



**STATE OF  
OHIO**  
BOARD OF PHARMACY

IN THE MATTER OF:

CASE NO. A-2019-0252

**Drug Store of Perrysburg**

c/o Prakash Naik, R.Ph.  
580 Craig Drive, Suite #12  
Perrysburg, OH 43551

License No. 02-1951850

### **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 Drug Store of Perrysburg for the purpose of resolving all issues between the parties relating to the Board investigation of questionable dispensing. Together, the Board and Drug Store of Perrysburg 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. Drug Store of Perrysburg is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1951850.

#### **FACTS**

1. The Board initiated an investigation of Drug Store of Perrysburg, Terminal Distributor of Dangerous Drugs license number 02-1951850, related to Drug Store of Perrysburg's questionable dispensing.
2. On or about September 15, 2021 the Board sent a Notice of Opportunity for Hearing to Drug Store of Perrysburg, 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 October 6, 2021, Drug Store of Perrysburg, through counsel Joseph R. Durham, timely requested an administrative hearing, which was subsequently scheduled for April 5, 2022.

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

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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. Drug Store of Perrysburg neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated September 15, 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. Drug Store of Perrysburg agrees to pay to the Board a monetary penalty the amount of \$3,000.00. 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](http://www.elicense.ohio.gov) and process the items in your cart.
4. The Board hereby imposes a written reprimand on Drug Store of Perrysburg's TDDD license, number 02-1951850
5. Drug Store of Perrysburg 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. Drug Store of Perrysburg 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 Drug Store of Perrysburg 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 Drug Store of Perrysburg by the Board and will NOT discharge Drug Store of Perrysburg from any obligation under the terms of this Agreement.
7. Drug Store of Perrysburg agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.

8. Drug Store of Perrysburg 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 Drug Store of Perrysburg will operate.
10. Drug Store of Perrysburg 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.

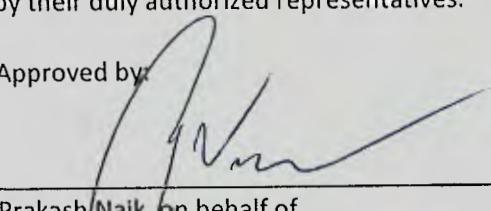
Approved by:

Prakash Naik, on behalf of,  
Drug Store of Perrysburg, Respondent

Joseph R. Durham  
Attorney for Respondent

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

Henry Appel, Ohio Assistant Attorney General



2022/3/2

Date of Signature

03/03/2022

Date of Signature

03.10.2022

Date of Signature

03.10.2022

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: 09/15/2021

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-2019-0252  
500-8866**

**The Drug Store of Perrysburg**  
c/o Prakash Naik, RPh  
580 Craig Drive, Suite #12  
Perrysburg, OH 43551

**License No. 02-1951850**

September 15, 2021

Dear The Drug Store of Perrysburg and Mr. Prakash Naik, 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, 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. The Drug Store of Perrysburg has a current TDDD license with the Board under license number 02-1951850 which lists Prakash Naik, RPh as the Responsible Person.

**ALLEGATIONS**

1. On or about September 25, 2017, October 19, 2017, and November 13, 2017, The Drugstore of Perrysburg, located at 580 Craig Drive, Suite #12, Perrysburg, Ohio, the following medications were dispensed without receipt of a valid prescription:
  - a. Rx 14292, Buspirone 15mg; 56 tablets dispensed.
  - b. Rx 14906, Seroquel XR 300mg; 28 tablets dispensed.

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- c. Rx 14908, Seroquel 100mg; 28 tablets dispensed.
- d. Rx 14905, Seroquel 50mg; 84 tablets dispensed.
- e. Rx 14910, Zyprexa 15mg; 28 tablets dispensed.
- f. Rx 14909, Zyprexa 10mg; 56 tablets dispensed.

