



IN THE MATTER OF:

CASE NO. A-2021-0354

Tremont Pharmacy
c/o Meredith Bailey, RPh
2144 Tremont Center
Upper Arlington, OH 43221

License No. 02-0529800

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 Tremont Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of the theft of drugs by an employee and drug security issues. Together, the Board and Tremont 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. Tremont Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-0529800.

FACTS

1. The Board initiated an investigation of Tremont Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-0529800, related to the theft of drugs by an employee and drug security issues.
2. On or about November 4, 2022, the Board sent a Notice of Opportunity for Hearing to Tremont 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 November 28, 2022, Tremont Pharmacy, through counsel Doug Graff, timely requested an administrative hearing, which was scheduled for April 3, 2023. The matter was continued and subsequently scheduled for October 11, 2023.

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

T: (614) 466.4143 | F: (614) 752.4836 | contact@pharmacy.ohio.gov | www.pharmacy.ohio.gov



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:

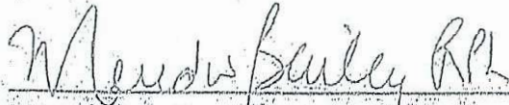
1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Tremont Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated November 4, 2022; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Tremont Pharmacy agrees to pay to the Board a monetary penalty the amount of \$2,500.00. 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.elicense.ohio.gov and process the items in your cart.
4. The Board hereby imposes a written reprimand on Tremont Pharmacy's TDDD license, number 02-0529800.
5. Tremont 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. Tremont 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 Tremont 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 Tremont Pharmacy by the Board and will NOT discharge Tremont Pharmacy from any obligation under the terms of this Agreement.
7. Tremont 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. Tremont 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 Tremont Pharmacy will operate.
10. Tremont 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.

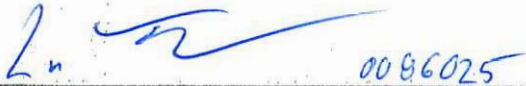
Approved by:



Meredith Bailey, RPh, on behalf of,
Tremont Pharmacy, Respondent

10/10/23

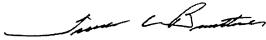
Date of Signature

 0096025

Attorney for Respondent (if applicable)

10/13/23

Date of Signature



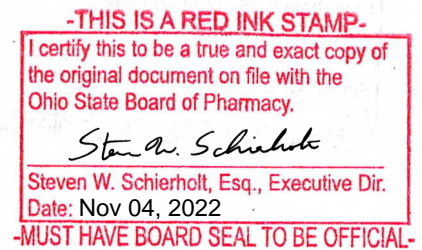
Trina Buettner, RPh, President,
State of Ohio Board of Pharmacy

10.30.2023

Date of Signature



**STATE OF
OHIO**
BOARD OF PHARMACY



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

IN THE MATTER OF:

CASE NO. A-2021-0354

Tremont Pharmacy
c/o Meredith Anne Bailey, RPh
2144 Tremont Center
Columbus, OH 43221

License No. 02-0529800

November 4, 2022

Dear Tremont Pharmacy and Meredith Anne Bailey, 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. Tremont Pharmacy, located at 2144 Tremont Center, Columbus, Ohio, has an active TDDD license with the Board under license number 02-0529800, which lists Meredith Anne Bailey, RPh, as the Responsible Person.

ALLEGATIONS

1. On or about February 24, 2021, an inspection of Tremont Pharmacy, located at 2144 Tremont Center, Columbus, Ohio, revealed a pharmacy employee was unlawfully removing a high volume of controlled substances from the Tremont Pharmacy over several months. The inspection revealed Lawrence Shonk II had been working as a certified pharmacy technician at Tremont Pharmacy. On or about February 16, 2021, Meredith Bailey, RPh, discovered the loss of approximately 800 tablets of 15mg oxycodone, a Schedule II controlled substance. She reported the loss to the Board on or about February 17, 2021. After notifying the Board, Meredith Bailey, RPh, detected a combined loss of over 6,000 tablets of oxycodone, methadone, and hydrocodone of varying strengths.



2. The audit of Tremont Pharmacy's oxycodone (a Schedule II controlled substance), hydrocodone (a Schedule II controlled substance), Xanax (a Schedule IV controlled substance), and Adderall (a Schedule II controlled substance) for a period of on or about November 2, 2020, to on or about February 24, 2021, revealed a potential loss of 15,034 tablets of various strengths. Additionally, discrepancies (both overages and shortages) were found in 109 of 162 controlled substances audited.
3. On February 24, 2021, Lawrence Shonk was interviewed by agents of the Board, and admitted he stole an unknown number of controlled substances from Tremont Pharmacy over a four-month period from November 1, 2020, to on or about February 16, 2021.
4. On or about February 22, 2021, Meredith Bailey, RPh, spoke with an agent of the Board. She admitted:
 - a. She allowed Lawrence Shonk II, a certified pharmacy technician, to order, receive and enter inventory for most of the dangerous drugs and controlled substances without pharmacist oversight.
 - b. She does not maintain a perpetual inventory of the drug stock or conduct bottle back counts. Either of these practices would have detected or potentially prevented the high volume of controlled substances from being diverted over the four to eight-month period.
 - c. Although not required by the Board, she said since taking ownership of Tremont Pharmacy, she never compared the wholesale and dispensing records against the on-hand drugs to validate the inventory.
 - d. She performed the annual controlled substance inventory on October 30, 2020, which consisted of counting the on-hand drugs; however, no reconciliation was done.
 - e. Tremont Pharmacy is not alarmed and has been broken into several times since she took over ownership. The latest Breaking & Entering occurred on November 1, 2020, which was investigated by the Upper Arlington Police Department, and reported to the Board. The suspect(s) stole a substantial volume of controlled substances (intermingled throughout the shelves), and cash from the register.
 - f. A second controlled substance inventory was conducted on November 2, 2020, the day after the theft. This inventory was the last count of the on-hand drugs and was used as a baseline for the Board agent's audit.

