

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of )  
HOME INFUSION SOLUTIONS ) PHA-2012-0255  
Pharmacy Registration No. DS3592 )  
Expiration Date: December 31, 2013 )

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Home Infusion Solutions ("Licensee" or "Home Infusion"), a pharmacy located at 295 Main Street, Falmouth, Massachusetts, and licensed by the Board, DS3592, 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. Home Infusion acknowledges that the Board opened a Complaint against its Massachusetts Pharmacy registration (registration<sup>1</sup>) related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2011-0255 ("the Complaint").
2. The Board and Home Infusion acknowledge and agree to the following facts:
  - a. On or about October 16, 2012, Home Infusion, through its Manager of Record James Hermansen, submitted an Attestation of Compliance to the Board attesting that Home Infusion 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. Board investigators conducted an unannounced inspection of Home Infusion on or about December 26 & 27, 2012. During the inspection, Board investigators observed Home Infusion 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.

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

c. As a result of Home Infusion's non-compliance, on or about December 27, 2012, Home Infusion was notified to immediately cease the preparation and dispensing of sterile compounded medications, and quarantine all sterile compounded medications on Home Infusion's premises.

d. Board investigators conducted a re-inspection of Home Infusion on April 4, 2013. During the inspection, Board investigators observed that Home Infusion 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.

3. Home Infusion 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 Home Infusion further agrees that it shall comply with all laws and regulations governing the practice of pharmacy and comply with the United States Pharmacopoeia. Licensee further agrees to timely renew its registration.
5. 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.
6. 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 Probationary Period will terminate no earlier than one (1) year after the Effective Date upon written notice to the Licensee from the Board<sup>2</sup>.
7. 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 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:

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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.

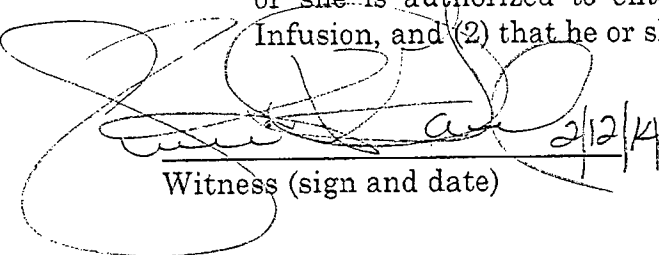
<sup>3</sup> The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the April 4, 2013 inspection, which (1) alleges that the Licensee engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Licensee shall have an opportunity to respond.

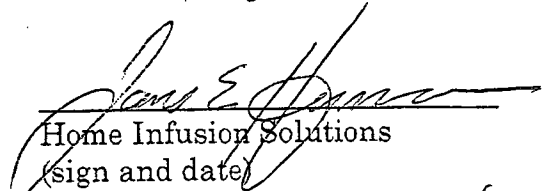
- i. EXTEND the Probationary Period; and/or
    - ii. MODIFY the Probation Agreement requirements; and/or
    - iii. IMMEDIATELY SUSPEND the Licensee's registration.
  - b. If the Board suspends the Licensee's registration pursuant to Paragraph 7(a)(iii), the suspension shall remain in effect until:
    - 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
    - iv. 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 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 registration<sup>4</sup>.
9. 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.
10. 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.

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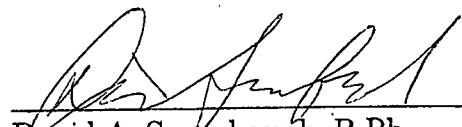
<sup>4</sup>Any evidence of unlicensed practice or misrepresentation as a Pharmacy after the Board has notified the Pharmacy of his registration suspension shall be grounds for further disciplinary action by the Board and the Board's referral of the matter to the appropriate law enforcement authorities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

11. 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, G.L. ch. 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.
12. 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.
13. The Licensee Representative sign signing this Agreement certifies (1) that he or she is authorized to enter into this Agreement on behalf of the Home Infusion, and (2) that he or she has read this Agreement.

  
Witness (sign and date) 2/12/14

  
Home Infusion Solutions  
(sign and date) 2/12/14

Print Name: James Hermanson

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

Effective Date: 2-19-14

Fully Signed Agreement Sent to Registrant on <sup>Atty</sup> 2/19/14 by  
Certified Mail No. 7010 1870 0002 2380 5431



12/27/2012 13:47 FAX 617 973 0982

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## COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of Home Infusion Solutions, )  
295 Main Street )  
Falmouth, MA 02540 )

Docket No. PHA-2012-0255

## CEASE AND DESIST NOTICE

Home Infusion Solutions is hereby notified to IMMEDIATELY CEASE AND DESIST engaging in the compounding of sterile medications and the distribution of compounded sterile medications.

This Notice is issued pursuant to the authority of the Department of Public Health ("Department") through the Board of Registration in Pharmacy ("Board") and the Division of Food and Drugs, pursuant to M.G.L. c. 94, § 189A, M.G.L. c. 94C, §§ 13 and 14, M.G.L. c. 112, §§ 39 and 42A, and Board Regulation 247 CMR 10.08, related to observed pharmacy practices and conditions at Home Infusion Solutions, Pharmacy Registration No. DS3592, 295 Main Street, Falmouth, Massachusetts.

Home Infusion Solutions was observed to be non-complaint with requirements of Board regulations, including but not limited to, 247 CMR 9.01 and United States Pharmacopoeia ("USP") Standard <797> Pharmaceutical Compounding - Sterile Preparations, with regard to its facility design and controls and its compounding and dispensing of sterile medications.

Home Infusion Solutions must immediately cease all pharmacy operations pertaining to the preparation and dispensing of compounded sterile medications.

Pursuant to this Notice, no dispensing of sterile compounded medications (Schedules II through VI) or any sterile "compounded" controlled substances may occur without the express approval of the Department.

Home Infusion Solutions may not resume the aforementioned pharmacy operations without the express approval of the Department. Home Infusion Solutions shall conduct an orderly transition of patient care and pharmacy related compounding services.

In accordance with 247 CMR 10.08, a hearing limited to the determination of the necessity of this Notice shall be afforded to the licensee within 21 days of the issuance of this Notice.

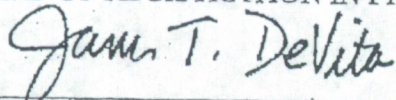
Direct questions to Samuel Penta, Board Investigator, 617-973-0888, or Madeleine Biondolillo, M.D., Director, Bureau of Health Care Safety and Quality, Department of Public Health 781-789-2180.



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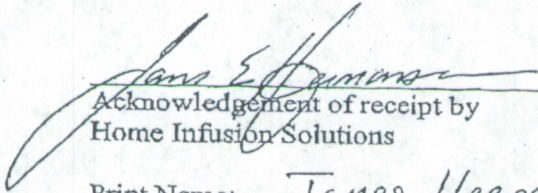
## BOARD OF REGISTRATION IN PHARMACY



James T. DeVita, R.Ph

President

Effective Date: December 27, 2012

  
Acknowledgement of receipt by  
Home Infusion SolutionsDate: 12/27/12  
Time: 4pmPrint Name: James Hermansen

Manager of Record

Home Solutions / Falmouth