

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN
PHARMACY

In the Matter of)
RICHARD BRISSON)
PH15092)

PHA-2013-0036

Received

OCT 18 2013

BOARD OF
PHARMACY

CONSENT AGREEMENT FOR SUSPENSION

The Massachusetts Board of Registration in Pharmacy ("Board") and Richard Brisson ("Licensee"), a pharmacist registered by the Board, Registration No. PH15092, 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. The Licensee acknowledges that the Board opened a complaint against his Massachusetts pharmacist registration ("registration"¹) related to the conduct set forth in paragraph 2, identified as Docket No. PHA-2013-0036 ("the Complaint").
2. The Board and Licensee acknowledge and agree to the following facts:
 - a. Licensee is the owner of PharmaHealth Pharmacy, DS3056, 458 Dartmouth Street, Suite B, New Bedford, Massachusetts ("PharmaHealth").
 - b. Prior to December 6, 2012, PharmaHealth prepared and dispensed compounded sterile medications on a regular basis.
 - c. On October 17, 2012, Licensee signed and submitted to the Board an Attestation of Compliance attesting under the pains and penalties of perjury that "PharmaHealth Pharmacy is engaged in the compounding of sterile preparations and that all sterile compounding pharmacy practices are in COMPLIANCE WITH ALL Massachusetts Board of Registration in Pharmacy regulations (247 CMR) and USP Standard <797> in the compounding of sterile preparations."
 - d. In a letter to the Board dated December 6, 2012, signed by Licensee, the Licensee advised the Board of the following:

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

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.

e. On or about December 27, 2012, Board Investigator Penta visited PharmaHealth unannounced in order to conduct a USP 797 compliance audit. The Board Investigator Penta was informed that PharmaHealth was no longer engaging in sterile compounding and that owner Richard Brisson had sent a letter to the Board stating same. During the visit, Board 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.

f. 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.

g. 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.

h. On or about February 1, 2013 the Board issued a Cease and Desist and Quarantine Notice directing PharmaHealth to immediately cease and desist engaging in the compounding and dispensing of sterile medications.

3. The Licensee acknowledges that his conduct constitutes failure to comply with Board regulations including but not limited to 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding – Sterile Preparations and warrants disciplinary action.

4. The Licensee agrees to the **SUSPENSION** his registration for a minimum of one (1) year ("Suspension Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
5. After the Suspension Period, and when the Licensee can complete to the satisfaction of the Board all of the requirements set forth in this Paragraph and in the Board's policy 2011-02 "License Reinstatement following Surrender, Suspension, or Revocation," the Licensee may petition the Board for reinstatement of his registration. The petition must be in writing and must include the following documentation of the Licensee's ability to practice as a pharmacist in a safe and competent manner, all to the Board's satisfaction:
 - a. All documentation required pursuant to Board's policy 2011-02 "License Reinstatement following Surrender, Suspension, or Revocation,"
 - b. Authorization for the Board to obtain a Criminal Offender Record Information ("CORI") report of the Licensee conducted by the Massachusetts Criminal History Systems Board.
 - c. Certified documentation from the state board of pharmacy of each jurisdiction in which the Licensee has ever been registered to practice as a pharmacist, sent directly to the Massachusetts Board identifying his registration status and discipline history, and verifying that his pharmacist registration is, or is eligible to be, in good standing and free of any restrictions or conditions.
6. If and when the Board determines that the Licensee has complied to the Board's satisfaction with all the requirements contained in Paragraph 5 and that reinstatement is in the best interest of the public health, safety, and welfare, the Board shall send written notice to the Licensee² which shall terminate the Suspension Period.
7. The Licensee agrees that he will not practice as a registered pharmacist in Massachusetts from the Effective Date unless and until the Board reinstates his registration³.

² 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.

³ The Licensee understands that practice as a registered pharmacist includes, but is not limited to, seeking and/or accepting a paid or voluntary position as a registered pharmacist, or a paid or voluntary position requiring that the applicant hold a current pharmacist registration. The Licensee further understands that if he accepts a voluntary or paid position as a registered pharmacist, or

8. The Licensee agrees that, in the event his license is reinstated following the Suspension Period, his license shall be placed on PROBATION for no less than 36 months ("Probationary Period"), commencing with the date on which the Board reinstates the license.
9. The Board may require, as a condition of reinstatement, specific Probationary Terms for monitoring and continuing education, which will be determined when the Board considers the Licensee's petition for reinstatement.
10. 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.
11. 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.
12. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate **36 months** after the Licensee's license was reinstated.⁴
13. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint⁵ 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.

engages in any practice of pharmacy after the Effective Date and before the Board formally reinstates his registration, evidence of such practice shall be grounds for the Board's referral of any such unlicensed practice to the appropriate law enforcement authorities for prosecution.

⁴ 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.

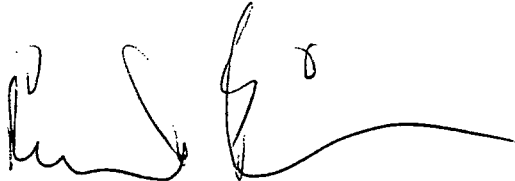
⁵ The term "Subsequent Complaint" applies to any complaint arising from acts, omissions, or events occurring after February 1, 2013, which (1) alleges that the Licensee engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Licensee shall have an opportunity to respond.

- b. If the Board suspends the Licensee's pharmacy license pursuant to Paragraph 13(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.
14. Licensee agrees that if the Board suspends his pharmacist license in accordance with Paragraph 12, 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.
15. Licensee understands that he has a right to a 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 its right to a formal adjudication of the Complaints.
16. The Licensee acknowledges that he has been represented by legal counsel in connection with the Complaint and this Agreement.
17. 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.

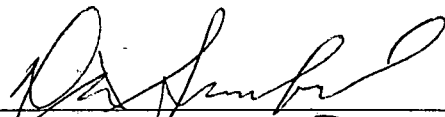
18. The Licensee certifies that he has read this Agreement. The Licensee understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal or judicial review.



Witness (sign and date)



RICHARD BRISSON, R. Ph.
Licensee (sign and date)



~~Margaret Cittadino~~ ~~David A. Sencabaugh~~
~~Associate Director~~ ~~Executive Director~~
Board of Registration in Pharmacy

10-21-13

Effective Date of Suspension Agreement

Fully Signed Agreement Sent to Licensee on ^{ATH} 10/25/13 by
Certified Mail No. 7012 3460 0061 7330 8807