

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

)
In the Matter of)
CVS #730 Pharmacy)
Registration No. DS1048)
Expires: December 31, 2017)
_____)

Docket No. PHA-2015-0087

CONSENT AGREEMENT FOR REPRIMAND

The Massachusetts Board of Registration in Pharmacy (“Board”) and CVS #730 located at 501 Boston Post Road in Sudbury (“Pharmacy”), a pharmacy licensed by the Board, registration number DS1048 (“Registration”), 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 at docket number PHA-2015-0087 (“Complaint”).
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about September 11, 2014, Office of Public Protection (“OPP”) investigators conducted a retail compliance inspection of the Pharmacy (“Inspection I”) and observed the following regulatory deficiencies:
 - i. Pharmacy failed to maintain required supervisory ratios in that one pharmacist, two certified pharmacy technicians, two registered non-certified technicians and one technician trainee were observed on duty at time of Inspection I in violation of 247 CMR 8.06(3);
 - ii. Pharmacy failed to maintain expired Schedule II controlled substances in the perpetual logs in violation of 247 CMR 9.01(14);
 - iii. Pharmacy failed to provide personal protective equipment in the compounding area while compounding with salicylic acid was performed in violation of 247 CMR 6.01(5)(a)5;

- iv. OPP Investigators observed instances where Pharmacy's Beyond Use Dating (BUD) exceeded USP Chapter <795> recommendations without documentation in violation of 247 CMR 9.01(3) and USP <795> ;
 - v. OPP investigators observed that compounding components without assigned expiration date by manufacturer were not labeled with an expiration date in violation of 247 CMR 9.01(3) and USP <795> ; and
 - vi. Pharmacy failed to label compounded medications with label stating "this is a compounded preparation" in violation of 247 CMR 9.01(3) and USP <795>.
- b. On or about April 14, 2015, OPP investigators conducted a retail compliance inspection of the Pharmacy ("Inspection II") and observed the following regulatory deficiencies:
- i. Pharmacy failed to maintain required supervisory ratios in that one pharmacist, two registered, non-certified technicians and one certified, non-registered pharmacy technician were observed on duty at the time of Inspection II in violation of 247 CMR 8.06(3); and
 - ii. Pharmacy, through its Manager of Record, failed to establish, monitor and enforce policies and procedures which maintain the standards of professional pharmacy practice in violation of 247 CMR 6.07(1)(e), by permitting an unregistered certified pharmacy technician to work in the capacity of a certified technician in violation of 247 CMR 8.04.
3. The Pharmacy acknowledges that the foregoing facts warrant disciplinary action by the Board under M.G.L. c. 12, §§ 42A and 61 and under 247 CMR 10.03.
4. The Pharmacy agrees that the Board shall impose a REPRIMAND on its Registration based on the facts admitted in Paragraph 2, effective as of the date on which the Board signs this Agreement ("Effective Date").
5. The Board acknowledges the receipt of a Board-approved plan of correction ("POC") concerning the remediation of deficiencies from Inspection II. Licensee and the Board acknowledge that the Board's receipt of said

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documentation was a precondition to be met before the Board entered into this Agreement.

6. Licensee acknowledges receipt of the Board's General Advisory on Staffing Ratios, appended at Attachment A.
7. The Board agrees that in return for the Pharmacy's execution and successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.
8. The Pharmacy understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication the Pharmacy 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 the Pharmacy is knowingly and voluntarily waiving its right to a formal adjudication of the Complaint.
9. 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.
10. The Pharmacy acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board subject to the Commonwealth of Massachusetts' Public Records Law, M.G.L. c. 4, § 7. 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.
11. 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.
12. 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.

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[Signature] 4/13/16
Witness (sign and date)

[Signature] 4/13/16
CVS #730 (sign and date)
Director, Rx Reg. Affairs
Karen D. Stefano
(print name)

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

5/5/16
Effective Date of Reprimand Agreement

Fully Signed Agreement Sent to Registrant on 5/9/16 by

Certified Mail No. 7015 3610 0001 6944 5567

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