#### COMMONWEALTH OF MASSACHUSETTS

SUFFOLK COUNTY

BOARD OF REGISTRATION IN PHARMACY

In the Matter of **ELISE M. VARKONYI, R. Ph.** REGISTRATION NO. PH 20141 REG. EXP. DATE: 12/31/2014

DOCKET NO. PHA-2013-0033

## CONSENT AGREEMENT FOR VOLUNTARY SURRENDER

The Massachusetts Board of Registration in Pharmacy ("Board") and Elise M. Varkonyi ("Registrant"), a registered pharmacist by the Board, Registration No. PH20141, do hereby stipulate and agree that the following information shall be entered into and become a permanent part of the Registrant's record maintained by the Board:

- 1. The Registrant acknowledges that a complaint has been filed with the Board against her Massachusetts pharmacy registration ("registration") related to the conduct set forth in paragraph 2, identified as Docket No. PHA-2013-0033 ("the Complaint").
- 2. The Registrant admits to the following events concerning her License to practice as a pharmacist in the state of Rhode Island:
  - a. On or about March 1, 2013, the Rhode Island Board of Pharmacy issued a Summary Suspension of her license to practice as a pharmacist in that state. A copy of that Order of Summary Suspension is attached hereto as Attachment A and incorporated by reference.
  - b. On or about May 23, 2013, the Registrant signed a Consent Order issued by the Rhode Island Board of Pharmacy. A copy of that Order of Summary Suspension is attached hereto as Attachment B and incorporated by reference.
  - c. Per the terms of May 2013 Consent Order, the Summary Suspension of the Registrant's Rhode Island registration will remain in place until at least September 1, 2013 (provided conditions for vacating the summary suspension have been met), at which time it will be placed on probation for a period of two years commencing from the date that she resumes practicing.
- of Pharmacy, and her conduct as described in the Rhode Island Board of Pharmacy, and her conduct as described in the Rhode Island Board of Pharmacy Consent Order recitation of findings of facts, constitutes failure to comply with the Board's regulations at 247 Code of Massachusetts Regulations ("CMR") 9.01 (1), (2), (3), (6) and (9) and 247 CMR 10.03 (a), (b), (e), (k), (l), (m), (t), (u), (v), (w), (y) and (z) and warrants disciplinary action by the Board.

<sup>&</sup>lt;sup>1</sup> The term "registration" applies to both a current registration and the right to renew an expired registration.

- 4. The Registrant agrees to SURRENDER her pharmacy registration for a minimum of one (1) year ("Surrender Period"), commencing with the date on which the Board signs this Agreement ("Effective Date").
- 5. After the Surrender Period, and when the Registrant can complete to the satisfaction of the Board all of the requirements set forth in this Paragraph and in the Board's policy 2011-02 "License Reinstatment following Surrender, Suspension, or Revocation," the Registrant may petition the Board for reinstatement of her registration. The petition must be in writing and must include the following documentation of the Registrant's ability to practice as a pharmacist in a safe and competent manner, all to the Board's satisfaction:
  - a. All documentation required pursuant to Board's policy 2011-02 "License Reinstatment following Surrender, Suspension, or Revocation,"
  - b. A performance evaluation sent directly to the Board from each of the Registrant's employers, prepared on official letterhead that reviews the Registrant's attendance, general reliability, and specific job performance during the year immediately prior to the date on which the Registrant submits her petition ("petition date")<sup>2</sup>.
  - c. Authorization for the Board to obtain a Criminal Offender Record Information ("CORI") report of the Registrant conducted by the Massachusetts Criminal History Systems Board.
  - d. Certified documentation from the Rhode Island Board of Pharmacy, and any and all other jurisdictions in which the Registrant has ever been registered to practice as a pharmacist, sent directly to the Massachusetts Board identifying her registration status and discipline history, and verifying that her pharmacist registration is, or is eligible to be, in good standing and free of any restrictions or conditions.
- 6. If and when the Board determines that the Registrant has complied to the Board's satisfaction with all the requirements contained in Paragraph 5, the Board shall send written notice to the Registrant<sup>3</sup> which shall terminate the Surrender Period.
- 7. The Registrant agrees that she will not practice as a registered pharmacist in Massachusetts from the Effective Date unless and until the Board reinstates her registration<sup>4</sup>.

