



**STATE OF
OHIO**
BOARD OF PHARMACY

IN THE MATTER OF:

Case No. A-2020-0416

I-2020-0419

**Wellness 1 Pharmacy
c/o Amro Elsayed, RPh
2420 S. Smithville Road
Kettering, OH 45420**

License No. 02-2323250

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 Wellness 1 Pharmacy for the purpose of resolving all issues between the parties relating to Board case no. A-2020-0416. Together, the Board and Wellness 1 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. Wellness 1 Pharmacy has an active Terminal Distributor of Dangerous Drugs (TDDD) license with the Board under license number 02-2323250, which lists Amro Elsayed, RPh, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Wellness 1 Pharmacy, TDDD license number 02-2323250, which resulted in the Board issuing a May 21, 2021, Notice of Opportunity for Hearing to Wellness 1 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.

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

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



TERMS

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

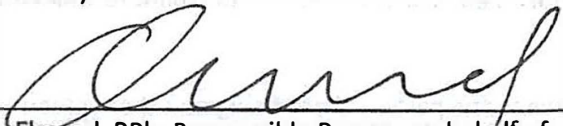
- 1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.**
- 2. Wellness 1 Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated May 21, 2021, however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.**
- 3. Wellness 1 Pharmacy agrees to pay to the Board a monetary penalty the amount of \$5,000.00. This fine will be attached to Wellness 1 Pharmacy's license record and must be paid no later than 6 months from the effective date of this Agreement. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.**
- 4. Wellness 1 Pharmacy is subject to a one-year probationary period, starting on the effective date of this Agreement.**
- 5. Wellness 1 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. Wellness 1 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 Wellness 1 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 Wellness 1 Pharmacy by the Board and will NOT discharge Wellness 1 Pharmacy from any obligation under the terms of this Agreement.**
- 7. Wellness 1 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. Wellness 1 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 Wellness 1 Pharmacy will operate.**
- 10. Wellness 1 Pharmacy waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to 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. 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:



Amro Elsayed, RPh, Responsible Person, on behalf of
Wellness 1 Pharmacy, Respondent

9/30/2021


Date of Signature



Zachary Swisher
Attorney for Respondent

10-22-21

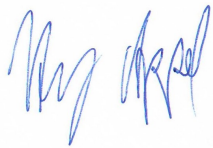
Date of Signature



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

11.10.2021

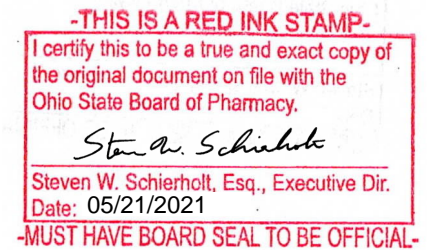
Date of Signature



Henry Appel, Ohio Assistant Attorney General

11.10.2021

Date of Signature



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

IN THE MATTER OF:

**Case No. A-2020-0416
I-2020-0419**

**Wellness 1 Pharmacy
c/o Barbara Burger, RPh
2420 S. Smithville Road
Kettering, OH 45420**

License No. 02-2323250

May 21, 2021

Dear Wellness 1 Pharmacy and Barbara Burger:

You are hereby notified, in accordance with the provisions of ORC 119.07, 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 ORC 4729.57.

JURISDICTION

1. Pursuant to ORC 4729.57, 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 ORC 4729.54 to practice as a TDDD in the state of Ohio. Additionally, ORC 4729.57 grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the ORC for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the ORC.
2. Wellness 1 Pharmacy has an active TDDD license with the Board under license number 02-2323250 which lists Barbara Burger, RPh, as the Responsible Person.

ALLEGATIONS

1. On or about March 3, 2020, during an inspection of Wellness 1 Pharmacy, located at 2420 S. Smithville Road, Kettering, Ohio, the following violations were observed:
 - a. From approximately September 16, 2019, to approximately March 3, 2020, Amro Elsayed had been performing duties of a pharmacy intern and/or a pharmacy technician without a Board-issued license and/or registration. Specifically, his pharmacy intern license expired on or about September 15, 2019, and he did not apply for registration as a pharmacy technician trainee until on or about March 3, 2020.
 - i. During a March 3, 2020, interview with a Board agent, Elsayed admitted to performing the following duties during the period that he did not hold an active Board-issued license and/or registration:

