# COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs

VS.

Case No.

25-54-005908

Boothwyn Pharmacy, Respondent

# **CONSENT AGREEMENT AND ORDER**

#### **PARTIES**

The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and Occupational Affairs ("Commonwealth") and **Boothwyn Pharmacy** ("Respondent") stipulate as follows in settlement of the above-captioned case.

#### APPLICABLE LAW

1. This matter is before the State Board of Pharmacy ("Board") pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, No. 699 ("Act"), as amended, 63 P.S. §§ 390-1 to 390-13; and/or 63 Pa.C.S. Chapter 31 ("Chapter 31"), 63 Pa.C.S. §§ 3101-3118.

#### LICENSURE STATUS

2. At all relevant and material times. Respondent held the following permit to practice as a pharmacy in the Commonwealth of Pennsylvania: permit no. PP410228L, which was originally issued on September 29, 1977, and which is currently set to expire on August 31, 2025.

#### STIPULATED FACTS

- 3. Respondent admits the following:
- a. Absent additional Board action, Respondent's permit may be continually renewed or reactivated upon the filing of the required documentation and payment of the applicable fees.
  - b. Respondent's address is: 221 Gale Lane, Kennett Square, PA 19348.
- c. Respondent's physical plant consists of two separate buildings, 221A
   and 221B.
- d. Building 221A contains the Respondent's licensed pharmacy, which consists of production and/or compounding rooms.
- e. Respondent intended to have Building 221B added to the licensed pharmacy operations.
- f. Building 221B was never inspected and did not receive approval for licensure by the Board.
- g. Respondent's Building 221A had several rooms located inside, which were inspected and approved for compounding by Pharmacy Board Inspectors.
- h. Not all rooms located within Building 221A were approved for compounding.
- i. Rooms PS112A and PS112B were located inside Building 221A but were not inspected and did not receive approval for compounding by the Pharmacy Board Inspectors.
- j. Rooms PS112A and PS112B contained two (2) manufacturing hoods which were both certified.

- k. On or about September 3, 2024, Respondent started compounding GLP-1 medications.
- l. On or about April 15, 2025, Respondent submitted an application to conduct compounding for Rooms PS112A and PS112B.
- m. Respondent's staff was compounding GPL-1 medications in Rooms PS112A and PS112B at a minimum of five (5) days per week and producing over one thousand (1000) doses each day.
- n. Respondent produced compounded GLP-1 medications in Building 221A and then transferred the medications to Building 221B for storage and shipping.
- o. The compounded GLP-1 medications would be inspected, verified, and packaged by a pharmacist in Building 221B.
- p. Companion drugs were being filled,, verified, labeled, and shipped in
   Building 221B to accompany the GLP-1 shipments.
- q. Respondent's Building 221A was subjected to Directed and Non-Directed inspections on the following dates:
  - (1) November 13, 2024;
  - (2) January 13, 2025;
  - (3) January 28, 2025; and
  - (4) March 11, 2025;
- r. Respondent did not disclose the compounding that was occurring in Rooms PS112A and PS112B at any of the inspections listed above.

s. At no time was Building 221B issued a pharmacy permit by the Board or included in Respondent's licensed pharmacy operations.

## **AUTHORITY OF THE BOARD**

4. The Board is authorized to suspend or revoke, or otherwise restrict Respondent's permit under sections 5(a and/or b) & (8) of the Act, 63 P.S. §§ 390-5(a and/or b) & 390-8; impose a civil penalty upon Respondent under section 8(15.1) of the Act, 63 P.S. § 390-8(15.1), or 63 Pa.C.S. § 3108(b)(4); and/or impose the costs of investigation upon Respondent under 63 Pa.C.S. § 3108(b)(5).

#### **SUMMARY OF DISCIPLINE**

- 5. The following encapsulates the discipline as set forth in the Proposed Order:
  - Respondent shall pay a CIVIL PENALTY of \$1,000,000.00.
  - Respondent's permit will be placed on INDEFINITE PROBATION.

#### PROPOSED ORDER

- 6. The parties, intending to be legally bound, consent to the issuance of the following Order in settlement of this matter:
  - a. **VIOLATIONS**: Respondent violated the Act at:
    - (1) Section 4(a)(6)(h) of the Act, 63 P.S. § 390-4(a)(6)(h), by operating or advertising a pharmacy without being granted a pharmacy permit by the board. Specifically, the Respondent was operating as a pharmacy in Building 221B without having a permit issued by the board;
    - (2) Section 5(a)(6) of the Act, 63 P.S. § 390-5(a)(6) by and through a violation of a board regulation at 49

Pa. Code §27.16(a)(2)(ii), by failing to submit an application to the Board within 30 days before beginning alterations to the pharmacy. Specifically, the Respondent converted rooms, PS112A and PS112B into a compounding area without submitting the plans to the Board for approval prior to starting compounding of medication.

