

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of Western
Mass. Compounding Center
Registration No. DS89965
Expires December 31, 2017

Docket No. PHA-2016-0108

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Western Mass Compounding Center ("Pharmacy"), a pharmacy registered by the Board, DS89965 ("Registration"), do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Pharmacy's record maintained by the Board:

1. The Pharmacy acknowledges that a complaint has been opened by the Board against its Registration¹ related to the conduct set forth in Paragraph 2, identified as docket no. PHA-2016-0108 ("Complaint").
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. As a result of a retail and USP <795> compliance inspection conducted on March 17, 2016, Office of Public Protection ("OPP") investigators found the following deficiencies:
 - i. Pharmacy failed to comply with the requirements of 247 CMR 9.04(8) concerning the dispensing of hydrocodone-only extended release products, specifically, by failing to obtain and keep a copy of a letter of medical necessity for each new prescription in a readily retrievable manner;
 - ii. Pharmacy regularly compounded and dispensed hydrocodone and oxycodone products that are essentially

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

copies of commercially available single entity oxycodone and hydrocodone products in violation of section 503A(b)(1)(D) of the federal Food, Drug and Cosmetic Act; and

- iii. Pharmacy failed to comply with USP <795> regarding maintaining a compounding record that includes results of quality control procedures in violation of USP<795> and 247 CMR 9.01(3).
3. The Pharmacy agrees that its Registration shall be placed on PROBATION for one (1) year ("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 it shall comply with all the following requirements to the Board's satisfaction:
 - a. Comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia;
 - b. Submit compounding list monthly for first three (3) months after Effective Date and once every three months thereafter;
 - c. Discontinue compounding products similar to commercially available products; and
 - d. Refer prescribers who are writing for schedule II controlled substances with similar, commercially available products to their respective boards of registration.
5. The Board agrees that in return for the Pharmacy's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaint.
6. If the Pharmacy has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate one (1) year after the Effective Date upon written notice to the Pharmacy from the Board².

² In all instances where this Agreement specifies written notice to the Pharmacy from the Board, such notice shall be sent to the Pharmacy's address of record.

7. If the Pharmacy does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint³ during the Probationary Period, the Pharmacy agrees to the following:
- a. The Board may upon written notice to the Pharmacy, 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 Pharmacy's Registration.
 - b. If the Board suspends the Pharmacy's Registration pursuant to Paragraph 7(a)(iii), the suspension shall remain in effect until:
 - i. the Board provides the Pharmacy written notice that the Probationary Period is to be resumed and under what terms; or
 - ii. the Board and the Pharmacy 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.
8. The Pharmacy agrees that if the Board suspends its Registration in accordance with Paragraph 7, it will immediately return its Registration to the Board, by hand or certified mail. The Pharmacy further agrees that upon said suspension, they will no longer be authorized to operate as a pharmacy in the Commonwealth of Massachusetts and shall not in any way represent itself as a pharmacy until such time as the Board reinstates its Registration or right to renew such Registration.

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 the Pharmacy engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Pharmacy shall have an opportunity to respond.

9. The Pharmacy 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, M.G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 *et seq.* The Pharmacy further understands that by executing this Agreement it's knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.
10. The Pharmacy acknowledges that it has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.
11. The Pharmacy 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.
12. The Pharmacy certifies that it has read this Agreement. The Pharmacy understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal or judicial review.

Linda H. Sprecher 06/18/19 By: [Signature] 06/18/19
Witness (sign and date) Western Mass Compounding Ctr.
(Signature and Date)

Bradley S. Sprecher
Print Name

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

6/25/19
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 7/8/19 by

Certified Mail No. 7618 3690 0000 6223 3705