COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY	BOARD OF REGISTRATION
	IN PHARMACY

In the Matter of
Alexander's Pharmacy
Registration No. DS6349
Expires December 31, 2017

Docket No. PHA-2015-0082

V

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and the Alexander's Pharmacy ("Pharmacy" or "Licensee"), registration no. DS6349, 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 a complaint has been opened by the Board against its Massachusetts pharmacy registration related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2015-0082.1
- 2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about June 3, 2015, Office of Public Protection ("OPP") investigators conducted a compliance inspection of the Pharmacy and observed the following regulatory deficiencies:
 - i. Pharmacy failed to securely store controlled substances in Schedules II through V in violation of 247 CMR 6.02(6)(c), by not having a locking door on the controlled substance closet.
 - ii. Pharmacy, through its Manager of Record ("MOR"), failed to establish, monitor and enforce policies and procedures regarding the standards of pharmacy practice in violation

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

of 247 CMR 6.07(1)(e), by improperly delegating pharmacy technicians to log in Schedule II controlled substances and using the MOR's Controlled Substance Order System ("CSOS") password without documented authorization.

- iii. Pharmacy, through its MOR, failed to properly maintain records for at least two years as provided by 105 CMR 700.006(b), 247 CMR 9.01(1) and 21 CFR 1304.21(d) and all other applicable federal and state laws in violation of 247 CMR 6.07(1)(b).
- iv. Pharmacy failed to have registered pharmacist reconcile Schedule II controlled substance perpetual inventories in violation of 247 CMR 9.01(14), by having pharmacy technician reconcile perpetual inventories.
- v. Pharmacy failed to properly reconcile CSOS in violation of 247 CMR 9.01(1) and 21 CFR 1305.22(4)(g).
- vi. Pharmacy failed to properly segregate prescriptions of controlled substances in violation of 247 CMR 9.05(1)-(3).
- 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.
- 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 the Pharmacy's policies and procedures regarding pharmacy technician duties and that all staff has signed off on having read and reviewed these policies and procedures.

- c. Conduct a self-inspection of the Pharmacy and submit the results to the Board.
- 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 Complaint.
- 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 license.
 - b. If the Board suspends the Pharmacy's license pursuant to Paragraph 8(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

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.

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.

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 8, it will immediately return its current Massachusetts registration to the Board, by hand or certified mail. The Pharmacy further agrees that upon said suspension, it will no longer be 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 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 Pharmacy further understands that by executing this Agreement it is knowingly and voluntarily waiving its right to a formal adjudication of the Complaints.
- 11. The Pharmacy 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 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.

14. The individual signing this Agreement certifies that he/she is authorized to enter into this Agreement on behalf of the Pharmacy, and that he/she has read this Agreement.

Witness (sign and date)

Alexander's Pharmacy (Sign and Date)

GEORGE KONTOS
Print Name

David Sencabaugh, R.Ph.

Executive Director

Board of Registration in Pharmacy

| 1 24 16 | Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 2/1/16 by Certified Mail No. 7015 3010 0001 7080 2 526