<sup>&</sup>lt;sup>2</sup> If the Registrant has not been employed during the year immediately prior to the petition date, she shall submit an affidavit to the Board so attesting.

<sup>&</sup>lt;sup>3</sup> In all instances where this Agreement specifies written notice to the Registrant from the Board, such notice shall be sent to the Registrant's address of record.

<sup>&</sup>lt;sup>4</sup> The Registrant understands that practice as a registered pharmacist includes, but is not limited to, seeking and/or accepting a paid or voluntary position as a registered pharmacist, or a paid or voluntary position requiring that the applicant hold a current pharmacy registration. The Registrant further understands that if she accepts a voluntary or paid position as a registered pharmacist, or engages in any practice of pharmacy after the Effective Date and before

- 8. The Board agrees that in return for the Registrant's execution of this Agreement it will not prosecute the Complaint.
- 9. The Registrant understands that she has a right to formal adjudicatory hearing concerning the allegations against her and that during said adjudication she would possess the right to confront and cross-examine witnesses, to call witnesses, to present evidence, to testify on her 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, G. L. c. 30A, and the Standard Adjudicatory Rules of Practice and Procedure, 801 CMR 1.01 et seq. The Registrant further understands that by executing this Agreement she is knowingly and voluntarily waiving her right to a formal adjudication of the Complaint.
- 10. The Registrant acknowledges that she has been at all times free to seek and use legal counsel in connection with the Complaints and this Agreement.
- 11. The Registrant acknowledges that after the Effective Date, the Agreement constitutes a public record of disciplinary action by the Board. 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 Registrant certifies that she has read this Agreement. The Registrant understands and agrees that entering into this Agreement is a final act and not subject to reconsideration, appeal or judicial review.

GIEN SMITH 6.12.13	Cull-Vay 6/10/13
Witness (sign and date)	ELISE M. VARKONYI, R. Ph.
EICH SMITH	Registrant (sign and date)
Witness (print name)	_
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	Margaret Cittadino
	Associate Director
	Board of Registration in Pharmacy

Effective Date of Surrender Agreement

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STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS PROVIDENCE, SC. Received

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RHODE ISLAND DEPARTMENT OF HEALTH:
HEALTH SERVICES REGULATION
BOARD OF PHARMACY
:

BOARD OF PHARMACY

ELISE VARKONYI, RPH (License #RPH03115):

#### SUMMARY SUSPENSION

The Rhode Island Board of Pharmacy (hereinafter "Board") has investigated a complaint regarding the professional pharmacist activities of Elise Varkonyi, RPh (hereinafter "Respondent"), the Pharmacist-in Charge of Rhode Island Village Pharmacy located at 1 Commerce Street, Lincoln, RI.

The Office of the Director of Health makes the following:

## Findings of Fact and Conclusions of Law

- 1. Respondent is a registered pharmacist in the State of Rhode Island and holds license number RPH03115.
- 2. Respondent is the Pharmacist-in-Charge of Rhode Island Village Pharmacy and has served as the Pharmacist-In-Charge during all relevant times outlined below.
- 3. Rhode Island Village Pharmacy is licensed as a retail pharmacy and holds license numbers PHA00328 & PHA00519 and controlled substances registrations CPHA00328 & CPHA00519 and has a registered location of 1 Commerce Street, Lincoln, RI.
- 4. Pursuant to Title 5, Chapter 19.1 of the Rhode Island General Laws and the Rules and Regulations promulgated thereunder, Respondent is administratively responsible for the overall operation and conduct of Rhode Island Village Pharmacy.
- 5. The Board conducted an inspection of Rhode Island Village Pharmacy on February 25, 26, and 27, 2013 and determined the following:
  - Respondent routinely accepted compounded sterile drugs from Village
    Fertility Pharmacy located at 335 Bear Hill Road, Waltham, MA, a facility
    which does not hold a license as a non-resident retail pharmacy, non
    resident drug manufacturer, or non resident drug wholesaler with the State
    of Rhode Island. Respondent affixed a Rhode Island Village Pharmacy
    label to these compounded medications and further dispensed these

compounded medications to patients in Rhode Island in violation of RIGL 21-31-3.

