

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
Ed's Discount Drug)
DS2640)
Expiration: December 31, 2017)

PHA-2016-0110

Received

OCT 24 2017

BOARD OF
PHARMACY

CONSENT AGREEMENT FOR REPRIMAND

The Massachusetts Board of Registration in Pharmacy ("Board") and Ed's Discount Drug ("Pharmacy" or "Licensee"), a pharmacy licensed by the Board, DS2640, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Pharmacy's record maintained by the Board:

1. The Pharmacy acknowledges the Board opened a Complaint against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket Number PHA-2016-0110 ("Complaint").
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. Board investigators conducted an unannounced inspection of the Pharmacy on or about October 29, 2015. During the inspection, Board investigators observed numerous violations of Board regulations, including but not limited to the following:
 - i. Failure to maintain an accurate perpetual inventory of Schedule II controlled substances, in violation of 247 CMR 9.01(14);
 - ii. Allowed pharmacy technician to reconcile Schedule II controlled substances inventory, in violation of 247 CMR 8.05;
 - iii. Presence of prescription medication with labels from other pharmacies in inventory, in violation of 247 CMR 9.01(4) & (10);
 - iv. Failure to maintain proper refrigerator temperatures, in violation of Board Policy 2011-01;
 - v. Failure to comply with non-sterile compounding standards pertaining to hazardous drugs, in violation of 247 CMR 9.01(3) and USP 795;
 - vi. Failure to maintain non-sterile compounding policies and procedures, in violation of 247 CMR 9.01(3) and USP 795;
 - vii. Beyond use dates not in compliance with USP 795 standards, in violation of 247 CMR 9.01(3);

- viii. Failure to maintain compounding components and active pharmaceutical ingredients in compliance with USP 795 standards, in violation of 247 CMR 9.01(3);
 - ix. Failure to maintain accurate Master Formulation Records and Compounding Records, in violation of 247 CMR 9.01(3) and USP 795; and
 - x. Failure to maintain documentation, policies, and procedures pertaining to Continuous Quality Improvement, in violation of 247 CMR 15.04.
- b. On or about May 27, 2016, the Pharmacy's Manager of Record submitted a written plan of correction and represented to the Board that deficiencies cited on October 29, 2015 had been corrected.
- c. The May 27, 2016 plan of correction included a prescription dated November 6, 2015 for valium 10 mg / lidocaine 25 mg suppository. The word "lidocaine" was crossed out on the prescription and there was no record of lidocaine being used to prepare the compound. However, the label attached to the prescription stated "diazepam/lidocaine suppository."
- d. On or about November 3, 2016, the Pharmacy's Manager of Record submitted a written response the Board and represented that all deficiencies had been corrected.
- e. Board investigators conducted a routine compliance inspection on November 30, 2016. Board investigators observed the following deficiencies:
- i. Failure to maintain an accurate perpetual inventory of Schedule II controlled substances, in violation of 247 CMR 9.01(14);
 - ii. A discrepancy in oxycodone 15 mg tablets that occurred on October 5, 2016 was not recognized or corrected during inventory reconciliations on October 29, 2016, November 12, 2016, November 19, 2016, and November 29, 2016, in violation of 247 CMR 9.01(14);
 - iii. Failure to maintain an accurate biennial inventory of Schedule III – V controlled substances, in violation of 247 CMR 9.01(1);
 - iv. Failure to maintain proper refrigerator temperatures, in violation of Board Policy 2011-01;

- v. Failure to maintain compounding components and active pharmaceutical ingredients in compliance with USP 795 standards, in violation of 247 CMR 9.01(3); specifically, multiple compounding components lacked expiration dates;
 - vi. Beyond use dates not in compliance with USP 795 standards, in violation of 247 CMR 9.01(3); specifically, Board investigators observed a compounded preparation labeled "hydrocort 100 mg supp" with a beyond use date of one year; and
 - vii. Failure to maintain accurate Master Formulation Records and Compounding Records, in violation of 247 CMR 9.01(3) and USP 795.
- f. Board investigators conducted a compliance inspection on December 2, 2016. Board investigators observed the following deficiencies:
- i. Failure to maintain an accurate perpetual inventory of Schedule II controlled substances, in violation of 247 CMR 9.01(14); and
 - ii. Allowed pharmacy technician trainee to handle and count Schedule II controlled substances inventory, in violation of 247 CMR 8.05.
- g. Board investigators conducted a compliance inspection on January 30, 2017. Board investigators observed the following deficiencies:
- i. Failure to maintain an accurate perpetual inventory of Schedule II controlled substances, in violation of 247 CMR 9.01(14); and
 - ii. Failure to monitor and maintain proper refrigerator temperatures, in violation of Board Policy 2011-01.
- h. Board investigators conducted a compliance inspection on August 8, 2017. Board investigators observed the following deficiencies:
- i. Failure to maintain an accurate perpetual inventory of Schedule II controlled substances, in violation of 247 CMR 9.01(14);
 - ii. Failure to monitor and maintain proper refrigerator temperatures, in violation of Board Policy 2011-01; and
 - iii. Failure to maintain controlled substances documentation, in violation of 247 CMR 9.01(1).

- i. The Pharmacy failed to submit a plan of correction and failed to correct deficiencies cited during inspections on October 29, 2015, November 30 2016, December 2, 2016, January 30, 2017, and August 8, 2017, in violation of 247 CMR 6.13.
2. The Pharmacy acknowledges that the foregoing facts warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(a), (b), (c), (d), and (v).
3. The Pharmacy agrees that the Board shall impose a REPRIMAND on its license based on the facts admitted in Paragraph 2, effective as of the date on which the Board signs this Agreement ("Effective Date").
4. The Board agrees that in return for the Pharmacy's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.
5. The Pharmacy understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication the Pharmacy would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on its own behalf, to contest the allegations, to present oral argument, to appeal to the courts, and all other rights as set forth in the Massachusetts Administrative Procedures Act, M.G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et seq.* The Pharmacy further understands that by executing this Agreement the Pharmacy is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.
6. The Pharmacy acknowledges that it has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.
7. The Pharmacy acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board subject to the Commonwealth of Massachusetts' Public Records Law, M.G.L. c. 4, § 7. The Board may forward a copy of this Agreement to other licensing boards, law enforcement entities, and other individuals or entities as required or permitted by law.
8. The Pharmacy understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal or judicial review.

9. The individual signing this Agreement certifies that he/she is authorized to enter into this Agreement on behalf of the Pharmacy, and that he/she has read this Agreement.

Louise McNamee
Witness (sign and date)
10-17-17

Ed's Discount Drug
Ed's Discount Drug
(sign and date)

Edward David RPA
(print name)

David Sencabaugh
David Sencabaugh, R. Ph.
Executive Director
Board of Registration in Pharmacy

10-25-17
Effective Date of Reprimand Agreement

Fully Signed Agreement Sent to Licensee on 10/26/17 by Certified Mail
No. 7015 3010 0601 7079 8119