- b. CIVIL PENALTY: Respondent shall pay a civil penalty of One Million (\$1,000,000.00) dollars as follows:
  - (1) Payment of the civil penalty is subject to the following terms:
  - (2) Five Hundred Thousand (\$500,000) Dollars of the civil penalty shall be tendered to the prosecution division of the Department of State with the executed consent agreement;
  - (3) The remaining Five Hundred Thousand (\$500,000) Dollars shall be paid within One (1) year of the Board accepting the agreement.
  - (4) Failure to pay the balance of the civil penalty within one(1) year, after the adoption of the consent agreement by the Board,will be considered a violation of the Board Order.
  - (5) Full payment of the Civil Penalty is required before the Respondent can apply to have the probation status removed from their license.

- (6) The civil penalty shall be paid by certified check, cashier's check, attorney's check, or money order issued by a usual, customary, and reputable issuer (e.g. U.S. Postal Money Order, Western Union Money Order, etc.);
- (7) Payment shall be valid for a period of at least 180 days and shall be made payable to the "Commonwealth of Pennsylvania"; and
- (8) Respondent agrees that payment shall only be made by one of the methods indicated and shall not be made by uncertified personal or corporate check.
- c. **PROBATION:** The Respondent's authorizations to practice the profession shall be placed on a period of **INDEFINITE PROBATION**. The period of indefinite probation shall remain in effect subject to the following terms and conditions:

#### d. GENERAL TERMS OF PROBATION:

- (1) The Respondent's period of indefinite probation shall be subject to the following terms and conditions:
  - (i) The Respondent will have Room PS112A and PS112B, inspected and approved to compound by the Board, prior to resuming any compounding activities in those areas, to be renumbered / referenced by Respondent as PS111, PS112 and PS 114 in accordance with an Amended Plan to be submitted to the Board;

- (ii) Respondent will have building 221B properly licensed, by the Board, prior to engaging in the practice of pharmacy in that building;
- (iii) In the alternative to having building 221B properly licensed, Respondent may opt to create a connection to join the buildings that would permit a unitary, secured, enclosed continuous space of operations which are subject to Board approval;
- (iv) Respondent will apply diligently for and provide proof of NABP Compounding Pharmacy Accreditation.
- (v) Respondent shall pay the remaining balance of the Civil Penalty of Five Hundred Thousand (\$500,00) Dollars.
- (2) Respondent shall abide by and obey all federal and state laws, including, but not limited to, statutes, rules and regulations.
- (3) The filing of criminal charges, other than summary traffic violations, or the initiation of a professional disciplinary matter against Respondent shall constitute a violation of this Order; however, any actions whatsoever that are based on the Respondent's resolution of this action and any subsequent resolutions with Pennsylvania and other states and jurisdictions that ultimately stem from conduct in 2024 and 2025, facts alleged in this settlement, and

the Respondent's compounding practices, before the effective date of this Order, are excluded and do not constitute a violation of probation and do not warrant further discipline;

(4) The address for Respondent's Department of State,
Bureau of Enforcement and Investigation (BEI) Probation
Compliance Officer is:

Probation Compliance Officer Bureau of Enforcement and Investigation P.O. Box 2649 Harrisburg, PA 17105-2649 717-783-7228

- (5) Unless otherwise directed, Respondent, Respondent's professional employer, and any other person needing or required to make reports under this Order concerning Respondent's practice and contact information, shall cause those reports, data or other information to be provided to the probation compliance officer.
- (6) Respondent shall notify the probation compliance officer, in writing, within twenty (20) days of the following:
  - (i) the filing of criminal charges;
  - (ii) the disposition of any criminal charge including, but not limited to, a conviction, an admission of guilt, a nolo contendere plea, the imposition of probation without verdict, a disposition in lieu of trial or entry into an Accelerated Rehabilitative Disposition (ARD) program;

- matter or any disciplinary action imposed by the professional licensing authority of any state or jurisdiction; however, any actions whatsoever that are based on the Respondent's resolution of this action and any subsequent resolutions with Pennsylvania and other states and jurisdictions that ultimately stem from conduct in 2024 and 2025, facts alleged in the settlement, and the Respondent's compounding practices, before the effective date of this Order, are excluded and do not constitute a violation of probation and do not warrant further discipline;
- (iv) any other legal action (civil or administrative) pertaining to the practice of the profession at issue.
- (7) Respondent shall notify the probation compliance office, in writing, within (20) twenty days of the Board's adoption of this Consent Agreement, of any actions set forth in the preceding paragraph that occurred within one (1) year prior to the Board's adoption of this Consent Agreement.
- (8) Respondent shall cooperate with the Commonwealth and the BEI, in the monitoring, supervision, and investigation of Respondent's compliance with the terms and conditions of this Order.