- Respondent submitted an affidavit to the Rhode Island Board of Pharmacy
  on 11/6/12 attesting to the fact that Respondent did not engage in the
  compounding of sterile pharmaceuticals. During inspection, Respondent
  admitted to Board investigators that she did engage in low risk sterile
  compounding before and after the date Respondent submitted the affidavit
  to the Board.
- Respondent engaged in low risk sterile compounding in an environment which failed to meet the standards set forth in the Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers and Distributors. Respondent admitted to performing low risk sterile compounding without use of a laminar airflow workbench or barrier isolator system in violation of R5-19.1-PHAR-19.21.
- Respondent failed to conduct environmental surface and air monitoring for viable microorganisms on a monthly basis as required for low risk sterile compounding in violation of R5-19.1-PHAR-19.28.
- Respondent failed to possess written quality assurance policy and procedures for low risk sterile compounding in violation of R5-19.1-PHAR-19.11(d) & R5-19.1-PHAR-19.12.
- Respondent distributed legend prescription drugs and controlled substances to various practitioner offices in MA, CT, GA, FL, IL, IN, OH, PA, NY, NJ, VT, NH, ME, VA, NC, SC, FL, TX without possessing a drug wholesaler license, obtaining a prescription from the practitioner or labeling the product with a prescription label in violation of RIGL 5-19.1-8, RIGL 5-19.1-18 & RIGL 21-28-3.18(h).
- Respondent failed to maintain a biennial inventory at the pharmacy in violation of RIGL 21-28-3.16.
- Respondent failed to have video surveillance cameras covering drug stock in violation of R5-19.1-PHAR-13.2.3.
- Respondent failed to post her name as Pharmacist-In-Charge in violation of R5-19.1-PHAR-11.3.1.
- Respondent failed to have technicians wear name badges denoting title in violation of R5-19.1-PHAR-24.7.

## **ORDER**

After considering the findings of the Board of Pharmacy regarding Elise Varkonyi, RPh, it has been determined that the continuation of Respondent's license to practice pharmacy would constitute an immediate danger to the public. Accordingly, the registered pharmacist license of Elise Varkonyi is hereby suspended until further Order of the Department of Health. Respondent is entitled to an administrative hearing in accordance to R.I. Gen Laws 42-35-14(c).

Michael Fine, MD

Director

Rhöde Island Department of Health

March 1 2013

Date

#### CERTIFICATION

I hereby certify that a copy of this ORDER was hand-delivered to Elise Varkonyi, RPh on this \_\_\_\_\_\_ day of \_\_\_\_\_\_\_, 2013 at the following address:

Elise Varkonyi, RPh 1 Commerce Street Lincoln, RI 02865 STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH
HEALTH SERVICES REGULATION
BOARD OF PHARMACY

VS.

Case No. C13-0121

ELISE VARKONYI, RPH03115

#### **CONSENT ORDER**

Pursuant to Rhode Island General Laws (1999 Reenactment) Sections 5-19.1-8, and 5-19.1-9 and the Rules and Regulations promulgated thereunder, the Department of Health, Board of Pharmacy (hereinafter "Department") has investigated a complaint charging Elise Varkonyi (hereinafter "Respondent") with a violation of Chapter 5-19.1 of the Rules and Regulations.

After consideration by the Department and the Director of the Department, the following constitutes the Findings of Fact with respect to the professional performance of the Respondent:

- 1. Respondent is a licensed pharmacist in the State of Rhode Island, and holds license number RPH03115.
- 2. Respondent served as the Pharmacist-In-Charge of Rhode Island Village Pharmacy (the "Pharmacy") during all relevant times outline below.
- 3. Rhode Island Village Pharmacy is licensed as a retail pharmacy and at all relevant times outlined below held license numbers PHA00328 and PHA00519 and controlled substance registrations CPHA00328 and CPHA00519 and has a registered location of 1 Commerce Street, Lincoln, Rhode Island.
- 4. Pursuant to Title 5, Chapter 19.1 of the Rhode Island General laws and the Rules and Regulations promulgated thereunder, Respondent is administratively responsible for the overall operation and conduct of Rhode Island Village Pharmacy.

