COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY		BOARD OF REGISTRATION IN PHARMACY
In the Matter of)	
Blue Hill Pharmacy, LLC)	Docket No.: PHA-2022-0122
DS89942)	CAS-2022-0664
Exp: 12/31/23)	

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Blue Hill Pharmacy ("Licensee" or "Pharmacy"), a pharmacy licensed by the Board, DS89942, 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 a complaint against its pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket No. PHA-2022-0523 ("the Complaint").1
- 1. 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 June 1, 2022, the Pharmacy was not open during its normal business hours and no licensed pharmacy personnel were present, and Board investigator(s) observed an unlicensed individual entering the Pharmacy.
 - b. On June 2, 2022, Board investigator(s) observed an unlicensed delivery driver unlocking the front door, removing totes, and leaving a delivery. The Pharmacy was not open for business at this time and no licensed pharmacy personnel were present.

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

- c. On June 8, 2022, an inspection with the US Drug Enforcement Administration ("DEA") was conducted. Multiple deficiencies were identified including:
 - i. failure to activate the alarm daily;
 - ii. no separate alarm for the Pharmacy;
 - iii. failure to properly maintain a security system to ensure proper functionality;
 - iv. incomplete biennial inventories;
 - v. perpetual inventory not maintained for all schedule CIIs;
 - vi. inability of the Floater Pharmacist to access controlled substance records;
 - vii. clutter;
 - viii. food in the medication refrigerator;
 - ix. incomplete temperature logs;
 - x. improperly labeled blister cards with vials from another pharmacy;
 - xi. dispensing reports that evidenced not all PMP drugs were reported;
 - xii. invoices that evidenced medications in schedules CIII through CV that were ordered but were not dispensed and not observed in inventory.
- d. In addition to the above, DEA accountability audits (the first from March 1, 2002 through June 8, 2022; and the second from November 17, 2021 through June 8, 2022) indicated inaccurate recordkeeping and significant schedule CIII-CV inventory discrepancies.
- e. On September 6, 2022, a site visit was performed with the DEA for follow up regarding DEA violations including those for controlled substance recordkeeping; alarm system security; back entrance security including the grate not on the hall side of the door which was not locked; security of keys including failure to change the lock as requested; and inventory issues.
- f. On September 30, 2022, the Pharmacy signed a Memorandum of Agreement ("MOA") with the DEA for a period of three (3) years.
- 2. The Board and Licensee acknowledge and agree the facts described in Paragraph 2 warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03 (1)(a), (b), (k), (m), (v), and (x).

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- 3. The Pharmacy agrees that its pharmacy license shall be placed on PROBATION for 3 years ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
- 4. 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. Comply with the following within 90 days of the Effective Date of this Agreement:
 - i. Submit an attestation to the Board acknowledging and agreeing that no deliveries shall be made during non-operational hours or when the pharmacy is not open for business;
 - ii. Submit an attestation to the Board acknowledging and agreeing that no key shall be issued, given, or provided to any people or person that does not hold a valid license issued by the Board;
 - iii. Submit an attestation to the Board demonstrating all employees of the Pharmacy licensed by the Board have read and reviewed 247 CMR in its entirety; and
 - iv. Submit an attestation to the Board demonstrating all employees of the Pharmacy licensed by the Board have read and reviewed the 2022 DEA Pharmacists Manual in its entirety.
- 5. The Board agrees that in return for the Pharmacy's execution of and its successful compliance with all the requirements of this Agreement, the Board will not prosecute the Complaint.
- 6. 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 3 years after the Effective Date upon written notice to the Licensee from the Board.

- 7. If the Pharmacy does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint² 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 7 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.
- 8. The Pharmacy agrees that if the Board suspends its license in accordance with Paragraph 7, 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.
- 9. 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

² 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.

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.

- 10. The Pharmacy acknowledges that it has at all times been free to seek legal counsel in connection with the Complaint and this Agreement.
- 11. 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.
- 12. 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.
- 13. 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.

09/19/23	09/17/23
Witness (sign and date)	(sign and date)
Alison Okeke	Victoria Okeke
	(print name)
	David Sencabaugh M B
	David Sencabaugh, R. Ph.
	Executive Director
	Board of Registration in Pharmacy
11/13/2023	
Effective Date	
Fully Signed Agreement Sent to Li	censee on _11/13/23by
Certified Mail No. 7021 2720 0000 75	04 2069

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Blue Hill Pharmacy, LLC

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