COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of	)	PHA-2014-0177
Joseph P. Serio, R.Ph	)	
PH16941	)	
Expires December 31, 2016	)	

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Joseph P. Serio, ("Licensee"), PH16941, 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 set forth in Paragraph 2, identified as Docket No. PHA-2014-0177.[1]

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

   a. Licensee has been the Manager of Record of Westminster Pharmacy ("Pharmacy"), Westminster, Massachusetts, DS1710, since at least July 5, 1989. As described in 247 CMR 6.07, Licensee, as Manager of Record, was responsible for the operation of Westminster Pharmacy in compliance with 247 CMR 2.00 *et seq.* and applicable state and federal laws and regulations.

   b. On or about June 16, 2014, Board investigators conducted an unannounced retail compliance and United States Pharmacopeia General Chapter 795 ("USP 795") inspection of the Pharmacy. During the inspection, Board investigators made observations from which they determined the Pharmacy to be non-compliant with certain requirements of Board regulations and USP 795.

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

c. Specifically, Board investigators observed retail compliance deficiencies including but not limited to the following:

i. Inadequate security for controlled substances, in violation of 247 CMR 6.02(6)(c).

ii. Lack of signs informing patients of their right to counseling by a pharmacist, in violation of 247 CMR 9.07(3)(c) and of the availability of lock boxes to secure prescription medications, in violation of M.G.L. c. 94C, § 21B.

iii. Lack of policies and procedures establishing standards pertaining to compounding of drugs and supervision of technicians, in violation of 247 CMR 6.07(1)(e).

iv. Lack of documentation pertaining to the duties and scope of pharmacy technicians and guidelines regarding pharmacy technician training program, in violation of 247 CMR 8.06(1)(b) & (c) and 247 CMR 8.06(2).

v. Inadequate documentation of biennial inventory, in violation of 247 CMR 6.07(1) and 247 CMR 9.01(1).

vi. Lack of proper equipment to mix creams and ointments, in violation of 247 CMR 6.01(5)(a)(5).

vii. Failure to maintain the pharmacy in a clean and sanitary manner, in violation of 247 CMR 6.02(1).

viii. Failure to maintain a sink equipped with hot and cold running water, in violation of 247 CMR 6.01(5)(a)(7).

ix. Storage of expired compounded medication on shelves, in violation of 247 CMR 9.01(10).

x. Improper and inadequate refrigeration and storage of drugs, in violation of 247 CMR 9.01(5).

xi. Lack of, or inaccessible, written standard operating procedures ("SOPs") pertaining to significant procedures performed in the compounding area, in violation of 247 CMR 6.07(1)(d) & (e) and 247 CMR 9.01(3).

xii. Inaccessibility of Continuous Quality Improvement ("CQI") Program to pharmacy personnel, in violation of 247 CMR 15.04(1) and 247 CMR 15.02(1)(a) and (d)-(f).

xiii. Failure to maintain a QRE record, in violation of 247 CMR 15.04(2).

d. Specifically, Board investigators observed violations of USP 795 non-sterile compounding standards and 247 CMR 9.01(3), including but not limited to the following:

i. Failure to properly store, prepare, and handle hazardous drugs.

ii. Absence of documentation evaluating and confirming staff competency prior to staff initiation of compounding.

iii. Absence of documentation confirming pharmacists' and pharmacy technicians' qualifications to perform their assigned duties.

iv. No availability of FDA list of components withdrawn or removed from the market for safety or efficacy reasons.

v. No evidence of studies performed to determine extended Beyond Use Dates or expiration dates.

vi. Inadequate or non-pharmaceutical grade equipment used for compounding.

vii. Absence of policies and procedures, SOPs, or training manuals pertaining to mechanisms to promptly address equipment problems.

viii. Absence of policies and procedures, SOPs, or training manuals pertaining to a quality assurance program for compounding.

ix. Absence of policies and procedures, SOPs, or training manuals pertaining to compounding.

x. No evidence of proper training on handling of hazardous compounds, including but not limited to attestations of risk to personnel of reproductive capability.

xi. The powder hood was not certified and the HEPA filters needed replacing.

xii. Lack of a purified water supply for use in compounding or washing.

xiii. Failure to label containers with date of receipt and expiration date for components for which there is no manufacturer or supplier assigned expiration date.

xiv. Preparation of drugs without a Master Formulation Record or a Compounding Record.

e. On or about July 15, 2014, the Board and Westminster Pharmacy entered into Consent Agreement to Refrain from Sterile Compounding and Non-Sterile Compounding.

f. On or about September 19, 2014, Board investigators conducted an unannounced retail compliance inspection of Westminster Pharmacy. During the inspection, Board investigators confirmed that all deficiencies identified on the June 16, 2014 inspection had been remediated in accordance with the plan of correction submitted in response to the June 16, 2014 inspection. Board inspectors did not observe any further deficiencies.

3. Licensee agrees the facts described in Paragraph 2 warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61, 247 CMR 6.07(1), and 247 CMR 10.03(1)(a) & (v).

4. Licensee agrees that his pharmacist license shall be placed on PROBATION for two (2) years ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").

5. During the Probationary Period, the Licensee further agrees that he shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.

6. During the Probationary Period, the Licensee further agrees to refrain from preparing and/or dispensing any sterile compounded medication unless and until he 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 the Pharmacy is fully compliant with USP 797 and all other state and federal laws and regulations pertaining to the practice of pharmacy.

7. During the Probationary Period, the Licensee further agrees to refrain from preparing and/or dispensing any non-sterile compounded medication unless and until he 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 the Pharmacy is fully compliant with USP 795 and all other state and federal laws and regulations pertaining to the practice of pharmacy.

8. The Licensee further agrees that he shall submit documentation, within 45 days of the Effective Date, demonstrating the following:

   a. Successful completion of at least four contact hours of continuing education in the area of pharmacy law; and

   b. Licensee read and reviewed 247 CMR 2.00 *et seq.*

9. 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.

10. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate **two (2) years** after the Effective Date upon written notice to the Licensee from the Board[2].

11. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint[3] during the Probationary Period, the Licensee agrees to the following:

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[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 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

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 pharmacy license pursuant to Paragraph 7(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.

12. Licensee agrees that if the Board suspends his pharmacist license in accordance with Paragraph 7, 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.

13. 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

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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.

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 Complaints.

14. The Registrant acknowledges that he has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.

15. 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.

16. 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)

Signature and Date

Joseph P. Serio, RPh

Print Name
Joseph P. Serio, R.Ph

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

9-18-15

Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 9/18/15 **by Certified Mail No.** 7015 1520 0002 8254 8846