(9) Respondent shall cause to be submitted at Respondent's own expense written reports, records, and verifications of actions that may be required by the Commonwealth and BEI.

# (10) Respondent shall:

- (i) provide written notice to the probation compliance officer of the name(s) and address(es) of the place(s) at which Respondent will practice within seventy-two (72) hours of the Board's adoption of this Consent Agreement;
- (ii) provide written notice to the probation compliance officer, within seventy-two (72) hours of any change in the name(s) and address(es) of the place(s) at which Respondent will practice;
- (iii) provide written notice to the probation compliance officer, within seventy-two (72) hours of a change in Respondent's home address or telephone number; and
- (iv) electronically update the Board's records within seventy-two (72) hours of a change of Respondent's address and telephone number on file with the Board.
- (11) Respondent shall not knowingly or voluntarily falsify, misrepresent, or make material omission of any information submitted pursuant to this Order.

- (12) Respondent's failure to materially cooperate and successfully comply with the terms and conditions of probation shall be deemed a violation of this Order.
- (13) Respondent shall make a written request for reinstatement to non-probationary status to:

Sean Barrett, Esquire State Board of Pharmacy P.O. Box 69523 Harrisburg, PA 17106-9523

- (14) Reinstatement may be subject to administrative requirements.
- (15) Reinstatement to non-probationary status shall be subject to the Board's determination that Respondent has complied with all terms and conditions of the probation imposed by this Order.

  The Board reserves the right to schedule a hearing to determine Respondent's compliance.
- e. VIOLATION(S) OF PROBATION: Notification of a violation of the terms or conditions of this Consent Agreement and Order shall result in the IMMEDIATE VACATING of the stay order, TERMINATION of the period of probation, and ACTIVATION of the entire period of suspension of Respondent's authorizations to practice the profession in the Commonwealth of Pennsylvania as follows:
  - (1) The prosecuting attorney for the Commonwealth shall file with the Board a Petition which alleges that Respondent has violated any terms or conditions of this Consent Agreement and

Order other than failure to complete the Ordered remedial action in a timely manner;

- (2) Upon a probable cause determination that Respondent has violated any of the terms or conditions of this Consent Agreement and Order, the Board shall, without holding a formal hearing, issue a preliminary order vacating the stay of the suspension in this matter, terminating the period of probation and activating the entire period of suspension of Respondent's authorizations to practice the profession, without credit for any period of suspension stayed in favor of probation;
- (3) Notification of the Board's Preliminary Order shall be mailed to Respondent within three (3) days of its issuance by certified mail and first-class mail, postage prepaid, sent to the last registered address on file with the Board. If service by mail is unsuccessful, the Commonwealth is authorized to attempt service by personal service and/or publication of legal notice in a newspaper of general circulation in the county of Respondent's last known address.
- (4) Within twenty (20) days of mailing of the notification of the Board's action, Respondent may answer the Commonwealth's Petition and request that a formal hearing be convened concerning Respondent's alleged violation of probation, in which Respondent may seek relief from the Preliminary Order activating the

paragraphs corresponding to the numbered paragraphs of the Petition. Respondent shall admit or deny each of the allegations set forth in the paragraphs in the Petition. Any answer submitted in this matter must be filed with the

Prothonotary for the Department of State via one of the following methods:

By E-Mail: ra-prothonotary@pa.gov

By Mail
Prothonotary
Department of State
2400 Thea Dr, Ste 201
PO Box 60130
Harrisburg, PA 17106-0130

By Facsimile: (717)772-1892

- (5) Respondent shall send a copy of the answer, request for hearing, and all subsequent filings in the matter to the prosecuting attorney for the Commonwealth named in the Petition;
- (6) If a request for a formal hearing is received from Respondent, the Board shall convene a formal hearing within forty-five (45) days from the date of the Board's receipt of Respondent's request for a formal hearing;
- (7) If Respondent files an answer and request for a hearing within the twenty (20) day period, the Preliminary Order activating the suspension shall remain in effect unless and until the Board issues a determination favorable to Respondent after holding the formal hearing;

- (8) The facts and averments in paragraphs 2and 3 and findings of the Board in paragraph 6(a) of this Consent Agreement and Order shall be deemed admitted and uncontested for purposes of the hearing;
- (9) If the Board after such hearing makes a determination adverse to Respondent, the Board will issue a Final Order activating the suspension of Respondent's permit and imposing any additional disciplinary measures it deems appropriate;
- (10) If a request for a formal hearing is not received from Respondent within the prescribed twenty (20) day period, the Board's Preliminary Order shall become a Final Order twenty (20) days after the date of its mailing;
- (11) If the stay is terminated, Respondent shall still comply with all terms and conditions of probation during the active suspension, other than those terms and conditions pertaining to the active practice of the profession. Continued failure by Respondent to comply with the unaffected terms and conditions of probation shall result in further disciplinary action against Respondent;
- f. Respondent's failure to fully comply with any terms of this Order may also constitute grounds for additional disciplinary action.

#### ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEEDINGS

7. Respondent agrees that this Consent Agreement and Order shall be admitted into evidence, without objection, in any proceeding before the Department of State related to Respondent's pharmacy license.

#### ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

8. Respondent waives receipt of an Order to Show Cause in this matter. Respondent knowingly and voluntarily waives the right to an administrative hearing in this matter and the following rights related to that hearing: to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any adverse final decision.

## **ACKNOWLEDGMENT OF RIGHT TO ATTORNEY**

9. Respondent acknowledges the right to consult with and be represented by private legal counsel of Respondent's choosing and at Respondent's expense when reviewing, considering and accepting the terms of this Consent Agreement. Respondent had an opportunity to consult with, and has been advised by, Attorney Joseph McHale regarding this Consent Agreement.

#### WAIVER OF CLAIMS

10. Should the Board vote not to adopt the Order proposed in this Consent Agreement, the presentation and consideration of this Consent Agreement shall not prejudice the Board or any of its members from further participation in the adjudication of this matter. Respondent expressly waives the right to raise any claims or issues, including any and all constitutional claims or issues, which may arise or have arisen during the review, presentation and deliberation of this Consent Agreement. These claims or issues include, but are not limited to, bias, the commingling of prosecutorial and adjudicative functions by the Board or its counsel, and the Board, in its discretion, recommending a different sanction based upon the facts set forth in the Consent Agreement. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations

contained in the Consent Agreement must be proven at a hearing unless otherwise separately stipulated.

#### **LIMITS ON MODIFICATION OF ORDER**

11. Respondent agrees not to seek modification of the Order adopting and implementing this Consent Agreement without first obtaining the express written permission from the prosecution division. Any modification is at the sole discretion of the Board.

## AGREEMENT NOT BINDING UNTIL APPROVED

12. This Consent Agreement is between the Commonwealth and Respondent. The Office of General Counsel has approved this Consent Agreement as to form and legality. The disciplinary provisions of this Consent Agreement do not take effect unless and until the Board issues an order adopting this Consent Agreement.

#### **ENTIRE AGREEMENT**

13. This Consent Agreement contains the entire agreement between the parties. There are no other terms, obligations, covenants, representations, statements, or conditions, oral or otherwise, of any kind whatsoever concerning this agreement.

#### AGREEMENT DOES NOT PREVENT FUTURE DISCIPLINE

14. Nothing in this Order shall preclude the prosecution division of the Department of State from filing charges, or the Board from imposing disciplinary or corrective measures, for violations or facts not contained in this Consent Agreement.

#### **VERIFICATION OF FACTS AND STATEMENTS**

15. Respondent verifies that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondent's knowledge, information and belief. Respondent

understands that statements in this Consent Agreement are made subject to the criminal penalties of 18 Pa.C.S.A. §4904 relating to unsworn falsification to authorities.

Nathan C. Giunta

Prosecuting Attorney

DATED: 8/12/2025

(25-54-005908)

For Respondent Boothwyn Pharmacy Respondent

DATED:

/s/ Joseph McHale\_

Joseph McHale

Attorney for Respondent

DATED: August 11, 2025

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Nothan C. Giunta

Prosecuting Attorney

DATED:

(25-54-005908)

(Please provi name of official for firm)

Chouis Massimo Nicolve

For Respondent Boothwyn Pharmacy Respondent

DATED:

Joseph McHale Automey for Respondent

DATED:

# COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF STATE BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania Bureau of Professional and Occupational Affairs

vs.

Case No.

25-54-005908

Boothwyn Pharmacy, Respondent

#### **ORDER**

AND NOW, this 26th day of August 2025, the STATE BOARD OF PHARMACY ("Board") approves and adopts the foregoing Consent Agreement and incorporates the terms of paragraph 6, which shall constitute the Board's Order and is now issued in resolution of this matter.

This Order shall take effect immediately.

<b>BUREAU OF PROFESSIONAL AND</b>
OCCUPATIONAL AFFAIRS

ARION R. CLAGGETT
ACTING COMMISSIONER

anon R Claggett

For the Board:

For the Commonwealth:

For the Respondent:

Date of mailing:

BY ORDER: STATE BOARD OF PHARMACY

CHRISTINE ROUSSEL, PHARM.D., R.PH.

**CHAIRPERSON** 

Sean C. Barrett, Esquire

Nathan C. Giunta, Esquire Prosecution Division

PO Box 69521

Harrisburg, PA 17106-9521

Joseph McHale, Esquire

Stradley Ronon

2005 Market Street, Suite 2600

Philadelphia, PA 19103

August 28, 2025