

COMMONWEALTH OF MASSACHUSETTS

BOARD OF PHARMACY

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
Boulevard Pharmaceutical)
Compounding Center)
DS90300)

PHA-2020-0028

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy ("Board") and Boulevard Pharmaceutical Compounding Center ("Licensee" or "Pharmacy"), a pharmacy licensed by the Board, DS90300, 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-2020-0028 ("the Complaint").¹
2. The Board and the Pharmacy acknowledge and agree to the following facts:
 - a. On or about October 31, 2019, Board investigators inspected the pharmacy and observed the following deficiencies:
 - i. Incomplete logs for room temperature, differential pressure, and incubator temperature monitoring;
 - ii. Incomplete or unavailable documentation regarding media fills and gloved fingertip sampling; and
 - iii. Equipment in ISO 7 area was not resistant to cleaning products;
 - iv. Incomplete or unavailable documentation regarding autologous serum eye drops.
 - b. On or about February 24, 2020, Board investigators inspected the pharmacy and observed the following deficiencies:

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

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- i. Incomplete documentation related to cleaning of positive and negative ISO areas.
 - c. On or about March 3, 2020, Board investigators inspected the pharmacy and observed the following deficiencies:
 - i. Unlabeled vials of compounded sterile products in the freezer;
 - ii. Incomplete compounding logs;
 - iii. Incubator temperatures were inconsistent and out of range;
 - iv. Incomplete documentation regarding February 28, 2020 air and surface environmental monitoring;
 - v. Inaccurate and incomplete cleaning log;
 - vi. Staff did not adhere to policy regarding handling of autologous serum eye drops;
 - vii. Alprostadil 500 mcg/mL stock solution with BUD of 150 days; and
 - viii. Compounding process for Alprostadil 500 mcg/mL did not follow the master formulation record.
 - d. On or about May 20, 2020, Board investigators inspected the Pharmacy and observed the following deficiencies:
 - i. Incubator temperatures were inconsistent and out of range.
 - e. Compounding records created between January 2, 2020 and April 28, 2020 were incomplete and/or inaccurate.
- 3. The Board and Licensee acknowledge and agree the facts described in Paragraph 2 constitute violations of 247 CMR 9.01(3) and USP <797> and warrant disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(a) & (v).
- 4. The Pharmacy agrees that its pharmacy license 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 agrees that it shall comply with all of the following requirements to the Board's satisfaction:

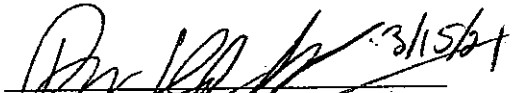
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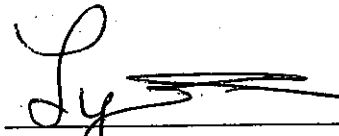
- a. Comply with all laws and regulations governing the practice of pharmacy.
 - b. The Pharmacy will engage a third party consultant to advise the pharmacy on compliance.
 - c. The Pharmacy will not engage in any sterile compounding without express, written approval from the Board.
6. The Board agrees 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 two (2) years 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 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 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

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.

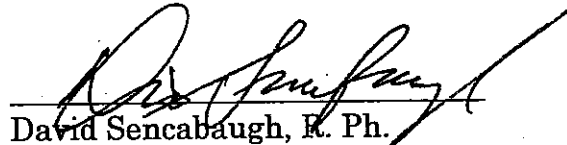
- iii. the Board issues a written final decision and order following adjudication of the allegations (1) of noncompliance with this Agreement, and/or (2) contained in the Subsequent Complaint.
9. The Pharmacy agrees that if the Board suspends its license in accordance with Paragraph 8, it will immediately 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 he/she is authorized to enter into this Agreement on behalf of the Pharmacy, and that he/she has read this Agreement.

 3/15/21
Witness (sign and date)

 03/15/2021
(sign and date)

Lynn Patsis
(print name)


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

3-26-21
Effective Date

Fully Signed Agreement Sent to Licensee on 4/6/2021 by

Certified Mail No. 7020 1810 0002 3137 8328