

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
JAMES HERMANSEN)
Pharmacist Registration No. PH17587)
Expiration Date: December 31, 2014)

PHA-2013-0064

RECEIVED
FEB 13 2014
BOARD OF
PHARMACY

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and James Hermansen ("Licensee"), a Pharmacist licensed by the Board, Registration No. PH17587, 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 his Massachusetts Pharmacist registration (registration¹) related to the conduct set forth in Paragraph 2, identified as Docket Nos. PHA-2013-0064 ("the Complaint").
2. The Board and Licensee acknowledge and agree to the following facts:
 - a. Licensee is currently the manager of record of Home Infusion Solutions ("Home Infusion"), DS3592, and has been the manager of record of Home Infusion Solutions continuously since at least May 1, 2008.
 - b. As described in 247 CMR 6.07, Licensee, as manager of record, was responsible for the operation of the Home Infusion Solutions pharmacy in compliance with 247 CMR 2.00 et seq. and applicable state and federal laws and regulations.
 - c. 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.

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

d. 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-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. The Licensee was the Manager of Record of Home Infusion at the time of the inspection December 26 & 27, 2012 inspection.

e. 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.

f. 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. The Licensee agrees that his Pharmacist registration shall be placed on PROBATION for no less than one (1) year 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 his 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 Board².

² 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.

7. If the Licensee does not comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint³ 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 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 the Probationary Period is to be resumed and under what terms; or
 - ii. the Board and the Licensee 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.
8. The Licensee agrees that if the Board suspends his registration in accordance with Paragraph 7, he will immediately return his current Massachusetts registration to practice as Pharmacist to the Board, by hand or certified mail. The Licensee further agrees that upon suspension, he will no longer be authorized to engage in practice as a Pharmacist in the Commonwealth of Massachusetts and shall not in any way represent himself as a Pharmacist until such time as the Board reinstates his registration⁴.

³ 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.

⁴Any evidence of unlicensed practice or misrepresentation as a Pharmacist after the Board has notified the Licensee 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.

9. The Licensee understands that he has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication he would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on his 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 he is knowingly and voluntarily waiving his right to a formal adjudication of the Complaint.
10. The Licensee acknowledges that he has been at all times free to seek and use legal counsel in connection with the Complaint and this Agreement.
11. The Licensee acknowledges that after the Effective Date, the Agreement constitutes a public record subject to the Commonwealth of Massachusetts' Public Records Law, M.G.L. c. 4, § 7.
12. The Licensee certifies that he 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.

[Signature]
Witness (sign and date)

[Signature] 2/12/14
James Hermansen
Licensee (sign and date)

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

2-19-14
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Licensee on 2/19/14 by
Certified Mail No. 7610 1890 0002 2380 5424