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BOARD OF PHARMACY

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
Amherst Pharmacy, LLC)
License No. DS89775)
Expires December 31, 2017)

Docket Nos. PHA-2016-0091
PHA-2017-0164

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Amherst Pharmacy, LLC ("Pharmacy"), a pharmacy registered by the Board, DS89775 ("Registration"), 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 two complaints have been opened by the Board against its Registration¹ related to the conduct set forth in Paragraph 2, identified as docket numbers PHA-2016-0091 and PHA-2017-0164 (the "Complaints").
2. The Board and the Pharmacy acknowledge and agree to the following facts:

In regards to PHA-2016-0091:

- a. On August 21, 2015, Office of Public Protection ("OPP") investigators conducted an USP <795> compliance inspection of the Pharmacy and observed the following deficiencies:
 - i. Pharmacy failed to follow the Master Formulation Record for compounding hydrocodone 20 mg capsules as published by Medisca®, specifically by using different ingredients and amounts and using different preparatory instructions as recorded in the compounding records in violation of USP <795> and 247 CMR 9.01(3);

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

- ii. Pharmacy's internal validity in compounding hydrocodone 20 mg. was inconsistent, e.g., amount of lactose used to prepare the same number of capsules differed in compounding records in violation of USP<795> and 247 CMR 9.01(3);
- iii. Pharmacy failed to record instructions and documentation of quality control measures in violation of USP<795> and 247 CMR 9.01(3).
- iv. Pharmacy failed to accurately record in perpetual inventory the amount of hydrocodone powder used in compounding; hydrocodone powder in compounding records was inconsistent with that recorded in the perpetual inventory log.
- v. Pharmacy compounded hydrocodone 20 mg capsules for Patient A that is essentially a copy of a commercially available drug, i.e., Hysingla® ER, in violation of section 503A of the federal Food, Drug and Cosmetic Act.

In regards to PHA-2017-0164:

- b. On August 3, 2016, OPP investigators conducted a retail compliance inspection of the Pharmacy and reviewed the perpetual inventory for eight Schedule II controlled substances ("controlled substances") and observed the following deficiencies:
 - i. Pharmacy failed to reconcile its perpetual inventory at least once every ten days for five of the eight controlled substances reviewed in violation of 247 CMR 9.01(14).
 - ii. Unresolved discrepancies of the balance on hand (BOH) for five of the eight controlled substances in eleven entries in violation of 247 CMR 6.07(1)(b).
 - iii. Perpetual entries not logged in chronological order in violation of 247 CMR 6.07(1)(b).
 - iv. Controlled substance return for Adderall XR 10mg documented as a quantity of 31 on the DEA 222 Form

with the perpetual log having a quantity of 29 as the BOH.

- c. On March 30, 2017, OPP investigators conducted a retail compliance inspection and the following deficiencies were observed:
 - i. The Pharmacy failed to reconcile its perpetual inventory at least once every ten days in violation of 247 CMR 9.01(14).
 - ii. Transcription errors for four controlled substances were observed in violation of 247 CMR 6.07(1)(b).
3. The Pharmacy acknowledges that the foregoing facts warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(a), (d) and (v).
4. The Pharmacy agrees that its Registration 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 Licensee further agrees that it shall comply with all the following requirements to the Board's satisfaction:
 - a. Comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia;
 - b. Submit compounding list in spreadsheet form monthly for first three (3) months after Effective Date and quarterly thereafter;
 - c. Discontinue compounding products similar to commercially available products; and
 - d. Refer prescribers to their respective Boards of Registration.
6. 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 Complaints.

7. 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.
8. 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 Registration.
 - b. If the Board suspends the Pharmacy's Registration pursuant to Paragraph 7(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.
9. The Pharmacy agrees that if the Board suspends its Registration in accordance with Paragraph 7, it will immediately return its Registration to the Board, by hand or certified mail. The Pharmacy further agrees that upon said suspension, they will no longer be

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.

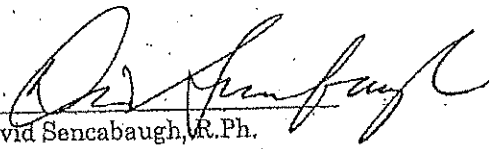
³ The term "Subsequent Complaint" applies to a complaint opened after the Effective Date concerning acts, omissions, or events occurring after the Effective Date, which (1) alleges that the Pharmacy engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence,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

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 Registration or right to renew such Registration.

10. The Pharmacy understands that it has a right to formal adjudicatory hearing concerning the Complaints 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's knowingly and voluntarily waiving its right to a formal adjudication of the Complaints.
11. The Pharmacy acknowledges that it has sought and used legal counsel in connection with the Complaints and this Agreement.
12. 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.
13. 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.

DMUSTAKI MAM 8/23/19 Ioanis Nikita 8/23/19
Witness (sign and date) Amherst Pharmacy, LLC
(Signature and Date)

Ioanis Nikita 8/23/19
Print Name


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

9/3/2019
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 9/6/19 by

Certified Mail No. 7017 1450 0002 2341 8733