



IN THE MATTER OF:

CASE NO. A-2021-0221

Rite Aid #2414

License No. 02-0154350

c/o Jermaine Smith Vice President of Regulatory Affairs
735 N. Water Street
Uhrichsville, OH 44683

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 Rite Aid #2414 for the purpose of resolving all issues between the parties relating to the Board investigation of drug security issues. Together, the Board and Rite Aid #2414 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. Rite Aid #2414 is a licensed Terminal Distributor of Dangerous Drugs under license number 02-0154350.

FACTS

1. The Board initiated an investigation of Rite Aid #2414, Terminal Distributor of Dangerous Drugs license number 02-0154350, related to drug security issues.
2. On or about January 18, 2023 the Board sent a Notice of Opportunity for Hearing to Rite Aid #2414, 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.

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



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:

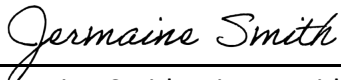
1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Rite Aid #2414 neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated January 18, 2023; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Rite Aid #2414 agrees to pay to the Board a monetary penalty the amount of \$7,000.00 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 and process the items in your cart.
4. The Board hereby imposes a written reprimand on Rite Aid #2414's TDDD license, number 02-0154350.
5. Rite Aid #2414 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. Rite Aid #2414 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 Rite Aid #2414 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 Rite Aid #2414 by the Board and will NOT discharge Rite Aid #2414 from any obligation under the terms of this Agreement.
7. Rite Aid #2414 agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. Rite Aid #2414 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 Rite Aid #2414 will operate.
10. Rite Aid #2414 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:




Jermaine Smith, Vice President of Regulatory Affairs,
on behalf of, Rite Aid #2414, Respondent

02/15/2023

Date of Signature

Attorney for Respondent (If Applicable)

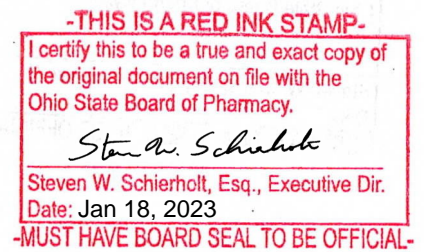
Date of Signature



Shawn 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 LICENSEE**

IN THE MATTER OF:

CASE No. A-2021-0221

Rite Aid #2414
c/o Tommy Stanley, R.Ph.
735 N. Water Street
Uhrichsville, OH 44683

License No. 02-0154350

January 18, 2023

Dear Rite Aid #2414 and Tommy Stanley, R.Ph.:

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, 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 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. Rite Aid #2414 has an active TDDD license with the Board under license number 02-0154350, which lists Tommy Stanley, R.Ph. as the Responsible Person.

ALLEGATIONS

1. On or about February 3, 2020, the Board was notified of a drug shortage of oxycodone/APAP, 5/325mg, 90 tablets, a Schedule II controlled substance, from Rite Aid #2414, located at 735 N. Water Street, Uhrichsville, Ohio. The shortage was believed to be due to theft by an employee but could not be proven. A DEA 106 Theft and Loss Report was submitted on March 12, 2020.
2. On or about February 23, 2020, a shortage of alprazolam, a Schedule IV controlled substance was discovered by Rite Aid #2414. The shortage was believed to be due to theft by an employee but could not be proven. A DEA 106 Theft and Loss Report was submitted on March 12, 2020. The missing alprazolam included the following strengths:

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- a. Alprazolam 0.25mg, two tablets, a Schedule IV controlled substance.
 - b. Alprazolam 1mg, 984 tablets, a Schedule IV controlled substance.
 - c. Alprazolam 2mg, 200 tablets, a Schedule IV controlled substance.
3. On or about June 4, 2020, the Board received a DEA 106 Theft and Loss Report from Rite Aid #2414 regarding missing controlled substances. The date of theft or loss was April 2, 2020. The Report stated there was no evidence of theft or diversion at this time. The following controlled substances were reported missing:
- a. Buprenorphine-naloxone 8/2mg, 30 tablets, a Schedule III controlled substance.
 - b. Clonazepam 0.5mg, 31 tablets, a Schedule IV controlled substance.
 - c. Clonazepam 2mg, 105 tablets, a Schedule IV controlled substance.
 - d. Lorazepam 0.5mg, 35 tablets, a Schedule IV controlled substance.
 - e. Lorazepam 1mg, 66 tablets, a Schedule IV controlled substance.
 - f. Phenobarbital 32.4mg, 30 tablets, a Schedule IV controlled substance.
 - g. Phenobarbital 97.2mg, nine tablets, a Schedule IV controlled substance.
4. On or about September 22, 2020, the Board was notified of a possible loss of 100 alprazolam 2mg tablets, a Schedule IV controlled substance, from Rite Aid #2414. On or about October 7, 2020 there was an additional discrepancy of 31 alprazolam 0.5mg tablets. A DEA 106 Theft or Loss Report was submitted on or about October 20, 2020. The following controlled substances were reported missing:
- a. Alprazolam 0.5mg, 31 tablets, a Schedule IV controlled substance.
 - b. Alprazolam 1mg, one tablet, a Schedule IV controlled substance.
 - c. Alprazolam 2mg, 100 tablets, a Schedule IV controlled substance.
 - d. Zolpidem 5mg, 4 tablets, a Schedule IV controlled substance.
5. On or about December 22, 2020, the Board was notified of additional discrepancies of controlled substances found while completing a change in responsible person inventory at Rite Aid #2414. The following controlled substances were reported missing:
- a. Lorazepam 0.5mg, 51 tablets, a Schedule IV controlled substance.
 - b. Buprenorphine 8mg, Five tablets, a Schedule III controlled substance.

6. On or about February 1, 2021, the Board was notified of missing controlled substances by Rite Aid #2414. A DEA Theft or Loss Report was submitted on or about February 22, 2021. An amendment to the February 22, 2021 DEA Theft or Loss Report was submitted on or about May 7, 2021. The following controlled substances were reported missing:
 - a. Hydrocodone/Acetaminophen 5/325mg, 90 tablets, a Schedule II controlled substance.
 - b. Vyvanse 40mg, 30 capsules, a Schedule II controlled substance.
7. From on or about December 8, 2016 through on or about April 7, 2021, Rite Aid #2414, located at 735 N. Water Street, Uhrichsville Ohio, has been involved in approximately seven investigations by the Board. All of the investigations have involved the unexplained loss of controlled substances. The investigations have found the following:
 - a. There have been five DEA 106 Theft or Significant Loss Reports submitted since March 2019.
 - b. There have been six Responsible Persons at since 2016.
 - c. There have been five inspections of the pharmacy since 2016.
 - d. On or about December 8, 2016, a written warning was issued for Alternative Record Keeping System (ARKS) record accuracy stemming from drug count adjustment.
 - e. On or about June 11, 2018, verbal warnings were issued for cleanliness and outdated drug stock.
 - f. On or about March 18, 2019, a written warning was issued for not being able to produce an annual drug inventory.
 - g. On or about July 1, 2020, a written warning was issued for security and control of dangerous drugs and record storage.
 - h. On or about April 7, 2021, a written warning was issued for security and control of dangerous drugs and a DEA 106 Theft and Loss Report not representing reported losses.

POTENTIAL VIOLATIONS OF LAW

1. 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, effective April 6, 2017, TDDD license requirements:
 - 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, 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

- 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 4729.55(C); and/or
 - d. 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).
2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(B) of the ORC, as effective September 29, 2017, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:
 - 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. 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).
 3. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729:5-4-01(B) of the OAC, as effective March 1, 2019, the Board may impose the sanctions as set forth in paragraph (A) of this rule for any of the following, each violation is 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).
 4. 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, Responsible Person of a Terminal Distributor, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
 - 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).
 - 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 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 4729:5-2-01(E)(6).
5. Such conduct as set forth in paragraphs (3)(a-g), (4)(a-d), (5)(a-b), and (6)(a-b) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-14(A) of the OAC, General Security Requirements, as effective March 1, 2020, each violation punishable by a maximum penalty of \$1,000:
- a. All terminal distributors of dangerous drugs shall provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs, OAC Rule 4729:5-3-14(A)(1); and/or
 - b. All terminal distributors of dangerous drugs shall provide effective controls and procedures to ensure 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, OAC Rule 4729:5-3-14(A)(2).
6. Such conduct as set forth in paragraphs (1), and (2)(a-c) of the Allegations section, if proven, each constitutes a violation of Rule 4729-9-05(A) of the OAC, as effective September 15, 2017, Security Requirements, 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, each violation 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, 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/jak/kll

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