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1. Preparing and affixing pharmacy labels;
 2. Placing dangerous drugs into containers prior to dispensing by a pharmacist;
 3. Packaging and selling a dangerous drug to a patient or patient representative; and/or
 4. Performing sterile compounding.
- ii. During a March 3, 2020, interview with a Board agent, Responsible Person Barbara Burger stated she believed Elsayed could hold a technician registration while he was seeking licensure as a pharmacist, but she should have clarified such with the Board.
- b. Several compounding records did not contain the lot number and/or the expiration date for the drug(s) utilized in each respective compound.
 - i. In an interview with Board agents on or about March 3, 2020, certified pharmacy technician Bonnie Dillavou initially stated if an expired medication were used in a compound, the pharmacy's computer system would not allow for the scanning and entry of the lot number and expiration date. However, upon further questioning, she admitted she had omitted that information from the records when she compounded drugs at the pharmacy. Specifically, she admitted she used expired medications to create compounded drugs if the prescriptions were needed the same day and expired medications were the only ones available and she left the lot number and expiration date off the compounding record to hide the use of expired medication.
 - c. From on or about February 1, 2019, to on or about February 25, 2020, Wellness 1 Pharmacy was dispensing compounded sterile prescriptions without a patient-specific prescription. Specifically, Board agents observed records of sterile eyedrops that were compounded as non-patient specific and subsequently dispensed to an eye surgery center. Patient names were subsequently provided and added to the compounding records.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in Paragraph (1)(a) of 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) of this section, 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 \$750.
2. Such conduct as set forth in Paragraph (1)(b) of the Allegations Section, if proven, constitutes a violation of ORC 3715.52(A)(1), The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded is prohibited, constituting a misdemeanor of the fourth degree, punishable by a maximum fine of \$250.

3. Such conduct, as set forth in Paragraph (1)(c) of the Allegations Section, if proven, constitutes a violation of ORC 2925.23 (as effective September 29, 2017, March 22, 2019), Illegal Processing of Drug Documents, constituting a felony of the fifth degree, punishable by a maximum fine of \$2,500.
4. Such conduct, as set forth in Paragraph (1)(c) of the Allegations Section, if proven, constitutes a violation of ORC 4729.01(F)(1)(a) (as effective September 29, 2017, March 20, 2019, July 30, 2019), Dispensing a drug without a prescription, each punishable by a maximum penalty of \$500.
5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, as 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).
6. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-5-11 of the OAC, as effective February 17, 2017, each punishable by a maximum penalty of \$500:
 - 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 4729-5-11(A)(3).
7. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of (B) of ORC 4729.57 (as effective September 29, 2017), each violation constituting a minor misdemeanor, each punishable by a maximum penalty of \$150:
 - a. Violating any rule of the Board, ORC 4729(B)(2); and/or
 - b. Violating any provision of this chapter, ORC 4729(B)(3); and/or
 - c. Except as provided in ORC 4729.89, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or ORC Chapter 3715., ORC 4729(B)(4); and/or
 - d. Violating any provision of the federal drug abuse control laws or ORC Chapters 2925. or 3719., ORC 4729(B)(5); and/or
 - e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in ORC 4729.55, ORC 4729(B)(7); and/or
 - f. Any other cause for which the Board may impose discipline as set forth in rules adopted under ORC 4729.26, ORC 4729(B)(10).
8. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of each of the following divisions of Rule 4729:5-4-01(B)(2) of the OAC (as effective March 1, 2019), each violation punishable by a maximum penalty of \$500:

- a. Violating any rule of the Board, OAC 4729:5-4-01(B)(2); and/or
- b. Violating any provision of ORC Chapter 4729., OAC 4729:5-4-01(B)(3); and/or
- c. Except as provided in ORC 4729.89, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or ORC Chapter 3715., OAC 4729:5-4-01(B)(4); and/or
- d. Violating any provision of the federal drug abuse control laws or ORC Chapters 2925. or 3719., OAC 4729:5-4-01(B)(5); and/or
- e. Ceasing to satisfy the qualifications of a terminal distributor of dangerous drugs set forth in ORC 4729.55, OAC 4729:5-4-01(B)(7).

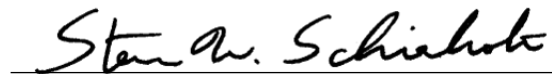
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

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.

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 Ohio 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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