

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

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

PHA-2015-0098
PHA-2016-0130

SECOND CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Saigon Pharmacy ("Licensee" or "Pharmacy"), license no. DS2696, 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 12, 2016 ("Original Agreement") in resolution of a complaint against its pharmacy license, docket number PHA-0215-0098 ("Original Complaint"). The Original Agreement is attached hereto and incorporated by reference.
2. On or about August 29, 2016, the Board opened a Subsequent Complaint against Licensee's Massachusetts pharmacy license, docket number PHA-2016-0130 ("Second Complaint").
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 4 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 7 of the Original Agreement, a Subsequent Complaint is grounds to modify the Agreement.

Saigon Pharmacy
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- c. On or about August 24, 2016 and August 25, 2016, Board investigators inspected the Pharmacy and observed the following deficiencies:
- i. Pharmacy failed to maintain a complete and accurate record of disposal or destruction of each controlled substance, in violation of 105 CMR 700.006 and 21 CFR 1304.21(a);
 - ii. Expired products were stored in active inventory, in violation of 247 CMR 9.01(10);
 - iii. The Pharmacy was not maintained in a clean and sanitary manner, in violation of 247 CMR 6.02(1);
 - iv. Multiple prescriptions in the will-call area were packaged in repurposed manufacturer stock bottles instead of new, clean prescription vials, in violation of 247 CMR 9.01(5); and
 - v. Multiple bags in the will-call area had prescription receipts billed to third party insurance for multiple dates filled, but did not contain any corresponding medication.
- d. Violations of 105 CMR 700.006, 21 CFR 1304.21(a), and 247 CMR 6.02(1) were also observed on or about June 1, 2015 and were the subject of complaint PHA-2015-0098.
- 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), (b), (d), (j), (v), and (x).
4. The Licensee agrees that its license shall remain on PROBATION for one 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 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 **one year** after the Effective Date upon written notice to the Licensee from the Board¹.

8. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint² 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:
 - 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.

¹ 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.

² 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.

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.

Kiet The Ngo
June 26, 2017
 Witness (sign and date)

Kiet The Ngo
June 26, 2017
 Saigon Pharmacy
 (sign and date)

KIET THE NGO
 (print name)

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

Saigon Pharmacy
 DS2696
 PHA-2015-0098
 PHA-2016-0130

7-11-17

Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 7/12/17 by

Certified Mail No. 7015 3010 0001 7080 3165

Saigon Pharmacy
DS2696
PHA-2015-0098
PHA-2016-0130



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

Tel: 617-973-0800
TTY : 617-973-0988
www.mass.gov/dph/boards

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

January 14, 2016

VIA U.S. FIRST CLASS CERTIFIED MAIL NO. 7015 3010 0001 7080 0171,
RETURN RECEIPT REQUESTED

Current Pharmacy Manager of Record
Saigon Pharmacy
1167 Dorchester Ave.
Dorchester, MA 02125

Re: Saigon Pharmacy; DS2696; PHA-2015-0098

Dear Sir/Madam:


This letter acknowledges receipt by the Board of Registration in Pharmacy ("Board") of two signed, originals of the Consent Agreement for Probation ("Agreement") between Saigon Pharmacy and the Board in resolution of the above-referenced complaint. The Board has now signed the Agreement, and submits a copy for your records. Please note carefully that the effective date of the Agreement is January 12, 2016, as stated on the signature page of the Agreement.

A copy of this letter and the Agreement will remain in complaint files Docket No. PHA-2015-0098. The file will be retained for no less than three (3) years in accordance with state public records laws.

In addition, Karen Fishman is responsible for monitoring compliance with the Probation Agreement. All correspondence and documentation in connection with the Probation Agreement should be directed to her at the Board's office listed above. You may also contact her at (617) 973-0951 with any questions regarding this matter.

Thank you for your cooperation.

Sincerely,


Samuel Leadholm, Esq.
Board Counsel

Enclosure

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.

Keel The Ngo
Jan. 01, 2016
Witness (sign and date)

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

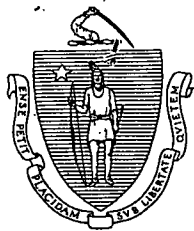
KIET THENGO
Print Name

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



The Commonwealth of Massachusetts
 Executive Office of Health and Human Services
 Department of Public Health
 Bureau of Health Professions Licensure
 239 Causeway Street, Suite 500, Boston, MA 02114

CHARLES D. BAKER
 Governor

KARYN E. POLITO
 Lieutenant Governor

Tel: 617-973-0800
 TTY : 617-973-0988
www.mass.gov/dph/boards

MARYLOU SUDDERS
 Secretary
 MONICA BHAREL, MD, MPH
 Commissioner

Received

JUN 29 2017

BOARD OF
 PHARMACY
 June 21, 2017

VIA FIRST CLASS & CERTIFIED MAIL NO. 7015 1730 0000 7974 1219,
RETURN RECEIPT REQUESTED

Kiet T. Ngo
 Manager of Record
 Saigon Pharmacy
 1167 Dorchester Avenue
 Dorchester, MA 02125

