

NOV 22 2013

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of BAYSTATE )  
HOME INFUSION & )  
RESPIRATORY SERVICES )  
211 Carando Drive, )  
Springfield, MA 01104 )

PHA-2012-0247

22 2013

**CONSENT AGREEMENT FOR PROBATION**

The Massachusetts Board of Registration in Pharmacy ("Board") and Baystate Home Infusion & Respiratory Services ("BHI&RS" or "Licensee"), DS3300, 211 Carando Drive, Springfield, Massachusetts, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of BHI&RS's record maintained by the Board:

1. BHI&RS acknowledges that a complaint has been filed with the Board against its Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2012-0247.<sup>1</sup>
2. The Board and BHI&RS acknowledge and agree to the following facts:
  - a. Board investigators conducted an unannounced inspection of BHI&RS on or about December 11 & 12, 2012. During the inspection, Board investigators made observations from which they determined BHI&RS to be non-compliant with 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding – Sterile Preparations, with regard to its compounding of sterile medications.
  - b. As a result of this determination of non-compliance, on or about December 12, 2012, BHI&RS was notified to immediately cease the preparation and dispensing of sterile compounded medications, and quarantine all sterile compounded medications on BHI&RS's premises.

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

c. In a letter dated May 15, 2013, BHI&RS, through its counsel, advised the Board that it would no longer engage in high risk sterile compounding.

d. Board investigators conducted a re-inspection of BHI&RS on May 17, 2013. During the inspection, Board investigators observed that BHI&RS appeared to be in compliance with United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding –Sterile Preparations. Accordingly, the Cease and Desist and Quarantine Notice was rescinded and BHI&RS was authorized by the Board to resume low and medium risk sterile compounding.

3. BHI&RS agrees that its pharmacy license shall be placed on PROBATION for no less than 12 months ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
4. During the Probationary Period, BHI&RS further agrees that it shall comply with all laws and regulations governing the practice of pharmacy and the United States Pharmacopoeia.
5. BHI&RS agrees to refrain from all high risk sterile compounding unless and until it receives written approval from the Board to resume the preparation and dispensing of high risk sterile compounded medications. Board approval shall not be granted unless and until BHI&RS demonstrates, upon inspection by Board investigators, that it is fully compliant United States Pharmacopoeia standards pertaining to high risk sterile compounding and all other state and federal laws and regulations pertaining to the practice of pharmacy.
6. The Board agrees that in return for BHI&RS's execution and successful compliance with all the requirements of this Agreement it will not prosecute the Complaint.
7. If the Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate **12 months** after the Effective Date upon written notice to the Licensee from the Board<sup>2</sup>.

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<sup>2</sup> 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.

8. If the Licensee does not comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint<sup>3</sup> during the Probationary 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
    - iii. IMMEDIATELY SUSPEND the Licensee's pharmacy license.
  - b. If the Board suspends BHI&RS's pharmacy license pursuant to Paragraph 8(a)(iii), the suspension shall remain in effect until:
    - i. the Board provides BHI&RS written notice that the Probationary Period is to be resumed and under what terms; or
    - ii. the Board and BHI&RS 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.
9. BHI&RS agrees that if the Board suspends its pharmacy license in accordance with Paragraph 8, it will immediately return its current Massachusetts pharmacy license to the Board, by hand or certified mail. BHI&RS further agrees that upon said suspension, it will no longer be authorized to operate a retail drug store in the Commonwealth of Massachusetts and shall not in any way represent itself as a retail drug store or pharmacy until such time as the Board reinstates its pharmacy license or right to renew such license.

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<sup>3</sup> The term "Subsequent Complaint" applies to a complaint opened after the Effective Date, 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.

10. BHI&RS 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 Complaints.
11. The Licensee acknowledges that it has been represented by legal counsel in connection with the Complaint and this Agreement.
12. 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.
13. The Licensee certifies that it 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.

Nancy S. Stebbins 11/20/13  
 Witness (sign and date)

[Signature] 11/20/13  
 Signature and Date

William H. Loomis  
 Print Name  
 Baystate Home Infusion &  
 Respiratory Services

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

11-22-13  
 Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 11/25/13 by  
Certified

Mail No. 7012 3460 0001 7330 8937