COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY		BOARD OF REGISTRATION IN PHARMACY
In the Matter of PharmaHealth Pharmacy Registration No. DS 3056 Registration expires 12/31/15)	Docket No. PHA-2013-0013

VOLUNTARY SURRENDER AGREEMENT

The Massachusetts Board of Registration in Pharmacy ("Board") and PharmaHealth Pharmacy a pharmacy licensed by the Board (Reg. No. DS3056) and formerly located at 458 Dartmouth Street in New Bedford, Massachusetts ("Pharmacy"), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the record maintained by the Board.

- 1. The Pharmacy and the Board enter into this Voluntary Surrender Agreement ("Agreement") to resolve the complaint against the Pharmacy currently pending before the Board as Docket No. PHA-2013-0013.
- 2. The Board and the Pharmacy acknowledge and agree that the complaint alleges the Pharmacy failed to conduct pharmacy operations in accordance with United States Pharmacopeia (USP) <797> (sterile compounding) and other Board regulations relating to the practice of pharmacy.
- 3. The Pharmacy acknowledges that sufficient evidence exists such that, if the matter were to proceed to a hearing, the Board could reasonably find that the Pharmacy was in violation of Board regulations including, but not limited to, provisions of 247 CMR 9.01(1), (3), (5) and (10) and 247 CMR 6.01(5)(b).
- 4. The Pharmacy further acknowledges that in or around December 17, 2014, it ceased its operations.
- 5. The Pharmacy hereby voluntarily tenders the surrender of its pharmacy registration (Reg. No. DS 3056) to the Board in resolution of the above-referenced complaint and agrees that said surrender shall become effective immediately upon the execution of this agreement by a duly authorized representative of the Board.

- 6. The Board hereby accepts the Pharmacy's surrender of its registration and agrees not to advance the prosecution of the above-referenced complaint as consideration for the surrender.
- 7. The Pharmacy understands and agrees that the decision to enter into this Agreement and to accept any terms and conditions described herein is a final act and is not subject to reconsideration or judicial review.
- 8. The Pharmacy acknowledges that he has been at all times free to seek and use legal counsel in connection with the complaint and this Agreement.
- 9. The Pharmacy understands that by executing this agreement it is knowingly waiving any and all rights to a formal hearing during which the Pharmacy would possess the right to call witnesses, to confront and cross-examine witnesses, to present evidence, to provide testimony on its own behalf, to contest the allegations, to present oral argument, to appeal to court in the event of an adverse ruling and all other rights set forth in G.L. c. 30A and 801 CMR 1.01 et. seq. The Pharmacy acknowledges and agrees that executing this document entitled "Voluntary Surrender Agreement" constitutes a knowing and voluntary waiver of any and all rights to a formal hearing and to all of the above-listed rights.
- 10. The individual signing this document on behalf of the Pharmacy certifies that he is the owner of the Pharmacy (or is properly authorized to act on behalf of the ownership of the pharmacy) and acknowledges that he has read this Agreement, is signing it voluntarily on behalf of the Pharmacy and understands that the Pharmacy's surrender of its registration is a final act and not subject to reconsideration, appeal, or judicial review.

PharmaHealth Pharmacy
Richard P. Brisson, R. Ph.
Board of Registration in Pharmacy David Sencabaugh, R. Ph. Executive Director

Effective Date of Agreement

COMMONWEALTH OF MASSACHUSETTS

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BOARD OF REGISTRATION IN PHARMACY

In the Matter of)	
PHARMAHEALTH PHARMACY)	
458 Dartmouth Street, Suite B)	
New Bedford, MA 02740)	

PHA-2013-0013

CEASE AND DESIST AND QUARANTINE NOTICE

PharmaHealth Pharmacy ("PharmaHealth") is hereby notified to IMMEDIATELY CEASE AND DESIST engaging in the compounding of sterile medications and the distribution of compounded sterile medications.

This Notice is issued pursuant to the authority of the Department of Public Health ("Department") through the Board of Registration in Pharmacy ("Board"), pursuant to M.G.L. c. 94, § 189A, M.G.L. c. 94C, §§ 13 and 14, M.G.L. c. 112, §§ 39 and 42A, and Board Regulation 247 CMR 10.08, related to observed pharmacy practices and conditions at PharmaHealth, Pharmacy Registration No. DS3056, located at 458 Dartmouth Street, Suite B, New Bedford, Massachusetts.

PharmaHealth was observed to be non-complaint with the requirements of Board regulations, including but not limited to 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding — Sterile Preparations with regard to its preparation of sterile compounded medications.

PharmaHealth must immediately cease the preparation and dispensing of compounded sterile medications (Schedules II through VI). PharmaHealth must immediately QUARANTINE the following:

ALL (1) compounded sterile medications (Schedules II through VI) located on Pharmacy premises; (2) sterile medications and pharmaceuticals contained in opened or sealed manufacturer stock bottles or other type of manufacturer packaging on PharmaHealth premises; and (3) any sterile "compounded" medications prepared for dispensing and stored at PharmaHealth.

Pursuant to this Notice, no dispensing of sterile compounded medications (Schedules II through VI) or any sterile "compounded" controlled substances may occur without the express approval of the Department. No disposition may be made of ANY of the above-referenced controlled substances subject to this QUARANTINE NOTICE without the express approval of the Department. An EMBARGO ORDER may be issued by the Department, pursuant to M.G.L. c. 94C, § 13, if necessary. Removal or disposition of the above-described articles without permission from the Department shall be subject to applicable statutory and regulatory penalties.

PharmaHealth may not resume the compounding or dispensing of sterile medications without the express approval of the Department. PharmaHealth shall conduct an orderly transition of patient care and pharmacy related compounding services.

In accordance with 247 CMR 10.08, a hearing limited to the determination of the necessity of this Notice shall be afforded to the licensee within 15 business days of the issuance of this Notice.

Direct questions to Heather Engman, Board Counsel, 617-973-0992, or Madeleine Biondolillo, M.D., Director, Bureau of Health Care Safety and Quality, Department of Public Health, 617-753-8100.

BOARD OF REGISTRATION IN PHARMACY

James 7. DeVita, R.Ph

President

Effective Date: February 1, 2013

Acknowledgement of receipt by PharmaHealth

Date: 2-1-13

Time: 17:45

Print Name: EDWARD MACEDO KPh