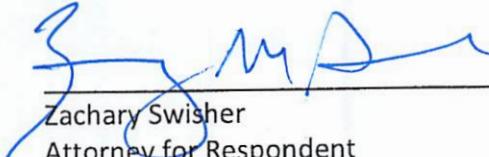
IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:


Lauren Bosch, on behalf of,
Okuley's Pharmacy & Home Medical, Inc., Respondent

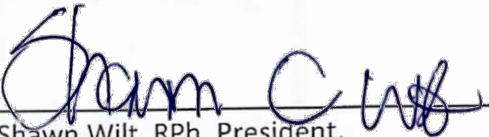
2-14-23

Date of Signature


Zachary Swisher
Attorney for Respondent

2-22-23

Date of Signature


Shawn Wilt, RPh, President,
State of Ohio Board of Pharmacy

03.09.2023

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.

Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Dir.
Date: 3/29/2022

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

**NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE**

IN THE MATTER OF:

CASE NO. A-2020-0473

Okuley's Pharmacy & Home Medical, Inc.
c/o Lauren Bosch, RPh, Responsible Person
1201 E. Second Street
Defiance, OH 43512

License No. 02-1184400

March 29, 2022

Dear Okuley's Pharmacy & Home Medical, Inc., and Lauren Bosch, RPh:

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 (TDDD) under authority of Section 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 4729.55 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. Okuley's Pharmacy & Home Medical, Inc. (Okuley's), located at 1201 E. Second Street, Defiance, OH 43512, has an active TDDD license with the Board under license number 02-1184400, which presently lists Lauren Bosch, RPh, as the Responsible Person.

ALLEGATIONS

1. On or about February 3, 2020, the Board discovered that a certified pharmacy technician employed at Okuley's, Lori Ward (registration no. 09-301772) was working at the pharmacy and performing pharmacy duties without a pharmacist present on-site.
2. On or about March 12, 2020, in an interview with Board agents, Okuley's Responsible Person at that time, Kieu Okuley, admitted the following:

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- a. The location was both a pharmacy and home medical equipment facility. On Mondays, the HME facility was open, but the pharmacy was closed and secured by an open-air barricade.
 - b. Ward was scheduled to work on Mondays when the pharmacy was closed but no pharmacist was scheduled to supervise her. On Mondays, Ward would refill prescriptions in the computer, perform data entry and answer the phone.
 - c. Ward was not permitted to send prescription copies, but she would receive prescription copies.
 - d. Ward would work on a computer located outside the pharmacy barricade that was equipped with pharmacy dispensing software.
3. Further investigation confirmed that Ward worked on January 27, 2020, from 9:00 AM to 5:00 PM, without a supervising pharmacist present, and during which a third-party pharmacist attempted to provide a prescription copy to Okuley's via telephone before learning that no pharmacist was present and supervising Ward.
4. On or about May 7, 2020, Kieu Okuley subsequently confirmed to Board agents that Ward had been performing the duties of a pharmacy technician without pharmacist supervision on Mondays at Okuley's since approximately March 2017.
5. In a written statement to the Board, Ward confirmed she routinely worked at Okuley's on Mondays when no pharmacist was on-site. During that time, her duties included placing orders for over-the-counter medications, answering telephone calls, taking refill requests from patients and other messages for the pharmacist. Ward stated that at the end of the day on Mondays, she would process data entry for the day, including prescription refill requests.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Section 4729.91(B) of the ORC, A certified pharmacy technician may, under the direct supervision of a pharmacist, engage in any of the activities listed in this section at a licensed TDDD to the extent that the activities do not require the exercise of professional judgment, each violation punishable by a maximum penalty of \$1,000.
2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Rule 4729:3-3-04(C) of the OAC as effective December 4, 2017, each violation punishable by a maximum penalty of \$1,000: A certified pharmacy technician may, under the direct supervision of a pharmacist, engage in the following activities at a licensed TDDD:
 - a. Entering information into and retrieving information for a database or patient profile, OAC Rule 4729:3-3-04(B)(2); and/or
 - b. Send or receive copies of non-controlled prescriptions provided a pharmacist on duty is supervising the activity of the certified pharmacy technician and is immediately available to answer questions or discuss the prescription copy that is sent or received by the pharmacy technician, OAC Rule 4729:3-3-04(B)(14).

3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Rule 4729:3-3-04(C) of the OAC as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000: A certified pharmacy technician may, under the direct supervision of a pharmacist, engage in the following activities at a licensed TDDD:
 - a. Entering information into and retrieving information for a database or patient profile, OAC Rule 4729:3-3-04(C)(2); and/or
 - b. Send or receive copies of non-controlled prescriptions provided a pharmacist on duty is supervising the activity of the certified pharmacy technician and is immediately available to answer questions or discuss the prescription copy that is sent or received by the pharmacy technician, OAC Rule 4729:3-3-04(C)(14).
4. 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 April 6, 2017, 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).
5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 4729.27 of the ORC, each violation constituting a third-degree misdemeanor, each punishable by a maximum penalty of \$500: A person not a pharmacist, who owns, manages, or conducts a pharmacy, shall employ a pharmacist to be in full and actual charge of such pharmacy. Any pharmacist who owns, manages, or conducts a pharmacy shall be personally in full and actual charge of the pharmacy, or shall employ another pharmacist to be in full and actual charge of the pharmacy.
6. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of section 4729.28 of the ORC, each violation constituting a third-degree misdemeanor, each punishable by a maximum penalty of \$500: No person who is not a pharmacist or a pharmacy intern under the personal supervision of a pharmacist shall compound or sell dangerous drugs or otherwise engage in the practice of pharmacy.
7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729-9-11(A)(a)(h) of the OAC, as effective August 15, 2016, each violation punishable by a maximum penalty of \$1,000: any designated area outside the prescription department at the location licensed as a TDDD intending to be used for records of dangerous drugs must be secured by a physical barrier with suitable locks or an electronic barrier to detect unauthorized entry, and such barrier must be approved by the State Board of Pharmacy before being put into use. Authorized personnel may have access if there is on-site supervision of a pharmacist.
8. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following sections of Rule 4729-9-11(E) of the OAC, as effective August 15, 2016, each violation punishable by a maximum penalty of \$1,000: Only individuals authorized under state laws or rules shall have unsupervised access to dangerous drugs.
9. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-5-11(A)(3) of the OAC, as effective April 17, 2017, each violation punishable by a maximum penalty of

\$1,000: 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 regulating governing the distribution of drugs and the practice of pharmacy.

10. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-2-01(A)(3) of the OAC, each violation punishable by a maximum penalty of \$1,000: 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 regulating governing the distribution of drugs and the practice of pharmacy.
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, 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 terminal distributor of dangerous drugs set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7).
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 March 1, 2019, 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. 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 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 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, 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/mlw/jrn

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