

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION
IN PHARMACY

In the Matter of)
SOFIE) Docket Nos.: PHA-2023-0170 / CAS-2023-0867
NU00021) PHA-2024-0013 / CAS-2023-1092
Exp: 12/31/1025) PHA-2024-0014 / CASE-2023-0564

CONSENT AGREEMENT FOR PROBATION

The Massachusetts Board of Registration in Pharmacy (“Board”) and SOFIE (“Licensee” or “Pharmacy”), a nuclear pharmacy licensed by the Board, NU00021, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Licensee’s record maintained by the Board:

1. The Licensee acknowledges the Board opened a complaint against its nuclear pharmacy license related to the conduct set forth in Paragraph 2, identified as Docket Nos. PHA-2023-0170, PHA-2024-0013, PHA-2024-0014 (“the Complaints”).¹
2. The Licensee and the Board agree to resolve these Complaints without making any admissions or findings and without proceeding to a formal adjudicatory hearing. The Complaint alleges the following:

PHA-2023-0170

- a. On June 6, 2023, July 21, 2023, and August 22, 2023, Licensee submitted multiple Disclosures of Above Action Level Environmental Results. The excursions were identified within the same ISO 5 PEC Designated Hot-Cell (DHC) enclosure used for dispensing patient specific compounded sterile radiopharmaceuticals.

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

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PHA-2024-0013

- a. On August 7, 2023, Licensee submitted a Disclosure of Defective Drug Preparation regarding study drug PYLARIFY (18F-Piflufolastat).
- b. The manufactured radiopharmaceutical was utilized for dispensing twenty (20) patient specific doses for administration by injection to regional medical centers and clinics.
- c. Nineteen (19) of the twenty (20) doses were administered to patients.
- d. The Licensee failed to notify impacted facilities of the defective drug preparation.

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- e. On September 12, 2023, Licensee submitted a Defective Drug Preparation regarding study drug PYLARIFY (18F-Piflufolastat).
 - f. The Licensee failed to notify impacted facilities of the defective drug preparation and failed to notify the Board in a timely manner.
 - g. The defective drug resulted in increased bone uptake in two (2) patients' scan procedures on August 28, 2023 and August 29, 2023 respectively.
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 Board Policy 2023-09, M.G.L. c. 112 § 39D(e), and warranting disciplinary action by the Board under M.G.L. c. 112, §§ 42A & 61 and 247 CMR 10.03(1)(a)(v).
4. The Licensee agrees that its nuclear pharmacy license shall be placed on PROBATION for twelve (12) months ("Probationary Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
5. During the Probationary Period, the Licensee 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 nuclear pharmacy.
 - b. Immediately upon the Effective Date, the Regional Director of Operations or Alternate SOFIE Director shall be on-site every six (6) to

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eight (8) weeks for one (1) week at a time for the duration of the probationary period. In addition, the Regional Director of Operations or Alternate SOFIE Director shall conduct weekly² calls with MOR Wang for a minimum of twelve (12) weeks, and provide a monthly report to the Board evidencing MOR Wang's satisfactory performance of MOR duties. Said report(s) shall be reviewed by Board staff to determine whether the time frame of the weekly calls will be extended beyond twelve (12) weeks and/or modified.

- c. Engage a qualified third-party authorized nuclear pharmacist with operational and regulatory expertise in nuclear pharmacy and USP <825> to assess all clean room procedures including, but not limited to, staff training & competency, hand hygiene & garbing, aseptic technique, cleaning & disinfecting, environmental sampling procedures, and policies & procedures. The Licensee shall provide a written report to the Board within 120 days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.
- d. Engage a qualified third-party microbiologist or similarly qualified professional (e.g., industrial hygienist, infection control professional, etc.) to conduct an assessment of environmental control and testing procedures to address multiple reports of "operator failure." The Licensee shall submit a written report to the Board within 120 days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.
- e. Perform quarterly gloved thumb/fingertip sampling for all radiopharmaceutical compounding / preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.
- f. Perform quarterly media fill qualification for all radiopharmaceutical compounding / preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

² Exclusive of weeks the Regional Director of Operations or Alternate SOFIE Director are on-site

- g. Perform quarterly qualification for all radiopharmaceutical compounding / preparation personnel on cleaning & disinfecting procedures for all ISO-classified areas including the DHC for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.
 - h. Submit an attestation to the Board demonstrating that all radiopharmaceutical compounding / preparation personnel have read and reviewed Licensee's policies & procedures on material transfer processes (prior to and within the clean room suite) to assure adherence to the policy within thirty (30) days of the Effective Date.
 - i. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed the Board's Advisory on Pharmacy Requirement to Maintain Defective Drug Preparation Log and associated reporting requirements within 30 days of the Effective Date.
 - j. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed Board Policy 2023-09: Action Level Environmental Monitoring Results within 30 days of the Effective Date.
6. The Board agrees that in return for the Licensee'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 Licensee has complied to the Board's satisfaction with all the requirements contained in this Agreement, the Probationary Period will terminate twelve (12) months after the Effective Date upon written notice to the Licensee from the Board.³
8. If the Licensee does not materially comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint⁴ during the Probationary Period, the Licensee agrees to the following:

³ 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.

⁴ 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 Licensee engaged in conduct that violates Board statutes or regulations, and (2) is substantiated by evidence,

- a. The Board may upon written notice to the Licensee, 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 Licensee's license.
 - b. If the Board suspends the Licensee's license pursuant to Paragraph 8 the suspension shall remain in effect until:
 - i. the Board provides the Licensee written notice that the Probationary Period is to be resumed and under what terms;
 - ii. the Board and the Licensee 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 Licensee 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 Licensee 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 Licensee 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 Licensee further understands that by executing this Agreement it is knowingly and voluntarily waiving its right to a formal adjudication of the Complaints.

as determined following the complaint investigation during which the Licensee shall have an opportunity to respond.

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11. The Licensee acknowledges that it has been at all times represented by Counsel or otherwise free to seek and use legal counsel in connection with the Complaint and this Agreement.
12. The Licensee 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 Licensee 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 Licensee, and that they have read this Agreement.

6/27/24

Date

Patrick Phelps

Patrick Phelps (Jun 27, 2024 13:18 EDT)

(signature)

Patrick Phelps

(print name)

David Sencabaugh

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

July 10, 2024

Effective Date

Fully Signed Agreement Sent to Licensee on 7/10/24 by _____

Certified Mail No. 9589 0710 5270 0429 9693 05

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Signature: Patrick Phelps

Patrick Phelps (Jun 27, 2024 13:18 EDT)

Email: patrick.phelps@sofie.com

Title: President & CEO