

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of )  
Preferred Pharmacy Solutions )  
DS3542 )

PHA-2016-0216

**CONSENT AGREEMENT FOR PROBATION**

The Massachusetts Board of Registration in Pharmacy ("Board") and Preferred Pharmacy Solutions Pharmacy ("Pharmacy" or "Licensee"), DS3542, 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 Massachusetts pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2016-0216.<sup>1</sup>
2. The Board and the Pharmacy acknowledge and agree to the following facts:
  - a. Board investigators inspected the Pharmacy on or about November 8, 2016 and observed the following deficiencies:
    - i. Five pharmacy technicians were practicing with expired licenses;
    - ii. Pharmacy did not comply with minimum staffing ratios, in violation of 247 CMR 8.06;
    - iii. Compounding personnel media fills not completed annually, in violation of 247 CMR 9.01(3) and USP 797;
    - iv. Certain sterile compounding procedures and aseptic techniques were not compliant with USP 797. Specifically,
      1. Non-sterile towelettes were used to access the buffer room;
      2. A partial vial of daptomycin without an open date label was located in the refrigerator;

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

3. A policy for cleaning and disinfecting the LAFW did not require sterile alcohol;
  4. Sterile water was not required when diluting bleach;
  5. Documentation of room pressure differentials did not allow for accurate interpretation because the logs listed the values in whole numbers instead of decimals; and
  6. Up to five entries into any one sterile container or sterile administration device were made when compounding TPNs.
- b. Board investigators inspected the Pharmacy on or about December 16, 2016 and observed the following deficiencies:
- i. Pharmacy failed to properly maintain perpetual inventory of Schedule II controlled substances, in violation of 247 CMR 9.01(14);
  - ii. Pharmacy failed to properly maintain biennial inventory, in violation of 21 CFR 1304.11(a);
  - iii. Pharmacy failed to properly maintain DEA 222 forms, in violation of 21 CFR 1304.21(a);
  - iv. Approximately four expired drugs stored in active inventory, in violation of 247 CMR 9.01(10);
  - v. Pharmacy failed to properly maintain refrigerator temperatures, in violation of Board Policy No. 2011-01.
- c. Board investigators conducted a USP 795 Non-Sterile Compounding inspection on or about December 22, 2016 and observed the following violations of USP 795:
- i. No documentation of staff competencies;
  - ii. No documentation of didactic training, visual process validation, and written assessment of personnel;
  - iii. Failure to maintain standard operating procedures;
  - iv. No evidence of a quality assurance program;

- v. Failure to maintain the compounding area and compounding equipment in a clean and sanitary manner;
  - vi. Duplicate labels did not reflect accurate beyond use date;
  - vii. Many non-sterile preparations did not have detailed formulation records.
3. The Board and Licensee acknowledge and agree that Licensee's conduct described in Paragraph 2 warrants disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(a), (b), (m), & (v).
  4. The Pharmacy agrees that its license 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 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 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;

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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.

- ii. MODIFY the Probation Agreement requirements; 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:
- i. the Board provides the Pharmacy written notice that the Probationary Period is to be resumed and under what terms;
  - 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 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.

MHC 8/16/17      Anthony Rozzi 8/16/17  
Witness (sign and date)      Signature and Date  
Anthony Rozzi  
Print Name

David Sencabaugh  
David Sencabaugh, R. Ph.  
Executive Director  
Board of Registration in Pharmacy  
8-18-17  
Effective Date of Probation Agreement

Fully Signed Agreement Sent to Registrant on 8/21/17 by  
Certified  
Mail No. 7015 3010 0001 7080 3554