

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

\_\_\_\_\_  
In the Matter of )  
Browns Rexall Drug )  
Registration No. DS1240 )  
Expires December 31, 2017 )  
\_\_\_\_\_ )

Docket No. PHA-2016-0238

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Browns Rexall Drug ("Pharmacy" or "Licensee"), Registration No. DS1240 ("Registration" or "license"),<sup>1</sup> located in Winthrop, 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-2016-0238.
2. The Board and the Pharmacy acknowledge and agree to the following facts:
  - a. On or about August 15, 2016, Office of Public Protection ("OPP") investigators conducted a retail compliance inspection of the Pharmacy and observed the following regulatory deficiencies:
    - i. Pharmacy failed to post a sign adjacent to prescription dispensing area informing customers of their right to counseling by a pharmacist in violation of M.G.L. c. 94C, §21A.
    - ii. Pharmacy failed to consistently reconcile its inventory of Schedule II controlled substances every ten days in violation of 247 CMR 9.01(14).

<sup>1</sup> The term "license" applies to both a current license and the right to renew an expired license.

Browns Rexall Drug  
DS1240  
PHA-2016-0238

- iii. Pharmacy failed to have on hand for inspection the CSOS certificate application for pharmacist Petruccelli for authorization of Schedule II controlled substances in violation of 21 CFR 1305.05(a).
  - iv. Pharmacy failed to have on hand for inspection a copy of the most recent drug return including controlled substances in violation of 21 CFR 1304.21(a).
  - v. Pharmacy failed to maintain a graduated cylinder on site in violation of 247 CMR 6.01(5)(a)5.
  - vi. Pharmacy maintain expired medications on shelves in violation of 247 CMR 9.01(10).
  - vii. Pharmacy failed to maintain a master formulation record for magic mouthwash and the corresponding compounding record in violation of 247 CMR 9.01(3) and USP Chapter <795>; and
  - viii. Pharmacy failed to maintain on hand for inspection annual CQI signoffs in violation of 247 CMR 15.02(1)(f).
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 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 an attestation to the Board demonstrating the pharmacy MOR has read and reviewed the Board's Advisory on New Managers of Record (adopted August 30, 2016), attached.

- c. Conduct a self-inspection using the Board's Compliance Inspection Report, located on the Board's website: <http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/compliance-inspection-tool.pdf>. The Pharmacy shall submit the completed Compliance Inspection Report to the Bureau's probation monitor and to the Director of Pharmacy Investigations.
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 Board<sup>2</sup>.
8. If the Pharmacy does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint<sup>3</sup> 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:

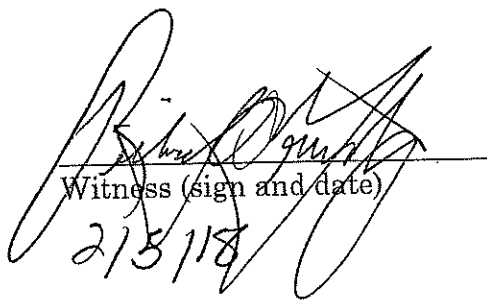
---

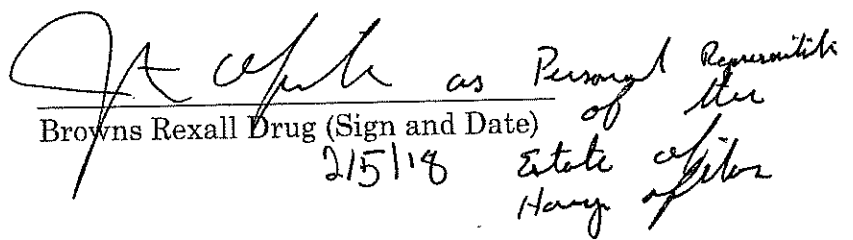
<sup>2</sup> In all instances where this Agreement specifies written notice to the Pharmacy from the Board, such notice shall be sent to the Pharmacy's address of record.

<sup>3</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.

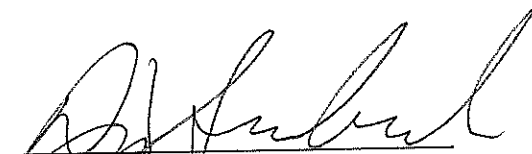
- i. the Board provides the Pharmacy written notice that the Probationary Period is to be resumed and under what terms; or
  - ii. the Board and the Pharmacy sign a subsequent agreement; or
  - iii. the Board issues a written final decision and order following adjudication of the allegations (1) of noncompliance 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 license 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 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)  
 2/5/18

  
 Browns Rexall Drug (Sign and Date) 2/5/18  
 as Personal Representative of the Estate of Harry Obilos

Jonathan M. Obilos Personal Rep  
 Print Name for the Estate of Harry Obilos

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

2-9-2018  
 Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 2/9/18 by

Certified Mail No. 7017 0530 0000 0551 6048