

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
WESTERN MASS)
COMPOUNDING CENTER)
Pharmacy Registration No. DS89799)
Expiration Date: December 31, 2013)

PHA-2012-0239

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Western Mass Compounding Center ("Licensee" or "Western Mass"), a pharmacy located at 138 Memorial Avenue in West Springfield, Massachusetts and licensed by the Board, Registration No. DS89799, 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 its Massachusetts pharmacy registration (registration¹) related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2012-0239 ("the Complaint").
2. The Board and Licensee acknowledge and agree to the following facts:
 - a. On or about October 19, 2012, Western Mass submitted an Attestation of Compliance to the Board attesting that Western Mass 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. On October 25, 2012 John Horan, manager of record, wrote a letter to Steven Cirillo, Western Mass President, recommending the pharmacy implement the following changes immediately:

All preparations of medium and high risk sterile products will cease until we are in full compliance with low risk preparation quality assurance practices. No preparation will have more than a 14 day beyond use date (BUD).

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

High risk preparations... will cease until we have set up and completed one cycle of sterility/beyond use date testing and completed successfully required annual testing once for those who will be involved in this type of preparation.

All sterile product preparations will be given a BUD of 14 days unless longer dating is supported by written data or our own testing.

In addition...it is time that we address procedures... I have asked that we implement the PCCA policy and procedures manual ASAP. All product preparation quality assurance practices need to begin to meet the industry standards for all types of product preparations.

c. Board investigators conducted an unannounced inspection of Western Mass on or about December 5 & 6, 2012. During the inspection, Board investigators observed Western Mass 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. Board investigators also observed a non-pharmacist providing patient counseling in violation of 247 CMR 9.07(3)(f).

d. Deficiencies observed on December 5 & 6, 2012 included, but were not limited to, deficiencies identified in the October 25, 2012 letter, such as lack of standard operating procedures, lack of substantial evidence to support BUD, and lack of a quality assurance program.

e. As a result of Western Mass' non-compliance, on or about December 6, 2012, Western Mass was notified to immediately cease the preparation and dispensing of sterile compounded medications, and quarantine all sterile compounded medications on Western Mass' premises. Western Mass was further notified to cease its provision of patient counseling by non-pharmacists.

f. In a March 6, 2013 letter, signed by Stephen Cirillo, Western Mass President, and John Horan, manager of record, Western Mass notified the Board that it permanently terminated all sterile compounding preparations.

3. The Licensee agrees that its registration shall be placed on PROBATION for no less than 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 laws and regulations governing the practice of the pharmacy, comply with the United States Pharmacopeia, and not engage in any continued or further conduct such as that set forth in Paragraph 2. The Licensee further agrees that it shall not provide patient counseling by non-pharmacists, nor shall it permit any non-pharmacist to provide patient counseling to patients receiving prescription medications at Western Mass.
5. The Licensee 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 Western Mass 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.
6. The Board agrees that in return for the Licensee's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.
7. If and when the Board determines that the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probation Period will terminate no earlier than one (1) year after the Effective Date upon written notice to the Registrant from the Board².
8. If the Licensee does not comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint³ during the Probation 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

² In all instances where this Agreement specifies written notice to the Registrant from the Board, such notice shall be sent to the Registrant'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 December 6, 2012 inspection, 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.

- iii. IMMEDIATELY SUSPEND the Registrant's registration.
 - b. If the Board suspends the Licensee's registration pursuant to Paragraph 7(a)(iii), the suspension shall remain in effect until:
 - i. the Board gives the Licensee written notice that Probationary Period is to be resumed and under what terms; or
 - ii. the Board and the Licensee enter into 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.
9. The Licensee agrees that if the Board suspends its registration in accordance with Paragraph 7, it will immediately return its current Massachusetts pharmacy registration to the Board, by hand or certified mail. The Licensee further agrees that upon suspension, it will no longer be authorized to operate as a pharmacy and shall not in any way represent itself as a pharmacy until such time as the Board reinstates its registration⁴.
10. The Licensee 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 Licensee further understands that by executing this Agreement it is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.
11. The Licensee acknowledges that it has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.

⁴Any evidence of unlicensed practice or misrepresentation as a Pharmacy after the Board has notified the Pharmacy of his registration suspension shall be grounds for further disciplinary action by the Board and the Board's referral of the matter to the appropriate law enforcement authorities for prosecution.

12. The Licensee 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, M.G.L. c. 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.
13. 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.
14. The individual signing this Agreement certifies (1) that he or she is authorized to enter into this Agreement on behalf of the Licensee, and (2) that he or she has read this Agreement.

Witness (sign and date)

John H 9/10/2013
 Print Name: John Horan

Western Mass Compounding Center

By: *[Signature]* 9/9/2013
 (sign and date)
 Print Name: Stephen Cirillo
 Title: owner

Margaret Cittadino
 Margaret Cittadino
 Associate Director
 Board of Registration in Pharmacy

9-12-13

Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on September 17, 2013 by
 Certified Mail No. 792 3460 001 7330 8708