

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

_____)
In the Matter of)
St. George Pharmacy)
Registration No. DS90034)
Expires December 31, 2017)
_____)

Docket No. PHA-2017-0035

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and St. George Pharmacy ("Pharmacy" or "Licensee"), registration no. DS90034 ("Registration" or "license"),¹ located in Marshfield, Massachusetts, 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 the Board opened a complaint against its Registration related to the conduct set forth in Paragraph 2, identified as docket no. PHA-2017-0035 (the "Complaint").
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about March 2, 2017, Office of Public Protection ("OPP") investigators conducted a retail compliance inspection of the Pharmacy and observed the following regulatory deficiencies:
 - i. Pharmacy failed to securely store schedule II controlled substances in violation of 247 CMR 6.02(6)(c), by not dispersing throughout schedule VI controlled substances and by storing in a filing cabinet.
 - ii. Pharmacy failed to secure access to the pharmacy area in violation of 247 CMR 6.02(6)(f), by leaving the door from pharmacy work area to parking lot unlocked.

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

- iii. Pharmacy failed to maintain perpetual inventory of schedule II controlled substances that was reconciled at least once every ten days in violation 247 CMR 9.01(14).
- iv. Pharmacy failed to secure balance on hand inventory by allowing access by pharmacy technicians and interns to make adjustments in violation of 247 CMR 6.07(1)(e).
- v. Pharmacy failed to redact patient information on return to stock bottles in violation of 247 CMR 9.01(19).
- vi. Pharmacy had incompletely labeled vials of controlled substances as partial fill completions in violation of 247 CMR 9.04(5).
- vii. Pharmacy stored multiple unlabeled bottles of controlled substances on pharmacy shelves in violation of 247 CMR 9.01(10).
- viii. Pharmacy, through its MOR, failed to establish, monitor and enforce policies and procedures regarding the standards of pharmacy practice by allowing personal use items and samples, unlabeled medicine, and food to be stored in pharmacy refrigerator in violation of 247 CMR 6.07(1)(e).
- ix. Pharmacy failed to notify and seek approval from the Board prior to remodeling its pharmacy department in violation of 247 CMR 6.04(1).
- x. Pharmacy failed to compound nonsterile drug preparations consistent with USP <795> and 247 CMR 247 CMR 9.01(3), specifically by: (1) maintaining an inadequate compounding area that was dirty and cluttered, e.g. fruit pits found in sink strainer, (2) by using water for reconstitution from an unlabeled, undated amber bottle, (3) by using extended BUDs without supporting documentation, (4) by failing to maintain master formulations, and (5) by failing to indicate on the preparations' prescription labels that "this is a compound preparation".
- xi. Pharmacy failed to maintain pharmacy department in a clean and sanitary manner in violation of 247 CMR 6.02(1).

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) and (b).
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 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 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.

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.

- b. If the Board suspends the Pharmacy's Registration 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 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 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 Complaint.
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 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.

Ag. to Good 06/22/17
Witness (sign and date)

[Signature] 6/22/17
St. George Pharmacy (sign and date)

atef ayoub
Print Name

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

6-26-2017
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 6/26/17 by

Certified Mail No. 7015 1730 0000 7974 0700