



IN THE MATTER OF:

Case No. A-2022-0551

Dillonvale Pharmacy
c/o Joseph Zelek, RPh
74 Main Street
Dillonvale, Ohio 43917

License No. 02-0164000

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 Dillonvale Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of an employee performing duties of a pharmacy technician without maintaining appropriate registration with the Board. Together, the Board and Dillonvale 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. Dillonvale Pharmacy has an active TDDD license with the Board under license number 02-0164000, which lists Joseph Zelek, RPh, as the Responsible Person.

FACTS

1. The Board initiated an investigation of Dillonvale Pharmacy, TDDD license number 02-0164000, related to an employee performing duties of a pharmacy technician without maintaining appropriate registration with the Board.
2. On or about January 30, 2023, the Board sent a Notice of Opportunity for Hearing to Dillonvale 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. Dillonvale Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated January 30, 2023; 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. Dillonvale Pharmacy agrees to pay to the Board a monetary penalty the amount of \$1,000. This fine will be attached to Dillonvale Pharmacy's 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.
4. The Board hereby imposes a written reprimand on Dillonvale's TDDD license, number 02-0164000.
5. Dillonvale 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. Dillonvale 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 Dillonvale 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 Dillonvale Pharmacy by the Board and will NOT discharge Dillonvale Pharmacy from any obligation under the terms of this Agreement.
7. Dillonvale 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. Dillonvale 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 Dillonvale Pharmacy will operate.
10. Dillonvale 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. 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:

Joseph Zelek
Joseph Zelek, RPh on behalf of,
Dillonvale Pharmacy, Respondent

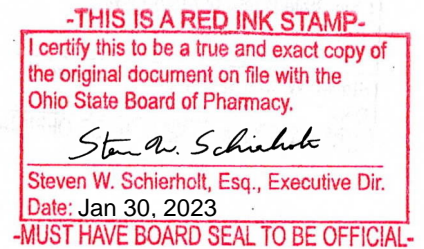
2-14-2023
Date of Signature

Attorney for Respondent (if applicable)

Date of Signature

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

02.17.2023
Date of Signature



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

IN THE MATTER OF:

Case No. A-2022-0551

Dillonvale Pharmacy
c/o Joseph Zelek, RPh
74 Main Street
Dillonvale, Ohio 43917

License No. 02-0164000

January 30, 2023

Dear Dillonvale Pharmacy and RP Joseph Zelek, 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 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. Dillonvale Pharmacy has an active TDDD license with the Board under license number 02-0164000, which lists Joseph Zelek, RPh, as the Responsible Person.

ALLEGATIONS

1. On or about June 9, 2022, an inspection of Dillonvale Pharmacy, located at 74 Main Street, Dillonvale, Ohio, revealed a pharmacy employee was performing pharmacy technician duties without maintaining proper registration with the Board. The inspection revealed the following:
 - a. Rosalyn Pasco had been working as a pharmacy technician trainee at Dillonvale Pharmacy from on or about July 1, 2021, to on or about July 19, 2022, without Board issued registration. Rosalyn Pasco's registration as a pharmacy technician trainee lapsed on July 1, 2021. During the

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inspection, she was observed performing duties of a pharmacy technician, including counting medications. She was issued registration as a pharmacy technician trainee on or about March 20, 2020.

2. On or about June 9, 2022, Rosalyn Pasco spoke with an agent of the Board and completed a written, notarized statement. She stated the following:
 - a. She has been employed at Dillonvale Pharmacy since September 1990.
 - b. She was unsure of the status of her license.
 - c. Her job includes counting medication, labeling vials, among other pharmacy technician duties.
 - d. She received an e-mail regarding an extension due to the COVID-19 pandemic. However, she did not take the opportunity to prioritize and complete the necessary steps to receive the license during the extension.
3. On or about July 12, 2022, Rosalyn Pasco again spoke with an agent of the Board. She stated the following:
 - a. She experienced difficulties completing the application for pharmacy technician, and she is still not licensed.
4. On or about July 19, 2022, Rosalyn Pasco was issued an extension of her Pharmacy Technician Trainee registration with a new expiration of January 19, 2023.
5. On or about June 9, 2022, Dillonvale Pharmacy's Responsible Person, Joseph Zelek, RPh, spoke with an agent of the Board and completed a written, notarized statement. He stated the following:
 - a. Rosalyn Pasco has worked for the pharmacy for over 30 years. The pharmacy was in the process of licensure during the pandemic, and there was communication with the Board; however, it stopped. The pharmacy will promptly restart the process to ensure proper licensure for Rosalyn Pasco.

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, and April 25, 2022, 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, and 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).

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

SWS/MLB/kll

CMRRR: 9414 7118 9956 2146 5335 67