POTENTIAL VIOLATIONS OF LAW

1. 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 March 22, 2020, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:
 - a. The applicant is equipped as to land, buildings, and equipment to properly carry on the business of a terminal distributor of dangerous drugs within the category of licensure approved by the board, ORC 4729.55(A); and/or

- b. A pharmacist, licensed health professional authorized to prescribe drugs, animal shelter licensed with the state board of pharmacy under section 4729.531 of the Revised Code, or a laboratory as defined in section 3719.01 of the Revised Code will maintain supervision and control over the possession and custody of dangerous drugs that may be acquired by or on behalf of the applicant, ORC 4729.55(B); and/or
 - c. Adequate safeguards are assured to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs, ORC 4729.55(C); and/or
 - d. 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
- 2. 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 September 29, 2017, 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729.57(B)(5); and/or
 - 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).
- 3. 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. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, OAC Rule 4729:5-4-01(B)(5); and/or
 - 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 of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed, OAC Rule 4729:5-4-01(B)(10); and/or
 - f. Commission of an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed, OAC Rule 4729:5-4-01(B)(15); and/or
 - g. Commission of an act that constitutes a misdemeanor drug offense, except for a minor misdemeanor drug offense, regardless of the jurisdiction in which the act was committed, OAC Rule 4729:5-4-01(B)(16); and/or
 - h. 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)(20); and/or
 - i. The method used by the terminal distributor to store, possess or distribute dangerous drugs poses serious harm to other, OAC Rule 4729:5-4-01(B)(25).
4. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following the following paragraphs of Rule 4729:5-3-14 of the OAC, General Security Requirements, as effective March 1, 2020, each violation punishable by a maximum fine of \$1,000:
- a. All terminal distributor of dangerous drugs shall provide effective controls and procedures to:
 - i. Deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
 - ii. 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 law, as required in section 4729.55 of the Revised Code, OAC Rule 4729:5-3-14(A)(2).
5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following the following paragraphs of Rule 4729:5-5-23(A) of the OAC, Security, control and storage of dangerous drugs in an outpatient pharmacy, as effective March 1, 2020, each violation punishable by a maximum fine of \$1,000:
- a. A pharmacist shall provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted permission for such records to be stored at a secure off-site location in accordance with this chapter of the Administrative Code, at all times in order to deter and detect theft or diversion, OAC Rule 4729:5-5-23 (A)(1); and/or
 - b. All Schedule II controlled substance dangerous drugs shall be stored in a securely locked, substantially constructed cabinet or safe and shall not be dispersed through the stock of dangerous drugs. The cabinet or safe shall remain locked and secured when not in use. Schedule III through V controlled substance dangerous drugs may be stored with Schedule II controlled substance dangerous drugs, OAC Rule 4729:5-5-23(A)(5); and/or

- c. Whenever a pharmacist cannot meet the supervision requirements in paragraph (A)(3)(a) of this rule, security of the pharmacy must be provided in accordance with the following:
 - i. The pharmacy must be secured by either:
 - 1. A physical barrier (i.e. barricade) with suitable locks approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation, OAC Rule 4729:5-5-23(A)(6)(a)(i); and/or
 - 2. An alarm system approved by the board that is monitored by a central station for control and can detect unauthorized access to the pharmacy. The alarm system shall be tested on a biannual basis. The pharmacy or the entity that manages security for the pharmacy shall maintain testing records for three years from the date of testing and shall make such records readily retrievable. The pharmacy shall be responsible for obtaining testing records if such records are maintained by a third-party. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation. This notification requirement does not apply if a pharmacy also utilizes an approved physical barrier in accordance with paragraph (A)(6)(a)(i) of this rule, OAC Rule 4729:5-5-23(A)(6)(a)(ii).
- 6. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following the following paragraphs of Rule 4729:5-5-24(I) of the OAC, Prescription Processes, as effective March 1, 2020, each violation punishable by a maximum fine of \$1,000:
 - a. All records required in accordance with this chapter shall comply with the following:
 - i. Be maintained under appropriate supervision and control to restrict unauthorized access, including security features to prevent unauthorized access to computerized records, OAC Rule 4729:5-5-24(I)(1); and/or
 - ii. All computerized records shall contain daily back-up functionality to protect against record lose, OAC Rule 4729:5-5-24(I)(2).
- 7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following paragraphs of Rule 4729:5-2-01(A)(2) of the OAC, effective March 1, 2019, 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, each violation punishable by a maximum penalty of \$1,000.

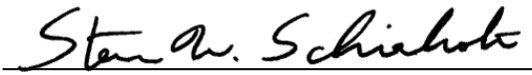
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

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/jak/kll

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