

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

)
In the Matter of)
Saigon Pharmacy)
License No. DS2696)
Expires December 31, 2017)

Docket No. PHA-2015-0098

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") Saigon Pharmacy ("Pharmacy"), DS2696, 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 registration¹ related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2015-0098 ("Complaint").
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about June 1, 2015, Office of Public Protection ("OPP") investigators conducted a compliance inspection of the Pharmacy ("Inspection I") and observed the following regulatory deficiencies:
 - i. Pharmacy failed to comply with 247 CMR 6.02(8)(a), by failing to post hours of operation prominently at all consumer entrances to the pharmacy;
 - ii. Pharmacy failed to maintain perpetual inventory of each controlled substance in Schedule II and failed to reconcile same at least once every ten days in violation of 247 CMR 9.01(14);

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

- iii. Pharmacy failed to maintain a biennial inventory of all controlled substances in violation of 247 CMR 6.07(1)(i) and 247 CMR 9.01(1);
 - iv. Pharmacy failed to maintain a complete and accurate record of the disposal or destruction of each controlled substance in violation on 105 CMR 700.006 and 21 CFR 1304.21(a);
 - v. Pharmacy failed to maintain premises in a clean and sanitary manner in violation of 247 CMR 6.02(1);
 - vi. Pharmacy failed to maintain compounding area in sanitary manner; there was noted to be excessive debris in violation of 247 CMR 6.01(5)(b);
 - vii. OPP investigators observed that Pharmacy was deficient in all aspects of simple, non-sterile compounding in violation of 247 CMR 9.01(3) and USP Chapter <795>; and
 - viii. OPP investigators observed that Pharmacy was deficient in all aspects of implementing and maintaining a Continuous Quality Improvement program in violation of 247 CMR 15.01 *et seq.*
- b. On or about, August 10, 2015, OPP investigators conducted a compliance inspection of the Pharmacy ("Inspection II") and observed the following regulatory deficiency:
- i. Pharmacy failed to maintain a biennial inventory of all controlled substances in violation of 247 CMR 6.07(1)(i) and 247 CMR 9.01(1).
3. 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").
4. During the Probationary Period, the Pharmacy 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.

5. 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.
6. 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.
7. 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

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.

noncompliance with this Agreement, and/ or (2) contained in the Subsequent Complaint.

8. The Pharmacy agrees that if the Board suspends its registration in accordance with Paragraph 7, it will immediately return its current Massachusetts registration to the Board, by hand or certified mail. The Pharmacy further agrees that upon said suspension, they 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 registration or right to renew such registration.
9. 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.
10. 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.
11. 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.
12. 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.

Keet The Ngo
Jan. 01/2016
Witness (sign and date)

Keet The Ngo
Jan. 01, 2016
Saigon Pharmacy (Signature and Date)

KIET THENGO
Print Name

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

1/12/16
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 1/14/16 by

Certified Mail No. 7015 3010 0001 7080 0171