

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of )  
Plainville Prescription Center )  
Registration No. DS1584 )  
Expires December 31, 2015 )

PHA-2015-0031

Received

DEC 22 2015

BOARD OF  
PHARMACY

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and the Plainville Prescription Center ("Pharmacy" or "Licensee"), DS1584, 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 registration related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2015-0031.<sup>1</sup>
2. The Board and the Pharmacy acknowledge and agree to the following facts:
  - a. On or about March 2, 2015, Board Investigators conducted a compliance inspection of the Pharmacy and observed the following violations:
    - i. Pharmacy did not maintain a biennial inventory of controlled substances, in violation of 247 CMR 9.01(1) and 21 CFR 1304.11(a) & (c);
    - ii. Pharmacy failed to maintain accurate records of outdated medications, in violation of 247 CMR 9.01(1) and 21 CRF 1304.21(a);
    - iii. Pharmacy was not maintained in a clean and sanitary manner and had excess debris, a leaking roof, and water damaged ceiling tiles, in violation of 247 CMR 6.02(1);
    - iv. Pharmacy was not equipped with appropriate sanitary appliances, including a suitable sink with hot and cold

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

- running water that is situated in or near the prescription area, in violation of 247 CMR 6.01(5)(a)(7);
- v. The Schedule II safe and pre-pack area were located in an unsecured area, in violation of 247 CMR 9.01(5);
  - vi. Investigators observed expired medications in the pharmacy inventory, in violation of 247 CMR 9.01(10);
  - vii. Pharmacy did not have sufficient space to accommodate pharmaceutical equipment, apparatus, and supplies, and to facilitate the proper preparation of prescribed medications, in violation of 247 CMR 6.01(5)(b).
  - viii. Pharmacy failed to maintain a daily temperature log for refrigeration and did not have a certified thermometer, in violation of 247 CMR 9.01(1) & (5) and Board Policy No. 2011-01;
  - ix. Pharmacy failed to maintain policies and procedures to respond to out of range temperature readings, in violation of 247 CMR 9.01(1) & (5) and Board Policy No. 2011-01;
  - x. Pharmacy failed to maintain policies to not allow beverages to be stored in the refrigerators or freezers with controlled substances, in violation of 247 CMR 9.01(1) & (5) and Board Policy No. 2011-01;
  - xi. Hazardous drugs were not stored appropriately, in violation of 247 CMR 9.01(3) and USP 795;
  - xii. Pharmacy failed to maintain written standard operating procedures for all significant procedures performed in the compounding area, in violation of 247 CMR 6.07(1)(d) & (e), 247 CMR 9.01(3), and USP 795;
  - xiii. Pharmacy possessed medications previously dispensed by CVS Pharmacy for the purpose of re-dispensing in seven day planners, in violation of 247 CMR 9.01(4);
  - xiv. The seven day medication planners were not properly labeled, in violation of M.G.L. c. 94C, § 21;
  - xv. Pharmacy failed to maintain a master formulation records and compounding records for compounded medications, in violation of 247 CMR 9.01(3) and USP <795>;
  - xvi. Pharmacy failed to properly label compounded medications, in violation of 247 CMR 9.01(3) and USP <795>; and
  - xvii. Pharmacy was deficient in all requirements for a CQI program, in violation of 247 CMR 15.00.

3. The Pharmacy acknowledges that the foregoing facts warrant disciplinary action by the Board under M.G.L. c. 12, §§ 42A & 61 and 247 CMR 10.03.
4. The Pharmacy agrees that its registration shall be placed on PROBATION for **two (2) years** (“Probationary Period”), commencing with the date on which the Board signs this Agreement (“Effective Date”).
5. 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.
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 **two (2) years** 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:

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<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 license in accordance with Paragraph 8, it will immediately return its current Massachusetts 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 license or right to renew such license.
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 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.

John R. Hinley 12/20/15      Jacquelyn Stanley 12/20/15  
Witness (sign and date)      Signature and Date

JACQUELYN STANLEY  
Print Name  
Plainville Prescription Center

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

1-4-16  
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 2/5/16 by  
Certified  
Mail No. 7015 3010 0001 7080 0157