

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of )  
EDWARD DAVID )  
PH14039 )

PHA-2016-0218

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Edward David ("Licensee"), PH14039, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Licensee's record maintained by the Board:

1. Licensee acknowledges the Board opened a complaint against his Massachusetts pharmacist license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2016-0218.<sup>1</sup>
2. The Board and Licensee acknowledge and agree to the following facts:
  - a. Licensee is the owner and manager of record at Ed's Discount Drug ("Pharmacy"), DS2640, a pharmacy licensed by the Board, at all times relevant hereto.
  - b. As described in 247 CMR 6.07, Licensee, as manager of record, is responsible for the operation of the Pharmacy in compliance with 247 CMR 2.00 et seq. and applicable state and federal laws and regulations.
  - c. 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);

<sup>1</sup> The term "license" applies to both a current license and the right to renew an expired license.

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- 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.
- d. On or about May 27, 2016, the Licensee submitted a written plan of correction and represented to the Board that deficiencies cited on October 29, 2015 had been corrected.
- e. 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."
- f. On or about November 3, 2016, the Licensee submitted a written response the Board and represented that all deficiencies had been corrected.
- g. 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.
- h. 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.
- i. 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.
  - j. 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).
  - k. Licensee 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.
3. The Licensee 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).
4. Licensee agrees that his pharmacist license shall be placed on PROBATION for two (2) years ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
5. During the Probationary Period, the Licensee agrees that he shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.
6. The Licensee further agrees that he will not serve as pharmacist Manager of Record of any pharmacy during the Probationary Period.
7. The Board agrees that in return for Licensee's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.

8. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate two (2) years after the Effective Date upon written notice to the Licensee from the Board<sup>2</sup>.
9. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint<sup>3</sup> during the Probationary Period, the Licensee agrees to the following:
  - a. The Board may upon written notice to the Licensee, as warranted to protect the public health, safety, or welfare:
    - i. EXTEND the Probationary Period; and/or
    - ii. MODIFY the Probation Agreement requirements; and/or
    - iii. IMMEDIATELY SUSPEND the Licensee's pharmacist license.
  - b. If the Board suspends the Licensee's pharmacy license pursuant to Paragraph 9(a)(iii), the suspension shall remain in effect until:
    - i. the Board provides Licensee written notice that the Probationary Period is to be resumed and under what terms; or
    - ii. the Board and Licensee sign a subsequent agreement; or
    - iii. the Board issues a written final decision and order following adjudication of the allegations (1) of noncompliance with this Agreement, and/ or (2) contained in the Subsequent Complaint.

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<sup>2</sup> In all instances where this Agreement specifies written notice to the Licensee from the Board, such notice shall be sent to the Licensee's address of record.

<sup>3</sup> The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the Effective Date, which (1) alleges that the Licensee engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Licensee shall have an opportunity to respond.

10. Licensee agrees that if the Board suspends his pharmacist license in accordance with Paragraph 9, he will immediately return his current Massachusetts pharmacist license to the Board, by hand or certified mail. Licensee further agrees that upon said suspension, he will no longer be authorized to practice as a pharmacist in the Commonwealth of Massachusetts and shall not in any way represent himself as a pharmacist until such time as the Board reinstates his pharmacist license or right to renew such license.
11. Licensee understands that he has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication he would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on his 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 Licensee further understands that by executing this Agreement he is knowingly and voluntarily waiving his right to a formal adjudication of the Complaints.
12. The Licensee acknowledges that he has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.
13. The Licensee acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board. 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.

14. The Licensee certifies that he has read this Agreement. The Licensee understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal or judicial review.

Laurel M. Mores  
Witness (sign and date)  
10-17-17

Edward David  
Edward David (sign and date)  
10-17-17

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

10-25-17  
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 10/26/17 by  
Certified  
Mail No. 7915 3010 0001 7079 8102