

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)	
Option Care)	Docket Nos.: PHA-2020-0066 / CAS-2020-0797
DS90107)	PHA-2022-0016 / CAS-2021-0685
Exp: 12/31/2025)	PHA-2022-0045 / CAS-2022-0242
)	PHA-2022-0135 / CAS-2022-0516
)	PHA-2023-0267 / CASE-2023-0741
)	PHA-2024-0079 / CASE-2023-0827
)	PHA-2024-0080 / CASE-2024-0114
)	PHA-2024-0081 / CASE-2024-0011
)	PHA-2024-0082 / CASE-2024-0073

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Option Care ("Licensee" or "Pharmacy"), a pharmacy licensed by the Board, DS90107, 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 the Board opened complaints against its pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket Nos. PHA-2020-0066, PHA-2022-0016, PHA-2022-0045, PHA-2022-0135, PHA-2023-0267, PHA-2024-0079, PHA-2024-0080, PHA-2024-0081, and PHA-2024-0082 ("the Complaints").¹
2. The Pharmacy and the Board agree to resolve these Complaints without making any admissions or findings and without proceeding to a formal adjudicatory hearing. The Complaints allege the following:

PHA-2020-0066

- a. On September 2, 2020, the Pharmacy conducted environmental monitoring ("EM"). The Pharmacy received above action level EM

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

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results on September 9, 2020. The Pharmacy failed to report the above action level results to the Board within seven (7) days, in violation of 247 CMR 6.15(7).

- b. On September 8, 2020, the Pharmacy conducted EM. The Pharmacy received above action level EM results on September 18, 2020. The Pharmacy failed to report the above action level results to the Board within seven (7) days, in violation of 247 CMR 6.15(7).
- c. A Board investigator inspected the pharmacy on September 21, 2020 and observed the Pharmacy failed to document remedial cleaning following above action level EM results.
- d. On October 28, 2020, the Pharmacy conducted EM. The Pharmacy received above action level EM results on November 9, 2020.

PHA-2022-0016

- a. On or about September 16, 2021, the Pharmacy operated for approximately 1.5-2 hours with one pharmacist supervising six pharmacy technicians on site, in violation of 247 CMR 8.06(3).
- b. Prior to August 23, 2022, the Pharmacy, at times, allowed unlicensed warehouse staff to label medications for patient dispensing, in violation of 247 CMR 8.02(1) and Board of Registration in Pharmacy Policy 2020-15: License Scope of Practice.

PHA-2022-0045

- a. On or about January 7, 2022, the Pharmacy notified the Board of an unknown loss of six (6) ml of hydromorphone injection 10mg/ml, in violation of 247 CMR 9.01(5).

PHA-2022-0135

- a. On April 19, 2022, The Pharmacy conducted EM. The Pharmacy received above action level EM results on April 25, 2022. The Pharmacy failed to properly remediate these findings, in violation of Board Policy 2019-08 and recognized standards of pharmacy practice.

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PHA-2023-0267

- a. On November 14, 2023, The Board received notice from the FDA indicating The Pharmacy reported an issue with an improperly compounded total parenteral nutrition (TPN) on or about July 26, 2023, in which there was "particulate matter in the port."
- b. The Pharmacy failed to submit a timely Defective Drug Preparation report to the Board within seven (7) days of dispensing the improperly compounded sterile preparation pursuant to M.G.L. c. 112C §39D(e), in violation of 247 CMR 9.01(1) and Board Advisory: Pharmacy Requirement to Maintain Defective Drug Preparation Log.

PHA-2024-0079

- a. On or about December 4, 2023, The Pharmacy submitted a "Pharmacy Report of Defective Drug Preparation" and a "Reporting of Serious Adverse Drug Events," indicating that a prescription for gentamicin 14.4mg/30ml was compounded and dispensed as gentamicin 0.029mg/ml from October 17, 2023 through November 28, 2023 causing a complicated urinary tract infection (UTI) in the patient, in violation of recognized standards of practice.

PHA-2024-0080

- a. On or about December 13, 2023, The Pharmacy submitted a "Pharmacy Report of Defective Drug Preparation," indicating that a refill of a prescription for esomeprazole 40mg injection was compounded and dispensed on December 6, 2023, but two (2) of seven (7) bags were mislabeled as a different medication for the same patient, in violation of recognized standards of practice.

