



**STATE OF
OHIO**
BOARD OF PHARMACY

IN THE MATTER OF:

**CASE No. A-2020-0508
I-2019-0383-A**

Essentra Pharmacy

c/o Nicholas Newman, RPh
73 Sportsman's Drive, Suite B
Marengo, Ohio 43334

License No. 02-2629350

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 Essentra Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of a loss of controlled substances before or during transport to another pharmacy. Together, the Board and Essentra 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, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Essentra Pharmacy, located at 73 Sportsman's Drive, Suite B, Marengo, Ohio 43334, has an active TDDD license with the Board under license number 02-2629350, which lists Nicholas Newman, RPh as the Responsible Person.

FACTS

1. The Board initiated an investigation of Essentra Pharmacy, TDDD license number 02-2629350, related to the loss of controlled substances before or during transport to another pharmacy.
2. On or about September 21, 2020, the Board sent a Notice of Opportunity for Hearing to Essentra 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 September 29, 2020, Essentra Pharmacy, through counsel Zachary Swisher, timely requested an administrative hearing, which was subsequently scheduled for January 5, 2021 and continued to March 3, 2021.

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WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial 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. Essentra Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 21, 2020, 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. Essentra Pharmacy agrees to pay to the Board a monetary penalty the amount of \$1,500.00. This fine will be attached to your license record and must be paid no later than 30 days from the effective date of this Order. To pay this fine you must login to www.license.ohio.gov and process the items in your cart.
4. Essentra 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.
5. Essentra 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 Essentra 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 Essentra Pharmacy by the Board and will NOT discharge Essentra Pharmacy from any obligation under the terms of this Agreement.
6. Essentra Pharmacy agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
7. Essentra Pharmacy 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 Essentra Pharmacy will operate.

9. Essentra Pharmacy expressly waives its opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, specifically withdraws its request for a hearing, and waives any right to 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. 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:

Nicholas W. Newman

Nicholas Newman, RPh on behalf of,
Essentra Pharmacy, Respondent

2/25/2021

Date of Signature

Zachary M. Swisher, Attorney for Respondent

Jennifer M. Rudell, RPh

Jennifer M. Rudell, RPh President,
State of Ohio Board of Pharmacy

MR

Henry Appel, Ohio Assistant Attorney General

03.02.2021

Date of Signature

03.02.2021

Date of Signature

03.02.2021

Date of Signature



**STATE OF
OHIO**
BOARD OF PHARMACY

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

IN THE MATTER OF:

**CASE NO. A-2020-0508
I-2019-0383-A**

Essentra Pharmacy

c/o Nicholas Newman, RPh
73 Sportsman's Drive, Suite B
Marengo, Ohio 43334

September 21, 2020

Dear Essentra Pharmacy and Mr. Newman,

License No. 02-2629350

-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: 09/21/2020

-MUST HAVE BOARD SEAL TO BE OFFICIAL-

You are 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, or refuse to grant or renew any license issued pursuant to Section 4729.55 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. Essentra Pharmacy has a current TDDD license with the Board under license number 02-2629350 which lists Nicholas Newman as the Responsible Person.

ALLEGATIONS

1. On or about March 19, 2019, Nicholas Newman, RPh, Responsible Person for Essentra Pharmacy, notified the Board that Essentra Pharmacy, located at 73 Sportsman's Drive, Suite B, Marengo, Ohio, experienced a loss of 150 hydromorphone 8 mg tablets, a Schedule II controlled substance.
2. On or about March 19, 2019, Nicholas Newman, RPh (Newman) spoke with an agent of the Board and made the following statements about the missing hydromorphone:

