

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
PHARMACY

In the Matter of )  
EDWARD MACEDO )  
PH14977 )

PHA-2013-0035

**CONSENT AGREEMENT FOR PROBATION**

The Massachusetts Board of Registration in Pharmacy ("Board") and Edward Macedo ("Licensee"), PH14977, 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 a complaint has been opened by the Board against his Massachusetts pharmacist license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2013-0035.<sup>1</sup>
2. The Board and Licensee acknowledge and agree to the following facts:
  - a. The Licensee was the Manager of Record of PharmaHealth Pharmacy, DS3056, 458 Dartmouth Street, Suite B, New Bedford, Massachusetts ("PharmaHealth") October 2012 though February 2013, and has been the Manager of Record since at least April 3, 2012.
  - b. Richard Brisson was the owner of PharmaHealth at all relevant times.
  - c. Prior to December 6, 2012, PharmaHealth prepared and dispensed compounded sterile medications on a regular basis.

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

- d. On or about October 17, 2012, Richard Brisson signed and submitted to the Board an Attestation of Compliance attesting that PharmaHealth was compliant with all Massachusetts Board of Registration in Pharmacy regulations (247 CMR) and USP Standard <797>. Licensee maintains that he was unaware of the October 17, 2012 sterile compounding attestation and that he did not complete, review, or sign the attestation.
- e. On or about November 9, 2012, Licensee signed and submitted to the Board a Sterile Compounding Information Sheet. Licensee maintains that he did not supply any of the information contained in the Sterile Compounding Information Sheet and did not complete the form. Licensee maintains that he does not have the requisite knowledge about sterile compounding to have completed the Sterile Compounding Information Sheet.
- f. In a letter to the Board dated December 6, 2012, Richard Brisson advised the Board of the following:

PharmaHealth, located at 458 Dartmouth Street, Suite B, New Bedford, MA 02740 is notifying you that it is in the process of planning to renovate our existing sterile cleanroom. We are immediately stopping preparing sterile compounded medications.

We have reached a decision that in the interest of continued quality improvement and the advice of our expert USP 797 consultant that we would expand our clean room and to update the facility design.

We are currently only in the planning stage for this clean room design. Once we have final plans we will forward to you for your approval.

- g. Licensee maintains that he was unaware of Richard Brisson's December 6, 2012 letter to the Board until sometime after the Board notified him of the Complaint.

- h. On or about December 27, 2012, Board Investigator Penta visited PharmaHealth unannounced in order to conduct a USP 797 compliance audit. Licensee was present during the December 27, 2012 visit. Investigator Penta was informed that PharmaHealth was no longer engaging in sterile compounding. During the visit, Investigator Penta spoke with PharmaHealth's USP 797 consultant on the telephone who stated that PharmaHealth was not engaged in sterile compounding because it was not compliant with USP 797.
  - i. On January 31, 2013, Board investigators conducted an unannounced inspection of PharmaHealth. During the inspection, Board investigators obtained evidence demonstrating that PharmaHealth compounded sterile medications between December 6, 2012 and January 31, 2013. Investigators also observed inspectional deficiencies and multiple violations of Board regulations pertaining to the practice of pharmacy.
  - j. On February 1, 2013, Board investigators conducted a USP 797 compliance audit. Board investigators observed PharmaHealth to be non-complaint with 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding – Sterile Preparations, with regard to its compounding of sterile medications.
  - k. Prior to at least February 1, 2013, Licensee was not familiar with or knowledgeable about sterile compounding or USP 797 requirements. At the time the Attestation of Compliance and the Sterile Compounding Information Sheet were submitted to the Board, Licensee lacked the knowledge to determine whether or not the pharmacy of which he was Manager of Record was in compliance with USP 797.
3. Licensee agrees that his pharmacist license shall be placed on PROBATION for 12 months ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
  4. During the Probationary Period, the Licensee further agrees that he shall not serve as a Manager of Record of any pharmacy.
  5. During the Probationary Period, the Licensee further agrees to comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.

6. Licensee further agrees that following the termination of the Probationary Period, he shall refrain from serving as the Manager of Record for any pharmacy that engages in any sterile compounding activity unless and until he receives written approval from the Board to serve as Manager of Record for any pharmacy that engages in any sterile compounding.
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 **12 months** 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 pharmacist license pursuant to Paragraph 9(a)(iii), the suspension shall remain in effect until:

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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.

- 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.
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 Complaint.
12. The Licensee acknowledges that he has been represented by 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.

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Witness (sign and date)

Edward Macedo 12/17/13  
Signature and Date

EDWARD MACEDO  
Print Name  
Edward Macedo

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

12-30-13  
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 12/30/13 by  
Certified

Mail No. 7012 0470 0601 3526 6615