

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
Option Care)
DS3584)
Expires: December 31, 2017)

PHA-2016-0026

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and the Option Care Pharmacy ("Pharmacy" or "Licensee"), DS3584, 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-2016-0026.¹
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about February 12, 2016 and February 16, 2016, Option Care improperly compounded and dispensed prescriptions written for blinatumomab 65 mcg in 280 ml 0.9 % NaCl. Specifically, the final volume of the infusion bags, as dispensed, was approximately 180 ml.
 - b. The root cause analysis indicated the repeater pump used to prepare the compounded sterile preparations was incorrectly programmed or not properly calibrated, resulting in the errors.
3. The Pharmacy acknowledges that the foregoing facts warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A and 61 and under 247 CMR 10.03(1)(v).

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

4. The Pharmacy agrees that its license 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, and within 90 days of the Effective Date, the Pharmacy agrees to submit documentation demonstrating all staff received training from an ICU Medical PharmaAssist representative on the proper use of the ICU Medical PharmaAssist Pump.
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. 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.
9. 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 license.

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.

- b. If the Board suspends the Pharmacy's license pursuant to Paragraph 9(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.
10. The Pharmacy agrees that if the Board suspends its license in accordance with Paragraph 9, it will immediately return its current Massachusetts license 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 its license or right to renew such license.
11. 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 Complaints.
12. 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.

13. 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.
14. 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.

Megan Haggland 6/30/17
 Witness (sign and date)

[Signature] 6/30/17
 Signature and Date

MICHAEL SHAPIRO
 Print Name

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

7-11-17
 Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 7/12/17 by
 Certified
 Mail No. 7015 3010 0001 7080 3134