COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY		BOARD OF REGISTRATION IN PHARMACY
In the Matter of EDWARD DAVID PH14039	)))	PHA-2016-0218

AGREEMENT TO REFRAIN FROM STERILE COMPOUNDING AND NON-STERILE COMPOUNDING

The 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 that the Board opened a complaint against his Massachusetts pharmacist license related to the conduct and conditions set forth in Paragraph 2, identified as Docket No. PHA-2016-0218.[1]

2. The Board and Licensee acknowledge and agree to the following facts:

   a. Licensee was the owner and manager of record at Ed's Discount Drug ("Pharmacy"), DS2640, a pharmacy licensed by the Board, at times relevant hereto.

   b. As described in 247 CMR 6.07, Licensee, as manager of record, was 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:

[1] The term "license" applies to both a current license and the right to renew an expired license.

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.

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 routine 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.

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.

4. The Board and Licensee acknowledge and agree that, based on the conduct described in Paragraph 2, Licensee's continued or further preparation and dispensing of sterile or non-sterile compounded medications presents an immediate or serious threat to the public health, safety, or welfare warranting a Cease and Desist Notice as set forth in 247 CMR 10.08.

5. Licensee agrees to refrain from preparing and/or dispensing any sterile compounded medication unless and until it receives written approval from the Board to resume the preparation and dispensing of sterile compounded medications. Board approval shall not be granted unless and until Licensee demonstrates, upon inspection by Board investigators, that it is fully compliant with USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations and all other state and federal laws and regulations pertaining to the practice of pharmacy.

6. Licensee agrees to refrain from preparing and/or dispensing any non-sterile compounded medication unless and until it receives written approval from the Board to resume the preparation and dispensing of non-sterile compounded medications. Board approval shall not be granted unless and until Licensee demonstrates, upon inspection by Board investigators, that it is fully compliant with USP General Chapter <795> Pharmaceutical Compounding – Non-Sterile Preparations and all other state and federal laws and regulations pertaining to the practice of pharmacy.

7. The Board agrees that in return for Licensee's execution and successful compliance with the requirements of this Agreement it will not issue a Notice to Cease and Desist all sterile and non-sterile compounding activities based upon the inspections described in Paragraph 2.

8. The Board and Licensee agree that this Agreement shall remain in effect unless and until it is superseded by a subsequent agreement or the Board provides written approval for Licensee to resume compounding. If the Board receives credible information that Licensee has failed to comply with this Agreement, the Board will immediately SUSPEND Licensee's pharmacist license. Violation of this agreement is grounds for disciplinary action pursuant to 247 CMR 10.03(j).

9. 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.

10. Licensee acknowledges that after the Effective Date, the Agreement constitutes a public record of 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.

11. 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.

12. The Licensee certifies that he has read this Agreement.

12/9/16

Witness (sign and date)

Edward David
Signature and Date

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

12-9-16

Effective Date of Agreement

Fully Signed Agreement Sent to Registrant on 12/22/16 **by Certified Mail No.** 7016 0340 0000 4975 9476