2. On or about January 9, 2018, February 6, 2018, and March 5, 2018, The Drugstore of Perrysburg, located at 580 Craig Drive, Suite #12, Perrysburg, Ohio, the following medications were dispensed without receipt of a valid prescription or with a quantity of tablets greater than what was remaining on the prescription:

- a. Rx 15725, Buspirone 15mg 60 tablets prescribed, #168 tablets dispensed total, #164 tablets dispensed without a prescription.
- b. Rx 15421, Seroquel XR 300mg 30 tablets prescribed 12/14/2017 and 1/19/2018, #84 tablets dispensed total, #24 tablets dispensed without a prescription.
- c. Rx 15426, Seroquel 100mg 30 tablets prescribed 12/14/2017, and 1/19/2018, #84 tablets dispensed total, #24 tablets dispensed without a prescription.
- d. Rx 15420, Seroquel 50mg 90 tablets prescribed on 12/14/2017 and 1/19/2018, #336 tablets dispensed total, #156 tablets dispensed without a prescription.
- e. Rx 15423, Zyprexa 10mg 60 tablets prescribed on 12/13/2017 and 1/19/2018, #224 tablets dispensed total, #104 tablets dispensed without a prescription.

3. The Drugstore of Perrysburg, located at 580 Craig Drive, Suite #12, Perrysburg, Ohio, dispensed the following prescriptions on 3/28/2017, 17 days prior to the receipt of a valid prescription on 4/16/2018:

- a. Rx 16057, Buspirone 15mg 60 tablets dispensed.
- b. Rx 16061, Seroquel XR 300mg 28 dispensed.
- c. Rx 15056. Seroquel 100mg 28 dispensed.
- d. Rx 16059, Zyprexa 10mg 56 dispensed.

4. On or about August 30, 2018, an inspection was conducted at the Drug Store of Perrysburg. The following violations were found:

- a. Two employees, Melissa Reinhart and Leah (King) Rudnik, were working as pharmacy technicians without being registered with the Board.
- b. Pharmacy records were stored offsite without permission from the Board.

- c. Multiple drugs were packaged together in single containers and assigned beyond-use dates greater than sixty days.

5. On or about September 4, 2018, you made the following statement:

- a. You stated in the Fall of 2017, scheduling issues caused several delays in receiving medication refill authorization for Patient 1, therefore, using professional judgement, medications continued to be issued based off previous history.
- b. You stated the pharmacy did not receive any orders or communications of any changes, therefore the decision was made to continue Patient 1's medication regimen, acting in the best interest of the patient.
- c. You stated the pharmacy was informed of changes to Patient 1's medication regimen and that you were filling old prescriptions.
- d. You stated you felt waiting for refill authorization and having Patient 1 miss doses of multiple psychiatric medications would have been a risk Patient 1's health.
- e. You stated you used professional judgement in the case of Patient 1 to ensure her well-being was placed above the logistical issues surrounding communication between the prescriber, the residential care team, and the pharmacy.

#### **POTENTIAL VIOLATIONS OF LAW**

- 1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-5-21(A) or the Ohio Revised Code (OAC), manner of processing a prescription, punishable by a maximum fine of \$1,000 if committed by an organization.
- 2. Such conduct as set forth in paragraphs (1)(a)-(f), (2)(a)-(e), (3)(a)-(d) of the Allegations Section, if proven, each constitutes a violation of the following Section of 4729.281 of the ORC, conditions for refill of prescription, each punishable by a maximum fine of \$1000:
  - a. A pharmacist may dispense or sell a dangerous drug, other than a Schedule II controlled substance, without a written or oral prescription from a licensed health professional authorized to prescribe drugs if:
    - a. The pharmacist is unable to obtain authorization to refill the prescription from the health care professional who issued the prescription or another health professional responsible for the patient's care, ORC Section 4729.281(A)(2); and/or
    - b. Except as provided in division (A)(4)(b) of this section, the amount of the drug that is dispensed or sold under this section does not exceed a seventy-two-hour supply as provided in the prescription, ORC Section 4729.281(A)(4)(a); and/or
  - b. A pharmacist may dispense or sell a dangerous drug, other than a Schedule II controlled substance without a written or oral prescription from a licensed health professional authorized to prescribe

drugs if all of the following conditions are met: A pharmacist shall not dispense or sell a particular drug to the same patient in an amount described in division (A)(4)(b)(i) of this section more than once in any twelve-month period, ORC Section 4729.281(A)(4)(b)(ii); and/or

