COMMONWEALTH OF MASSACHUSETTS

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BOARD OF REGISTRATION IN PHARMACY

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In the Matter of)		•
JAMES NAHILL)	Docket Nos.	PHA-2012-0171
)		PHA-2013-0038
Pharmacist Reg. No. PH 21521)		PHA-2013-0039
Registration expired 12/31/16)		
)		

CONSENT AGREEMENT FOR SUSPENSION

The Massachusetts Board of Registration in Pharmacy ("Board") and James Nahill ("Pharmacist"), Lic. No. 21521, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Pharmacist's record maintained by the Board:

- 1. The Pharmacist acknowledges that the Board opened Complaints against his Massachusetts pharmacist registration related to the conduct set forth in Paragr. ph 2, identified as PHA-2012-0171, PHA-2013-0038, and PHA-2013-0039.
- 2. The Board and the Pharmacist acknowledge and agree that the Pharmacist was the Manager of Record for Pallimed Solutions, Inc. ("Pharmacy") at all times relevant to the above-referenced complaints and further agree that the complaints allege the following facts:

a. PHA-2012-0171

The Pharmacy improperly compounded a solution of injectable Lidocaine which resulted in the Pharmacy dispensing two prescriptions with the incorrect potency of the medication and causing harm to two patients;

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

b. PHA-2013-0039

The Pharmacy improperly advertised its compounding services and regularly compounded drugs to fill prescriptions that did not specify that a compounded version of the drug was necessary and/or dispensed compounded medications when a commercially produced version of the drug was available. Additionally, the Pharmacy used Sildenafil Citrate designated by its supplier as being for veterinary use in tablets prepared for human consumption.

c. PHA-2013-0038

A 2012 audit determined that the Pharmacy violated standards of practice relating to sterile compounding including, but not limited to, record-keeping failures, inadequate quality assurance policies, and evidence of failure to produce thorough root cause analysis reports. Additional violations including the presence of fifty-six (56) contaminated vials of compounded drugs necessitating a recall of medications from multiple states were identified in early 2013.

- 3. The Pharmacist acknowledges that sufficient evidence exists such that, if the matters were to proceed to a hearing, the Board could reasonably find that he violated Board regulations including 247 CMR 6.07(1)(d) & (e) and 9.01(1), (3), (10) and (13).
- 4. The Pharmacist agrees that his registration shall be SUSPENDED for six (6) months ("Suspension Period") commencing with the date on which the Board signs this Agreement ("Effective Date").
- 5. The Pharmacist agrees that During the Suspension Period he shall fulfill the following requirements to the Board's satisfaction:
 - a. complete a Certificate Program in sterile compounding which shall consist of at least 20 contact hours of continuing education in the area of sterile compounding with no more than 10 contact hours obtained through home study or complete a course of study in sterile compounding which shall consist of the CriticalPoint 30 contact hour e-study course in Sterile compounding; the sterile compounding portion of the Northeastern School of Pharmacy program titled: Compounding: Implementing Best Practices for USP <797> and <795>; and the MCPHS program titled: Sterile Compounding Practices 2015;
 - b. achieve a passing grade in the Multi-State Pharmacy Jurisprudence Examination ("MPJE"); and
 - c. complete a continuing education course of five (5) contact hours or more in Ethics.

(Continuing education credits applied to satisfy the requirements of Paragraphs 5. a and c may not be used to also satisfy the Pharmacist's continuing education requirement.)

- 6. The Pharmacist and the Board agree that, upon proof (satisfactory to Board staff) that the Pharmacist has completed the requirements set forth in Paragraph #5 and is in all other respects compliant with the Agreement, the Suspension Period will be terminated forthwith notwithstanding the order for a six (6) month suspension.
- 7. The Pharmacist agrees that the period during which his registration is suspended shall be followed by a three (3) year period of probation (the "Probationary Period").
- 8. During the Probationary Period, the Pharmacist is not required to be employed as a pharmacist, but he agrees that he shall comply in all material respects with all laws and regulations governing the practice of pharmacy and with the U.S. Pharmacopeia if he does engage in the practice of pharmacy during the probationary period.
- 9. During the Probationary Period, the Pharmacist further agrees that he shall comply with all of the following requirements to the Board's satisfaction:
 - a. The Pharmacist agrees not to have any ownership interests in any pharmacy;
 - b. The Pharmacist agrees not to: 1) serve in the role of Manager of Record for any pharmacy; 2) oversee or engage in any sterile compounding or complex non-sterile compounding; and 3) act as a preceptor;
- 10. If the Pharmacist has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate three (3) years after the completion of the Suspension Period and upon written notice to the Pharmacist from the Board².
- 11. If the Pharmacist does not comply with the terms of this Agreement, or if the Board opens a Subsequent Complaint³ during the Suspension or Probationary Periods, the Pharmacist agrees to the following:

² In all instances where this Agreement specifies written notice to the Pharmacist from the Board, such notice shall be sent to the Pharmacist'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 Pharmacist engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence, as determined following the complaint investigation during which the Pharmacist shall have an opportunity to respond.

- a. The Board may upon written notice to the Pharmacist, as warranted to protect the public health, safety, or welfare:
 - EXTEND the Suspension or Probationary Period; and/or
 - ii. MODIFY the Probation Agreement requirements; and/or
 - iii. IMMEDIATELY SUSPEND the Pharmacist's registration.
- b. If the Board suspends the Pharmacist's registration pursuant to Paragraph 11(a)(iii), the suspension shall remain in effect until:
 - i. the Board provides the Pharmacist written notice that the Probationary Period is to be resumed and under what terms; or
 - ii. the Board and the Pharmacist sign a subsequent agreement; or
 - iii. the Board issues a written final decision and order following adjudication of the allegations (1) of noncompliance with 'his Agreement, and' or (2) contained in the Subsequent Complaint.
- 12. The Pharmacist agrees that if the Board suspends his registration in accordance with Paragraph 11, he will immediately return his current Massachusetts registration to the Board, by hand or certified mail. The Pharmacist further agrees that upon said suspension, he will no longer be authorized to operate 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 registration or his right to renew such registration.
- 13. The Board agrees that in return for the Pharmacist's execution and successful compliance with the requirements of this Agreement it will not prosecute the Complaints.
- 14. The Pharmacist understands that he has a right to a formal adjudicatory hearing concerning the Complaints 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, M.G.L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 et seq. The Pharmacist further understands that by executing this Agreement he is knowingly and voluntarily waiving his right to a formal adjudication of the Complaints.

- 15. The Pharmacist acknowledges that he has been represented by legal counsel in connection with the Complaints and this Agreement.
- 16. The Pharmacist 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.
- 17. The Pharmacist acknowledges that he has read this Agreement and understands and agrees that entering into this Agreement is a voluntary and final act and not subject to reconsideration, appeal, or judicial review.

Signed:

Licensee (sign and date)

Print Name

Jethan Novel 9,21,15

Witness (sign and date)

David Sencabaugh, R. Ph. 9/23/2015

Executive Director

Board of Registration in Pharmacy

9/23/2015

Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 9/29/15 by Certified Mail No. 7009 1680 000/ 1520 2907