



IN THE MATTER OF:

CASE NO. 2014-1787-D

The Kroger Co. Central Prescription Processing
c/o Tyler Keith, RPh
1014 Vine Street
Cincinnati, Ohio 45202

License No. 02-2221850

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 The Kroger Co., for the purpose of resolving all issues between the parties relating to the Board investigation of an error in dispensing. Together, the Board and The Kroger Co. 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. The Kroger Co. is a licensed Terminal Distributor of Dangerous Drugs under license number 02-2221850.

FACTS

1. On or about August 12, 2014, the Board initiated an investigation of The Kroger Co., Terminal Distributor of Dangerous Drugs license number 02-2221850, related to The Kroger Co.'s error in dispensing.
2. On or about March 30, 2017, the Board sent a Notice of Opportunity for Hearing to The Kroger Co., 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.

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. The Kroger Co. neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated March 30, 2017; 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. The Kroger Co. agrees to pay to the Board a monetary penalty the amount of \$2,500.00, by means of a cashier's check made payable to "Treasurer, State of Ohio," mailed with the enclosed form to the Board, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126, no later than 30 days from the effective date of this Agreement.
4. The Kroger Co. agrees to continue education and training of its pharmacy staff in best practices.
5. The Kroger Co. agrees to continue safety meetings.
6. The Kroger Co. agrees to continue with increased number of supervisors for oversight.
7. The Kroger Co. 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.
8. The Kroger Co. 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 The Kroger Co. 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 The Kroger Co. by the Board and will NOT discharge The Kroger Co. from any obligation under the terms of this Agreement.
9. The Kroger Co. agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
10. The Kroger Co. understands that it has the right to be represented by counsel for review and execution of this agreement.

11. 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 The Kroger Co. will operate.
12. The Kroger Co. 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.
13. 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.
14. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
15. 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.
16. 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:



Tyler Keith, RPh, on behalf of,
The Kroger Co., Respondent

9/5/17

Date of Signature



Mary Barley-McBride, Attorney for Respondent

9.29.2017

Date of Signature



Michael A. Mulvihill, RPh
State of Ohio Board of Pharmacy

10/10/17

Date of Signature



Jonathan L. Dittel
Ohio Assistant Attorney General

10/11/2017

Date of Signature



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

IN THE MATTER OF:

CASE NO. 2014-1787-D

The Kroger Co. Central Prescription Processing
c/o Tyler Keith, R.Ph.
1014 Vine Street
Cincinnati, OH 45202

License No. 02-2221850

March 30, 2017

Dear The Kroger Co. Central Prescription Processing and Tyler Keith,



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 Kroger Co. Central Prescription Processing has a current TDDD license with the Board under license number 02-2221850, which lists Tyler Keith as the Responsible Person.

ALLEGATIONS

1. On or about August 11, 2014, the Board received a complaint from patient D.B. about an error in dispensing where D.B. received clomipramine 50mg capsules rather than the prescribed clomiphene 50mg tablets.
2. During the investigation, it was discovered the pharmacist performing data entry verification and drug utilization review on a prescription at The Kroger Co. Central Prescription Processing were solely relying on computer generated alerts to perform drug utilization review. Procedures described did not have the pharmacist reviewing the patient profile prior to approving a prescription to be dispensed.
 - a. During the investigation it was also discovered that the goal for each pharmacist is to have 800 pre-verifications in an 8-hour shift. Prescriptions that are rejected and sent back to data entry

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



are counted toward the pre-verification goal; however, prescriptions that are pushed back to the store to check do not count toward that goal.

3. On or about January 3, 2014, Trista Williamson misbranded a drug when she received a prescription under prescription number 01400405-6240572 for clomiphene 50mg tablets and caused another to dispense clomipramine 50mg capsules which was not specifically prescribed by the physician. Ms. Williamson relied on the computer alerts alone for prospective drug utilization review (DUR).
4. On or about January 6, 2014, Michelle Hounshell misbranded a drug when she received a prescription under prescription number 01400405-6240572 for clomiphene 50mg tablets and caused another to dispense clomipramine 50mg capsules which was not specifically prescribed by the physician. Ms. Hounshell relied on computer alerts alone for prospective DUR.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in paragraphs (1) through (4) of the Allegations Section, if proven, constitutes a violation of Section 4729.55(D) of the ORC, each violation punishable by a maximum penalty of \$1,000.
2. Such conduct as set forth in paragraphs (1) through (4) of the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57 of the ORC, each violation being a minor misdemeanor, punishable by a maximum penalty of \$150 if committed by an individual or \$1,000 if committed by an organization:
 - a. Violating any provision of this chapter, ORC 4729.57(A)(3); and/or
 - b. Ceasing to satisfy the qualifications of a TDDD set forth in 4729.55 of the Revised Code, ORC Section 4729.57(A)(7).
3. Such conduct as set forth in paragraphs (1) through (4) of the Allegations Section, if proven, constitutes a violation of the following Ohio Administrative Code Rule 4729-9-19(A)(4), not of good moral character and habits, punishable by a maximum fine of \$1,000.
4. Such conduct as set forth in paragraphs (1) through (4) of the Allegations Section, if proven, constitutes a violation of the following Ohio Administrative Code Rule 4729-5-20, prospective drug utilization review, punishable by a maximum fine of \$1,000.
5. Such conduct as set forth in paragraphs (3) and (4) of the Allegations section, if proven, constitutes a violation of Section 3715.52(A)(2) of the ORC, the adulteration or misbranding of any food, drug, device or cosmetic, a misdemeanor of the fourth degree, punishable by a maximum fine of \$2,000 if committed by an organization.
6. Such conduct as set forth in paragraphs (1) through (3) of the Allegations Section, if proven, constitutes a violation of Section 3715.64(A)(10)(d) of the ORC, Misbranding – the drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, is neither the brand or drug prescribed nor a generically equivalent drug, a misdemeanor of the fourth degree, punishable by a maximum penalty of \$2,000 if committed by an organization.

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 Ohio State 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 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 Ohio State 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/rlc

CMRRR: 7005 0390 0001 8571 8442

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

THE KROGER COMPANY
1014 Vine Street Ste 1000
Cincinnati OH 45202-1100



590 9402 2277 6225 9754 84

2. Article Number (Transfer from service label)

7005 0390 0001 8571 8442

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X

B. Received by (Printed Name)

C. Date of Delivery

☐ Agent

☐ Addressee

Address different from item 12
Delivery address below

☐ Yes

☐ No

USPS - 45202

3. Service type

- ☐ Adult Signature
- ☐ Adult Signature Restricted Delivery
- ☐ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery

- ☐ Priority Mail Express®
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- ☐ Registered Mail Restricted Delivery
- ☐ Return Receipt for Merchandise
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

Restricted Delivery

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