## COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY	BOARD OF REGISTRATION IN PHARMACY
In the Matter of Alexander's Pharmacy License No. DS6349 Expires December 31, 2017	) ) ) ) PHA-2015-0082 ) PHA-2016-0092 ) PHA-2016-0198

## SECOND CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Alexander's Pharmacy ("Licensee" or "Pharmacy"), license no. DS6349, 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 entered into a Consent Agreement for Probation on January 29, 2016 ("Original Agreement") in resolution of a complaint against its pharmacy license, docket number PHA-0215-0082 ("Original Complaint"). The Original Agreement is attached hereto and incorporated by reference.
- 2. On or about August 5, 2016 and October 27, 2016, the Board opened Subsequent Complaints against Licensee's Massachusetts pharmacy license, docket number PHA-2016-0092 and PHA-2016-0198 ("Second Complaints").
- 3. The Licensee agrees that this Second Consent Agreement for Probation ("Second Agreement") will supersede the Original Agreement. Further, the Licensee agrees that this Agreement has been executed as a result of the following:
  - a. Per Paragraph 5 of the Original Agreement, Licensee was required to comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.

b. Per Paragraph 8 of the Original Agreement, a Subsequent Complaint is grounds to modify the Agreement.

## c. Drug Losses

i. On or about October 1, 2015, the Pharmacy discovered the loss of 180 tablets of methadone 5 mg. During the Board's and the Pharmacy's subsequent investigation of the drug loss, it was determined the Pharmacy failed to maintain an accurate Schedule II controlled substance perpetual inventory, in violation of 247 CMR 9.01(14).

ii. On or about October 14, 2015, the Pharmacy discovered the loss of 90 tablets of oxycodone-acetaminophen 5 mg – 325 mg. During the Board's and the Pharmacy subsequent investigation of the drug loss, it was determined the loss resulted from a quality related event in which the Pharmacy incorrectly dispensed 90 tablets of oxycodone-acetaminophen 5 mg – 325 mg instead of 90 tablets of hydrocodone-acetaminophen 5 mg – 325 mg, as prescribed.

## d. Inspectional Deficiencies

- i. On or about October 11, 2016, Board Investigators inspected the Pharmacy and observed the following deficiencies:
  - 1. Insufficient technician to pharmacist staffing ratio, in violation of 247 CMR 8.06;
  - 2. Inaccurate and incomplete records regarding controlled substances, including DEA 222 forms;
  - 3. Failure to maintain master formulation records, in violation of 247 CMR 9.01(3) and USP 795; and
  - 4. On multiple occasions, the Pharmacy accepted opium elixir from a patient, previously dispensed by a different pharmacy, and compounded and redispensed the opium elixir to the patient, in violation of 247 CMR 9.01(4).
- e. The Licensee acknowledges and agrees the facts described Paragraph 3 of the Second Agreement warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(a) & (v).

- 4. The Licensee agrees the Probationary Period imposed by the Original Agreement shall be extended by six (6) months ("Probationary Period").
- 5. During the Probationary Period, the Licensee further agrees that it shall comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.
- 6. The Board agrees that in return for the Licensee's execution and successful compliance with the requirements of this Agreement it will not prosecute the Subsequent 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 on July 29, 2017 upon written notice to the Licensee from the Board<sup>1</sup>.
- 8. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint<sup>2</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 license.
  - b. If the Board suspends the Licensee's license pursuant to Paragraph 8(a)(iii), the suspension shall remain in effect until:

<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> 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.

- i. the Board provides 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.
- 9. The Licensee agrees that if the Board suspends his license in accordance with Paragraph 8, it will immediately return its current Massachusetts license to the Board, by hand or certified mail. The Licensee further agrees that upon said suspension, it will no longer be authorized to operate a pharmacy in the Commonwealth of Massachusetts until such time as the Board reinstates its license or right to renew such license.
- 10. The Licensee understands that it has a right to formal adjudicatory hearing concerning the Subsequent 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, M.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 at all times free to seek and use 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.

Witness (sign and date)

Alexander's Pharmacy (sign and date)

(nrint nava)

David Sencabaugh, R.Ph.

**Executive Director** 

Board of Registration in Pharmacy

7-1317

Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 7/14/17 by Certified Mail No. 7015 36/0 660 7680 7663