

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
Critical Care Systems)
Registration No. DS3327)
Expires December 31, 2015)

PHA-2014-0179

Received

JAN 22 2015

BOARD OF
PHARMACY

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Critical Care Systems ("Licensee" or "Pharmacy"), DS3327, 191 Bay Street, Braintree, Massachusetts, 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 the Board opened a complaint against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2014-0179.¹
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about June 23, 2014, Board Investigators conducted a sterile compounding inspection at the Pharmacy.
 - b. On or about June 23, 2014, Board Investigators observed the following violations of United States Pharmacopeia Chapter 797 ("USP 797") and 247 CMR 9.01(3):
 - i. Improper training for employees who perform environmental monitoring of compounding facility and inadequate documentation of such training;
 - ii. Excessive supplies located in and around the buffer room, ante room and bulk storage area of Pharmacy;
 - iii. Insufficient environmental monitoring action levels;

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

- iv. Inadequate mapping of areas to undergo environmental monitoring;
 - v. Inadequate viable air sampling technique;
 - vi. Non-functioning primary engineering control with an expired certification;
 - vii. Out-of-range pressure differentials between the buffer room and ante room;
 - viii. Ceiling panels were sealed by gaskets and not sealed by caulking;
 - ix. Compounding personnel in ante room were not properly gowned; and
 - x. Seam on buffer room floor required repair.
 - xi. Dust on window sills; and
 - xii. Stains and spotting on ceiling HEPA filter.
3. The foregoing facts, if proven at hearing, would warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03.
4. 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").
5. During the Probationary Period, the Pharmacy further agrees that it 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 Pharmacy further agrees that it shall submit documentation demonstrating that all personnel who engage in or oversee sterile compounding completed the Critical Point course consisting of both corresponding and live components, as described in the Pharmacy's plan of correction submitted to the Board on July 11, 2014.
7. 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.
8. The Pharmacy agrees that the Probationary Period will not terminate until such time as the Pharmacy successfully passes two consecutive sterile compounding inspections, conducted by Board Investigators.

The sterile compounding inspection conducted on September 23, 2015 will be counted as one of the two surveys required for the purposes of this Agreement.

9. If the Pharmacy has complied with all the requirements contained in this Agreement, the Probationary Period will terminate one (1) year after the Board signs this Agreement².
10. 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, 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 10(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.
 - c. The Licensee has the right to written notice and a hearing on the limited issue of whether or not the Pharmacy is in

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.

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.

compliance with, or in violation of, the terms of the Agreement prior to any extension of the probationary period, modification of the Agreement terms or requirements, or suspension of the Pharmacy's registration.

11. The Pharmacy agrees that if the Board suspends its registration in accordance with Paragraph 10, it will immediately return its current Massachusetts registration to the Board, by hand or certified mail. The Pharmacy further agrees that upon said suspension, it 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 registration or right to renew such registration.
12. 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 is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.
13. 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.
14. 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.
15. 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.

Jessica Hancock 1/20/16
Witness (sign and date)

Cliff Berman 1/20/16
Signature and Date

Clifford Berman
Print Name
Critical Care Systems
Corporate Secretary

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

2-5-16
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 2/5/16 by
Certified Mail No. 7015 3010 0001 7080 2557