

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
APOTHECARE OF SOUTH SHORE)
Pharmacy Registration No. DS89820)
Expiration Date: December 31, 2013)

PHA-2012-0252

CONSENT AGREEMENT FOR REPRIMAND

The Massachusetts Board of Registration in Pharmacy ("Board") and Apothecare of South Shore ("Registrant" or "Apothecare"), a Pharmacy licensed by the Board, Registration No. DS89820, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Registrant's record maintained by the Board:

1. The Registrant acknowledges that the Board opened a Complaint against its Massachusetts Pharmacy registration (registration¹) related to the conduct set forth in Paragraph 2, identified as Docket Nos. PHA-2012-0252 ("the Complaint").
2. The Board and Registrant acknowledge and agree to the following facts:
 - a. On or about October 17, 2012, Apothecare, through its Manager of Record David L. Young, submitted an Attestation of Compliance to the Board attesting that Apothecare was engaged in the compounding of sterile preparations and attesting that all sterile compounding practices were in compliance with all Massachusetts Board of Registration in Pharmacy regulations (247 CMR) and USP Standard <797> in the compounding of sterile preparations.
 - b. Board investigators conducted an unannounced inspection of Apothecare on or about December 20, 2012. During the inspection, Board investigators observed Apothecare to be non-compliant with requirements of Board regulations, *including but not limited to*, 247 CMR 9.01, United States Pharmacopoeia ("USP") Standard <795> Pharmaceutical Compounding – Non-Sterile Preparations, and USP Standard <797> Pharmaceutical Compounding – Sterile Preparations, with regard to its facility design and controls, storage of hazardous medications, and its compounding and dispensing of sterile medications.

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

c. As a result of Apothecare's non-compliance, on or about December 20, 2012, Apothecare was notified to immediately cease the preparation and dispensing of sterile and non-sterile compounded drugs, and quarantine all sterile compounded drugs on Apothecare premises.

d. Board investigators conducted a re-inspection of Apothecare on May 24, 2013. During the inspection, Board investigators observed that Apothecare appeared to be in compliance with United States Pharmacopoeia ("USP") Standard <795> Pharmaceutical Compounding - Non-Sterile Preparations.

e. During the May 24, 2013 re-inspection, the manager of record, Geoffrey D. Peterson, advised Board investigators that Apothecare would not prepare or dispense compounded sterile medications. Board investigators observed that Apothecare did not have a clean room or compounding area that was compliant with USP Standard <797> Pharmaceutical Compounding - Sterile Preparations.

f. On May 31, 2013, the Board and Apothecare entered into an Agreement ("the May 31, 2013 Agreement") whereby Apothecare agreed to refrain from all sterile compounding unless and until it receives written approval from the Board to resume the preparation and dispensing of sterile compounded medications. Further, based on Apothecare's compliance with United States Pharmacopoeia ("USP") Standard <795> Pharmaceutical Compounding - Non-Sterile Preparations on May 24, 2013 and Apothecare's agreement to refrain from sterile compounding unless and until it receives written approval from the Board to resume, the Board agreed to rescind the December 20, 2012 Cease and Desist and Quarantine Notice.

3. The Registrant 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 Registrant agrees to refrain from all sterile compounding 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 Apothecare demonstrates, upon inspection by Board investigators, that it is fully compliant USP Standard <797> Pharmaceutical Compounding - Sterile Preparations and all other state and federal laws and regulations pertaining to the practice of pharmacy.
5. Based on Apothecare's compliance with United States Pharmacopoeia ("USP") Standard <795> Pharmaceutical Compounding - Non-Sterile

Preparations on May 24, 2013 and Apothecare's agreement to refrain from sterile compounding unless and until it receives written approval from the Board to resume, the Cease and Desist and Quarantine Notice dated December 20, 2012 is hereby rescinded.

6. The Board and Apothecare agree that this Consent Agreement for Reprimand supersedes the May 31, 2013 Agreement.
7. If the Board receives credible information that Apothecare has failed to comply with this Agreement, the Board will immediately SUSPEND Apothecare's pharmacy license. Violation of this agreement is grounds for disciplinary action pursuant to 247 CMR 10.03(j).
8. The Board agrees that in return for the Registrant's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.
9. The Registrant understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication it 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, G. L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et seq.* The Registrant further understands that by executing this Agreement it is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.
10. The Registrant acknowledges that it has been represented by legal counsel in connection with the Complaint and this Agreement.
11. The Registrant 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, G.L. ch. 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.
12. The Registrant certifies that it has read this Agreement. The Registrant understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal, or judicial review.

[Signature] 8/29/13
Witness (sign and date)

[Signature] 8/29/13
Apothecare of South Shore
(sign and date)

Print Name: Roy DAJIE

8-30-13
Effective Date of Reprimand Agreement

[Signature]
Margaret Cittadino
Associate Director
Board of Registration in Pharmacy

Fully Signed Agreement Sent to Registrant on September 17, 2013 by
Certified Mail No. 7012 3460 0001 7330 F692