RE: Saigon Pharmacy; DS2696; PHA-2016-0130; PHA-2015-0098

NOTICE OF VIOLATION AND MODIFICATION OF LICENSURE CONDITIONS

Dear Mr. Ngo:

On January 12, 2016, Saigon Pharmacy ("Licensee" or "Pharmacy"), entered into a Consent Agreement for Probation ("Agreement") with the Board of Registration in Pharmacy ("Board"). The Agreement obligates Saigon Pharmacy to comply with specified licensure conditions during the period of time its license is on probation. A copy of the Agreement is enclosed with this letter for your review.

Additionally, on or about August 29, 2016, the Board opened a Subsequent Complaint against the Pharmacy's license, docket numbers PHA-2016-0130.

Saigon Pharmacy is in violation of the Agreement. Under Paragraphs 7 of the Agreement, the Board may extend the Probationary Period or modify the probationary terms if Saigon Pharmacy violates any provision of the Agreement or if the Board opens a Subsequent Complaint.

Notification of Violation and Modification of Licensure Conditions
 Saigon Pharmacy
 DS2696
 PHA-2015-0098
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At its meeting on February 2, 2017, the Board authorized me to consolidate PHA-2015-0098 and PHA-2016-0130 and to **EXTEND THE PROBATIONARY PERIOD BY ONE YEAR, effective in 7 days.** The Board also authorized me to resolve the Complaints with a Second Consent Agreement for Probation.

The basis for the contention that the Pharmacy is in violation of the Agreement is as follows:

1. On or about August 24, 2016 and August 25, 2016, Board investigators inspected the Pharmacy and observed the following deficiencies:
 - a. Pharmacy failed to maintain a complete and accurate record of disposal or destruction of each controlled substance, in violation of 105 CMR 700.006 and 21 CFR 1304.21(a);
 - b. Expired products were stored in active inventory, in violation of 247 CMR 9.01(10);
 - c. The Pharmacy was not maintained in a clean and sanitary manner, in violation of 247 CMR 6.02(1);
 - d. Multiple prescriptions in the will-call area were packaged in repurposed manufacturer stock bottles instead of new, clean prescription vials, in violation of 247 CMR 9.01(5); and
 - e. Multiple bags in the will-call area had prescription receipts billed to third party insurance for multiple dates filled, but did not contain any corresponding medication.
2. Violations of 105 CMR 700.006, 21 CFR 1304.21(a), and 247 CMR 6.02(1) were also observed on or about June 1, 2015 and were the subject of complaint PHA-2015-0098.
3. Per Paragraph 4 of the Agreement, the Pharmacy is required to comply in all material respects with all laws and regulations governing the practice of pharmacy and the United States Pharmacopeia.
4. As a result of the inspectional deficiencies described above, the Board opened a Subsequent Complaint against the Pharmacy's license, docket numbers PHA-2016-0130. Per Paragraph 7 of the Agreement, a Subsequent Complaint is grounds to modify the Agreement.

Saigon Pharmacy has a right to a hearing on the limited issue of whether it is in compliance with, or in violation of, the terms of the Agreement. The Pharmacy may claim its right to a hearing by submitting a written statement to the Board within 7 days of receipt of this letter. The written statement must include specific facts which support the determination that the Pharmacy is in compliance, and not in violation, with the provisions of the Agreement identified

Notification of Violation and Modification of Licensure Conditions
Saigon Pharmacy
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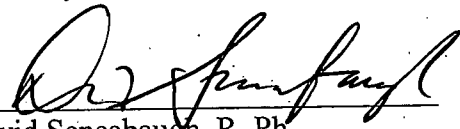
above. The written statement must also include a request for a hearing. Please send any written statement to:

**Heather A. Engman
Board Counsel
Board of Registration in Pharmacy
239 Causeway Street
Boston, MA 02114**

The Pharmacy's failure to submit a written statement of facts and request for a hearing within 7 days shall constitute a waiver of its right to a hearing on the issue of his violation of the Agreement.

Additionally, in lieu of a hearing regarding whether or not your client is in compliance with the terms of the Agreement, the Board offers to resolve the Complaint with a Second Consent Agreement for Probation that extends the Probationary Period by one year. Enclosed please find two copies of the proposed Agreement. If Saigon Pharmacy is interested in entering into the Second Consent Agreement for Probation, it should sign and date both copies before a witness and return both copies to the attention of Heather Engman, Board Counsel, on or before **July 3, 2017**.

Sincerely,



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

cc: Karen Fishman, Probation Monitor