PHA-2024-0081

- a. On or about December 14, 2023, The Pharmacy submitted a "Pharmacy Report of Defective Drug Preparation," indicating that a prescription for ceftazidime 2gm IV every 8 hours was compounded and dispensed on December 12, 2023 as ceftazidime 2gm in NS 100ml infuse every 24 hours, in violation of recognized standards of practice.

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PHA-2024-0082

- a. On January 3, 2024, The Pharmacy submitted a "Pharmacy Report of Defective Drug Preparation," indicating that a refill prescription for ceftazidime 2gm IV was compounded and dispensed instead of elastomeric pumps on December 29, 2023, in violation of recognized standards of practice.
3. The Board and Licensee acknowledge and agree that based upon the information described in Paragraph 2 the Board could find the Licensee in violation of 247 CMR 6.15(7), 247 CMR 8.06(3), 247 CMR 8.02(1), Board Policy 2020-15, 247 CMR 9.01(5), Board Policy 2019-08, and recognized standards of pharmacy practice, M.G.L. c. 112C §39D(c), 247 CMR 9.01(1), Board Advisory: Pharmacy Requirement to Maintain Defective Drug Preparation Log, warranting disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1(a), (b), (v), & (bb).
4. The Pharmacy agrees that its pharmacy license shall be placed on PROBATION for twenty-four (24) months ("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. Engage a qualified third-party professional(s) with expertise in cleanroom operations, work process flow, and prevention of medication errors. They must assess all activities related to sterile compounding, including, but not limited to:
 - i. quality procedures to prevent errors;
 - ii. review of RCA and CAPA processes;
 - iii. staff training and competency;
 - iv. hand hygiene and garbing;
 - v. aseptic technique;
 - vi. material transfer process;

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- vii. cleaning and disinfecting;
- viii. environmental monitoring; and
- ix. written policies and procedures.

The Pharmacy shall submit a written report to the Board within 120 days of the Effective Date summarizing the consultant's assessments and recommended corrective actions, as well as the Pharmacy's action plan and timeline for implementing said corrective actions including any changes to the Pharmacy's policies and procedures. After submission of the initial report, the pharmacy shall provide quarterly progress reports to the Board regarding implementation of said correct actions and ensuing results.

- c. The Pharmacy shall submit to the Board within 120 days of the Effective Date unredacted, original copies of any and all reports received from any and all third-party professional(s) hired, consulted, or otherwise engaged to satisfy paragraph (b) above.
 - d. Train all employees in LEAN concepts which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency. The Pharmacy shall provide to the Board written confirmation that this has been completed within 90 days of the Effective Date.
 - e. Documentation supporting compliance with the above will be readily retrievable and available to the Board upon request and to Board inspectors at the time of inspection.
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 Complaints.
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 twenty-four (24) months after the Effective Date upon written notice to the Licensee from the Board.²

² In all instances where this Agreement specifies written notice to the Licensee from the Board, such notice shall be sent to the Licensee's address and/or email of record.

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8. If the Pharmacy does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint^{3,4} 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:
 - 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.

³ 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.

⁴ The following matters are known pending matters before the Board and expressly excluded from consideration as a "Subsequent Complaint": PHA-2024-0147, PHA-2024-0148, INV12296, INV12108, INV11958, INV11957, and INV11956. No representations concerning resolution of the aforementioned pending matters are including in any way in this Agreement. Further, the instant Agreement does not in any way hinder, estop, or otherwise preempt the Board's authority and/or ability to resolve the aforementioned pending matters in any way, including but not limited to, issuing discipline of any kind up to and including summary suspension of the Pharmacy's license.

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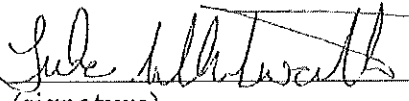
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10. The Pharmacy understands that it has a right to formal adjudicatory hearing concerning the Complaint and that during said adjudication it would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to 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 represented by Counsel or otherwise free to seek and use legal counsel in connection with the Complaints 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.

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8/22/24
Date


(signature)

Luke Whitworth (Chief Operating Officer)
(print name)

David Sencabaugh

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

8/23/24

August 29, 2024

Effective Date

Fully Signed Agreement Sent to Licensee on 8/29/24 by

Certified Mail No. 9589 0710 5270 0429 9694 59

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