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- a. On March 15, 2019, Newman set aside one box of fentanyl patches, one full stock bottle of hydromorphone 8 mg tablets (#100), and one amber vial of hydromorphone 8 mg tablets (#50). Newman placed the drugs on your desk at the pharmacy and later moved them to his briefcase, placed where pharmacy technicians could access it. There was a door in the back of the pharmacy that sometimes would not latch all the way.
 - b. Newman closed the pharmacy that evening and took the briefcase home with him. His intention was to bring the medication to Uptown Pharmacy on March 17, 2019. When Newman opened his briefcase on March 17, 2019, the hydromorphone was gone. The drugs could not be located.
 - c. Uptown Pharmacy and Essentra Pharmacy have the same owner. Newman was replacing medication he had previously taken from Uptown Pharmacy to fill a prescription at Essentra. Newman has done this multiple times before, however, he is not aware of a written policy allowing this transfer.
3. On or about April 21, 2020, William "Max" Peoples spoke with an agent of the Board and stated the following:
 - a. He owns both Uptown Pharmacy and Essentra Pharmacy. He authorized his pharmacists to transfer drugs between pharmacies.
 - b. As of the date of the interview, pharmacists were no longer allowed to have drugs overnight during transfers. Pharmacists are required to take drugs and items transferred to the pharmacy the same day. This was something learned from the March 2019 incident.
4. On or about December 4, 2019, during an investigation at Essentra Pharmacy, an agent of the Board identified the following:
 - a. Lack of adequate locks provided for the pharmacy barricade: the back door to the pharmacy sits in such a way to allow access with a credit card like device.
 - b. Perpetual controlled substance Schedule II inventory: fentanyl 25mcg/hr patches balance on-hand was less than perpetual inventory indicated.
 - c. Intracompany drug sales: pharmacy engages in intracompany sales between Essentra Pharmacy and Uptown Pharmacy. There is no written policy to address these sales including how drugs are transported, how drugs are stored, and how drugs are secured, particularly when kept out of the pharmacy overnight.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.55 of the ORC, effective April 6, 2017, each punishable by a maximum penalty of \$150:
 - 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... 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 Section 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 Section 4729.55(C); and/or
 - d. Adequate safeguards are assured to 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 Section 4729.55(D); and/or
 - e. If the applicant, or any agent or employee of the applicant, has been found guilty of violating section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., or 4729. of the Revised Code, or any rule of the board, adequate safeguards are assured to prevent the recurrence of the violation, ORC Section 4729.55(E).
- 2. 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 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, OAC Rule 4729:5-2-01(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 Rule 4729:5-2-01(A)(3); and/or
 - c. 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
 - d. 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); and/or
- 3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-05(A) of the OAC, as effective September 15, 2017, each punishable by a

maximum penalty of \$500: All licensees and registrants shall provide effective and approved controls and procedures to deter and detect theft and diversion of dangerous drugs. In order to determine whether a licensee or registrant has provided effective and approved controls against diversion, the state board of pharmacy shall use the security requirements set forth in rule 4729-9-11 of the Administrative Code as standards for the security controls and operating procedures necessary to deter and detect diversion, OAC Rule 4729-9-05(A).

4. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-11 of the OAC, each 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:
 - a. 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, OAC Rule 4729-9-11(A)(1); and/or
 - b. Whenever personal supervision of the dangerous drugs is not provided by a pharmacist, physical or electronic security of the dangerous drugs must be provided according to the following requirements:
 - i. Any designated area outside the prescription department at the location licensed as a terminal distributor of dangerous drugs intending to be used for the storage of dangerous drugs, D.E.A. controlled substance order forms, exempt narcotics, hypodermics, poisons, 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, and every other item or product that requires the personal supervision or sale by a pharmacist shall meet the following requirements:
 1. The designated area shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect unauthorized entry. Such a barrier, before being put into use, must be approved by the state board of pharmacy, OAC Rule 4729-9-11(A)(2)(h)(i); and/or
 2. No item, product, record, or equipment that must be accessible to anyone other than a pharmacist may be stored in the designated area, unless authorized by the board of pharmacy, OAC Rule 4729-9-11(A)(2)(h)(ii); and/or
 3. Authorized personnel may have access if there is on-site supervision by a pharmacist, OAC Rule 4729-9-11(A)(2)(h)(iii); and/or
 - c. Only individuals authorized under state laws or rules shall have unsupervised access to dangerous drugs, OAC Rule 4729-9-11(E).

5. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729-9-02 of the Ohio Administrative Code (OAC), minimum standards for a pharmacy, each punishable by a maximum penalty of \$1,000: All storage areas shall provide adequate physical security for all dangerous drugs in accordance with rules 4729-9-05 and 4729-9-11 of the Administrative Code, OAC rule 4729-9-02(E)(3).
6. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rules 4729-9-19(A)(4) and (B)(3)(f) of the OAC, not of good moral character and habits, and knowingly employing a person who is not of good moral character and habits, punishable by a maximum fine of \$1,000.
7. Such conduct as set forth in the Allegations Section, if proven, each 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 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 the Allegations Section, if proven, each constitutes a violation of the following divisions 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 TDDD 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.

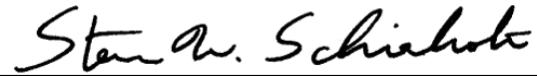
IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will not be accepted). **YOUR REQUEST MUST BE RECEIVED 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 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

SWS/alg/kll

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