- c. A pharmacist who dispenses or sells a drug under this section shall do all of the following:
  - i. Notify the health professional who issued the prescription described in division (A)(1) of this section or another health professional responsible for the patient's care not later than seventy-two hours after the drug is sold or dispensed, ORC Section 4729.281(B)(2); and/or
  - ii. If applicable, obtain authorization for additional dispensing from one of the health professionals described in division (B)(2) of this section, ORC Section 4729.281(B)(3).
- d. A pharmacist who dispenses or sells a drug under this section may do so once for each prescription described in division (A)(1) of this section, ORC Section 4729.281(C).

3. Such conduct as set forth in paragraph (4)(b) of the Allegations Section, if proven, each constituted a violation of the following sections of Rule 4729-5-27 of the OAC, each punishable by a maximum fine of \$1,000:
  - a. All records relating to the practice of pharmacy shall be uniformly maintained for a period of three years, be readily available, and promptly produced upon request for inspection by a state board of pharmacy officer, agent, and/or inspector during regular business hours, OAC Section 4729-5-27(C); and/or
  - b. Any pharmacy intending to maintain records relating to the practice of pharmacy at a location other than the place licensed with the state board of pharmacy must first send written notification to the state board of pharmacy. The request shall contain the terminal distributor of dangerous drugs name and license number of the requestor and the name and address of the alternate location, OAC Section 4729-5-27(E).
4. Such conduct as set forth in paragraph (4)(b) of the Allegations Section, if proven, each constituted a violation of the following section of Rule 4729-9-14(C) of the OAC, all records of receipt, distribution, administering, dispensing, personally furnishing, inventory, destruction, or using controlled substances shall be kept for a period of three years at the place wither the controlled substances are located. Any terminal distributor of dangerous drugs intending to maintain such records at a location other than this place must first send a written request to the state board of pharmacy.
5. Such conduct as set forth the Allegations Section, if proven, constitutes a violation of section 4729.55(D) of the ORC, adequate safeguards are assured to carry on the business of a TDDD in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner punishable by a maximum penalty of \$1,000.
6. 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 as effective April 6, 2017, each violation constituting a minor misdemeanor, each punishable by a maximum penalty of \$1,000:
  - a. Violating any rule of the board, ORC Section 4729.57(A)(2); and/or

- b. Violating any provision of this chapter, ORC Section 4729.57(A)(3); and/or
- c. Except as provided in 4729.89, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(A)(4); and/or
- d. Violating any provision of the federal drug abuse control laws or Chapter 2925. or 3719. of the Revised Code, ORC Section 4729-57(A)(5); and/or
- e. Ceasing to satisfy the qualifications of a TDDD set forth in 4729.55 of the Revised Code, ORC Section 4729.57(A)(7).

7. 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 as effective September 29, 2017, each violation constituting a minor misdemeanor, each 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. Except as provided in 4729.89, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or
- d. 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
- e. Ceasing to satisfy the qualifications of a TDDD set forth in 4729.55 of the Revised Code, ORC Section 4729.57(B)(7).

8. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-9-19(A)(4) of the OAC, not of good moral character and, punishable by a maximum fine of \$1,000.

9. Such conduct as set forth in paragraph (4)(c) of the Allegations Section, if proven, constitutes a violation of Rule 4729-9-23(D) of the OAC, each individual package must include a beyond-use date of not more than sixty days from the date the drugs were placed in the package, punishable by a maximum fine of \$1,000

10. Such conduct as set forth in paragraph (4)(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, punishable by a maximum penalty of \$1,000

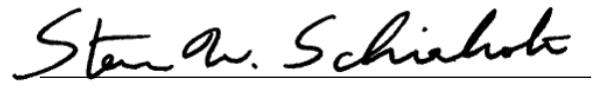
YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

**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, 17<sup>th</sup> Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to [legal@pharmacy.ohio.gov](mailto:legal@pharmacy.ohio.gov) (please note faxes will not be accepted). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30<sup>TH</sup> 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 30<sup>th</sup> 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](mailto: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

  
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Steven W. Schierholt, Esq., Executive Director

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