



**STATE OF
OHIO**
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2020-0506

TWC Pharmacy and Wellness Center, LLC
c/o Catherine Lopienski, Responsible Person
273-A W. Schrock Road
Westerville, OH 43081

License No. 02-2041100

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), TWC Pharmacy and Wellness Center, LLC, for the purpose of resolving Board Case No. A-2020-0506. Together, the Board and TWC Pharmacy and Wellness Center, LLC, are referred to hereinafter as "party" or "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, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. TWC Pharmacy and Wellness Center, LLC, located at 273-A W. Schrock Road, Westerville, OH 43081, is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2041100.

FACTS

1. The Board initiated an investigation of TWC Pharmacy and Wellness Center, LLC, Terminal Distributor of Dangerous Drugs license number 02-2041100 related to pharmacy supervision and drug security.
2. On or about February 4, 2022, the Board sent a Notice of Opportunity for Hearing to TWC Pharmacy and Wellness Center, LLC, 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 March 2, 2022, TWC Pharmacy and Wellness Center, LLC, through counsel, timely requested an administrative hearing, which was subsequently scheduled for June 6, 2022.

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4. On or about April 1, 2022, TWC Pharmacy and Wellness Center, LLC, through its Responsible Person Catherine Lopienski, RPh, notified the Board that it had closed, effective March 27, 2022, pursuant to its March 1, 2022, Written Notice of Discontinuing Business and subsequent communications with the Board related thereto.

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. TWC Pharmacy and Wellness Center, LLC, neither admits nor denies the allegations stated in the Notice of Opportunity for hearing letter dated February 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. **The Board agrees to accept TWC Pharmacy and Wellness Center, LLC's permanent and voluntary surrender to the State of Ohio Board of Pharmacy of its Terminal Distributor of Dangerous Drugs license, number 02-2041100, with discipline pending, effective the date of its discontinuation of business, March 27, 2022.**
4. **TWC Pharmacy and Wellness Center, LLC, agrees never to reapply for any license or registration, issued by the State of Ohio Board of Pharmacy pursuant to Chapters 3719., 3796., 4729., or 4752. of the Revised Code.**
5. TWC Pharmacy and Wellness Center, LLC, 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.
6. TWC Pharmacy and Wellness Center, LLC, agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
7. TWC Pharmacy and Wellness Center, LLC, understands that it has the right to be represented by counsel for review and execution of this agreement.
8. 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 TWC Pharmacy and Wellness Center, LLC, will operate.

9. TWC Pharmacy and Wellness Center, LLC, 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.
10. 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.
11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
12. 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.
13. 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.
14. 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:

DocuSigned by:

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Catherine Lopienski, RPh, on behalf of,
TWC Pharmacy and Wellness Center, LLC, Respondent

4/8/2022

Date of Signature


Brandon Smith,
Attorney for Respondent

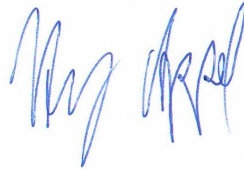
12 Apr. 2022
Date of Signature



Rich Miller, RPh President,
State of Ohio Board of Pharmacy

04.21.2022

Date of Signature



Henry Appel,
Ohio Assistant Attorney General

04.21.2022

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: 2/9/2022
-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-2020-0506

TWC Pharmacy and Wellness Center, LLC
c/o Catherine Lopienski, Responsible Person
273-A W. Schrock Road
Westerville, OH 43081

License No. 02-2041100

February 9, 2022

Dear TWC Pharmacy and Wellness Center, LLC, and Ms. Lopienski:

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. TWC Pharmacy and Wellness Center, LLC (TWC), located at 273-A W. Schrock Road, Westerville, OH, 43081, has an active TDDD license with the Board under license number 02-2041100, which lists Catherine Lopienski as the Responsible Person.

ALLEGATIONS

1. At all times mentioned below, Catherine Lopienski was listed as the Responsible Person at TWC.
2. In late 2017, Catherine Lopienski sold her ownership in TWC to her business partner, Laura Atkinson. No change of ownership notification was submitted to the Board at that time.
3. On or about November 1, 2018, during Board inspection, Board agents discovered the following related to pharmacy supervision and drug security:
 - a. Discrepancies in TWC's controlled substance inventory.

