

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION  
IN PHARMACY

In the Matter of )  
Amherst Pharmacy )  
License No.: DS89775 )  
Expires: 12/31/2023 )

Docket No.: PHA-2022-0018  
CAS-2021-1129

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Amherst Pharmacy ("Licensee" or "Pharmacy"), a pharmacy licensed by the Board, License No. DS89775, 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:

21, 2015

1. The Pharmacy acknowledges the Board opened a complaint against its pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2022-0018 ("the Complaint").<sup>1</sup>
2. The Pharmacy and the Board agree to resolve this Complaint without making any admissions or findings and without proceeding to a formal adjudicatory hearing. The Complaint alleges the following:
  - a. On or about November 15, 2021, the Pharmacy was cited for deficiencies during a USP Chapter <795> Compliance inspection (ISP-17377), including deficiencies in the compounding environment, in compounding procedures, and records management violations.
  - b. On or about November 15, 2021, the Pharmacy was cited for violations during a retail compliance inspection (ISP-17376), including controlled substance record keeping violations and immunization violations.
  - c. The plan of correction (POC) for the inspectional deficiencies in paragraphs (a) and (b) above were not implemented as continued deficiencies were observed during a site visit completed on January 6, 2022.

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

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- d. On or about September 29, 2022, the Pharmacy was cited for repeat deficiencies during a USP Chapter <795> Compliance inspection (ISP-19677), including deficiencies in the compounding environment, in compounding procedures, and observed rodent droppings in the non-hazardous compounding area. Additionally, the Pharmacy was unable to provide required training documentation for non-sterile compounding.
  - e. On or about September 29, 2022, the Pharmacy was cited for repeat deficiencies during a retail compliance inspection (ISP-19676) including controlled substance record keeping violations.
- 3. The Board and Licensee acknowledge and agree the facts described in Paragraph 2 constitute a violation of 247 CMR 9.01(1), 247 CMR 9.01(14), Board Policy 2020-11,<sup>2</sup> M.G.L. c. 94C, and USP <795>; and warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(a), (d), and (x).
  - 4. The Pharmacy agrees that its pharmacy 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 agrees that it shall comply with all of the following requirements to the Board's satisfaction:
    - a. Comply with all laws and regulations governing the practice of pharmacy.
    - b. Submit documentation demonstrating successful completion by all Board licensed individuals employed by the Pharmacy of at least 2 Continuing Education credits in the area of non-sterile compounding within 90 days of the Effective Date.<sup>3</sup>
    - c. Agree that the Pharmacy will not engage in the practice of compounding pharmacy, inclusive of sterile (<797>) and non-sterile (<795>) compounding, in the Commonwealth of Massachusetts.

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<sup>2</sup> Board Policy 2020-11 was in effect at the time of the relevant inspection(s) and Board vote(s).

<sup>3</sup> This continuing education requirement shall be *in addition to* any contact hours required for license renewal.



- d. Agree that the Pharmacy and all Board licensed individuals employed by the Pharmacy will not precept any intern(s) in the Commonwealth of Massachusetts assigned by any school of pharmacy.
- e. Submit an attestation to the Board demonstrating all Board licensed individuals employed by the Pharmacy have read and reviewed the following in their entirety within 90 days of the Effective Date:
  - i. 247 CMR;
  - ii. M.G.L. ch. 94C; and
  - iii. USP <795> and USP <800>.
- 6. The Board agrees that in return for the Pharmacy's execution and its successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.
- 7. If and when the Board determines that 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 Licensee from the Board.
- 8. If the Pharmacy does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint<sup>4</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;
    - 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 the suspension shall remain in effect until:

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<sup>4</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;
  - 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. 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 they are authorized to enter into this Agreement on behalf of the Pharmacy, and that they have read this Agreement.

Danaher WATTS  
Witness (sign and date)  
11/14/23

Ioannis Nikitas 11/14/23  
(sign and date)

Ioannis Nikitas  
(print name)

David Sencabaugh

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

December 14, 2023  
Effective Date

Fully Signed Agreement Sent to Licensee on 12/14/23 by

Certified Mail No. 7020 0090 0000 1273 4258