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- b. TWC had not conducted an annual controlled substance inventory since approximately December 2015.
 - c. Catherine Lopienski was working in the pharmacy one day per week.
 - d. TWC's non-pharmacist owner, Laura Atkinson, possessed the pharmacy key and alarm code, allowing her unauthorized access to the pharmacy while a pharmacist was not present.
4. As a result of the November 1, 2018, inspection, Board agents instructed Catherine Lopienski to complete the following:
 - a. Submit a request to change TWC's Responsible Person to ensure adequate supervision at the pharmacy.
 - b. Immediately complete a controlled substance inventory and identify any losses.
5. On or about December 14, 2018, upon completion of the controlled substance inventory, Catherine Lopienski filed a DEA-106 form listing the following losses:
 - a. Oxycodone HCL 10mg: 235 tablets
 - b. Oxycodone-Acetaminophen 5-325mg: 227 tablets
 - c. Oxycodone NE-Acetaminophen 10-325 mg: 295 tablets
6. On or about February 22, 2019, in an interview with Board agents, Catherine Lopienski stated the following:
 - a. From approximately October 2017 to approximately May 2018, due to health issues, she was unable to work.
 - b. In approximately May 2018, Catherine Lopienski resumed working at TWC one day per week and eventually progressed to two days per week. However, she was unable to work more than two days at that time.
 - c. From approximately August 2017 through approximately April 2020, at least 11 contracted pharmacists worked part-time at TWC, none of which served as TWC's Responsible Person. No full-time pharmacist was hired during your absence.
 - d. No request to change TWC's Responsible Person had been submitted after the November 1, 2018, inspection.
 - e. Although after the November 1, 2018, inspection pharmacy access was limited to Catherine Lopienski and 2 part-time pharmacists, Return Solutions previously had unsupervised access to the C-II safe while processing drug returns.
7. On or about February 22, 2019, Board agents discovered that pharmacy employee Monica Norah was observed performing pharmacy technician duties without active Board-issued registration, including data entry, counting, packaging, and labeling of drugs.
8. On or about February 22, 2019, while conducting a controlled substance audit at TWC, Board agents discovered approximately 12, 210 tablets of oxycodone products that TWC could not account for.
9. From approximately March 25 through approximately May 6, 2020, Board agents interviewed several of the part-time pharmacists described above in Paragraph (6)(c). During those interviews, Board agents were told the following:
 - a. Atkinson often participated in the pharmacy's operations, including data entry, and counting, packaging, and labeling drugs, despite not holding a Board-issued license or registration.

- b. Many of the pharmacists stated they notified Catherine Lopienski of potential controlled substances losses but that it did not appear corrective action had been taken.
 - c. Although Catherine Lopienski was listed as the RP, she was often not present and unable to supervise the pharmacy.
10. A request to change TWC's Responsible Person was not submitted to the Board until approximately June 15, 2020. Effective June 16, 2020, Catherine Lopienski was not listed as TWC's Responsible Person, until approximately January 6, 2022, when a new request to list her as TWC's Responsible Person was submitted to the Board.

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, each constitutes a violation of each of the following divisions of OAC Rule 4729-9-11(A)(1), effective August 15, 2017, each violation punishable by a maximum penalty of \$500:

A pharmacist, prescriber, and responsible person pursuant to rule 4729-5-11 of the Administrative Code shall provide 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, by the following procedures:

In a pharmacy:

Except as provided in paragraph (A)(2) of this rule, a pharmacist shall provide personal supervision of the dangerous drugs, exempt narcotics, hypodermics, poisons, D.E.A. controlled substance order forms, all records relating to the distribution of dangerous drugs, except where the board has granted a permission for such records to be stored at a secure off-site location pursuant to rules 4729-9-14 and 4729-9-22 of the Administrative Code, at all times in order to deter and detect theft or diversion.

3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of each of the following divisions of OAC Rule 4729-5-11, effective February 17, 2017, each violation punishable by a maximum penalty of \$500:

For a pharmacy licensed as a terminal distributor of dangerous drugs:

- 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 as required in rule 4729-9-11 of the Administrative Code and maintaining all drug records otherwise required, OAC 4729-5-11(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 4729-5-11(A)(3); and/or

For all locations licensed as a terminal distributor of dangerous drugs:

- c. A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times, OAC 4729-5-11(C)(1); and/or
 - d. 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 4729-5-11(C)(4); and/or
 - e. A responsible person must be physically present at the location for a sufficient amount of time to provide supervision and control of dangerous drugs on-site, OAC 4729-5-11(C)(5); and/or
- 4. 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 as required in rule 4729-9-11 of the Administrative Code and maintaining all records relating to the distribution dangerous drugs, OAC 4729-5-11(C)(6).
- 5. 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 and March 22, 2020, TDDD license requirements, each violation punishable by a maximum penalty of \$1,000:
 - a. 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
 - b. 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).
- 6. Such conduct as set forth in Paragraph (2) of the Allegations Section, if proven, constitutes a violation of Rule 4729-9-08(A) of the OAC, as effective February 1, 2017, each violation punishable by a maximum

penalty of \$500: Any change in ownership . . . requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in ownership.

7. 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 6, 2017 and 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. 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
 - 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).

8. 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); and/or
 - d. Employs a responsible person that does not meet the requirements set forth in rule 4729:5-2-01 of the Administrative Code, OAC Rule 4729:5-4-01(B)(21); and/or
 - e. 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).

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/mls/jrn

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