- 5. The Pharmacy routinely accepted compounded sterile drugs from Village Fertility Pharmacy located at 335 Bear Hill Road, Waltham, MA a facility which does not hold a Rhode Island license as a non-resident retail pharmacy, non resident drug manufacturer, or non resident drug wholesaler. Respondent affixed Rhode Island Village Pharmacy labels to these compounded medications and further dispensed these compounded medications to patients in Rhode Island in violation of RIGL 21-31-3.
- 6. Respondent submitted an affidavit to the Rhode Island Board of Pharmacy on 11/16/12 attesting to the fact that Respondent did not engage in the compounding of sterile pharmaceuticals. During inspection on February 25, 2013, Respondent admitted to the Board investigators that she did engage in low risk sterile compounding before and after the date Respondent submitted the affidavit to the Board.
- 7. Respondent engaged in low risk sterile compounding in an environment which failed to meet the standards set forth in the Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers and Distributors. Respondent admitted to performing low risk sterile compounding without use of a laminar airflow workbench or barrier isolator system in violation of R5-19.1-PHAR-19.21.
- 8. Respondent failed to conduct environmental surface and air Monitoring for viable microorganisms on a monthly basis as required for low risk sterile compounding involution of R5-19.1-PHAR-19.28.
- Pharmacy failed to possess written quality assurance policy and Procedures for low risk sterile compounding in violation of R5-19.1 PHAR-19.11(d) & R5-19.1-PHAR-19.12.
- 10. Pharmacy distributed legend prescription drugs and controlled Substances to various practitioner offices in MA, CT, GA, FL, IL, IN, OH, PA, NY, NJ, VT, NH, ME, VA, NC, SC, FL, TX without possessing a drug wholesaler license, obtaining a prescription from the practitioner or labeling the product with a prescription label in violation of RIGL 5-19-.18, RIGL 5-19.1-1-18 & RIGL 21-28-3.18(h).
- 11. Respondent failed to maintain a biennial inventory at the pharmacy In violation of RIGL-21-28-3.16.
- 12. Pharmacy failed to have video surveillance cameras covering drug Stock in violation of R5-19.1-PHAR-13.2.3.
- 13. Respondent failed to post her names as Pharmacist-In-Charge in Violation of R5-19.1-PHAR-24.7.

14. Respondent failed to have technicians wear name badges denoting title in violation of R5-19.1-PHAR-24.7.

# The parties agree as follows:

- Respondent admits to the jurisdiction of the Department and the Director and agrees to remain under the jurisdiction of the Department and the Director.
- 2. Respondent hereby acknowledges and waives:
  - a) The right to appear personally or by counsel or both before the Department;
  - b) The right to produce witnesses and present evidence in its behalf at a hearing;
  - c) The right to cross-examine witnesses;
  - d) The right to have subpoenas issued by the Department;
  - e) The right to further procedural steps except for those specifically contained herein;
  - f) Any and all rights of appeal of this Consent Order;
  - g) Any objection to the fact that this Consent Order will be presented to the Director for consideration and review;
  - h) Any objection to the fact that it will be necessary for the Department and the Director to become acquainted with all evidence pertaining to this matter in order to adequately review this Consent Order;
  - i) Any objection to the fact that potential bias against Respondent may occur as a result of the presentation of this Consent Order.

- This Consent Order shall become part of the public record of this proceeding once it is accepted by all parties.
- 4. The Respondent and the Director desire to settle and resolve this matter without administrative action. Acceptance by the Respondent and approval by the Director of this Consent Order does not constitute an admission of the facts contained herein or violations of law, except as provided below.
- 5. The Summary Suspension heretofore issued against Respondent will be vacated on September 1, 2013 as long as the following conditions have been met:
  - a. Respondent shows proof that she has successfully passed the Multistate Pharmacy Jurisprudence Examination ("MPJE") on or after March 1, 2013.
- 6. Respondent shall be on probation for a period of two years commencing from the date she resumes practicing. As special conditions of the probation, Respondent agrees to the following:
  - Respondent shall not serve as a Pharmacist-In-Charge during her probationary period;
  - Respondent shall not engage in any form of compounding during her probationary period;
  - d. Respondent shall submit monthly reports from her employer to the Department during her probationary period and such report shall be consistent with <a href="Exhibit A">Exhibit A</a> attached hereto;

e. Respondent must notify the Department before she changes employment at any time during the probationary period.

Elise Varkonyi, RPh

Michael Fine, MD
Director of Rhode Island
Department of Health

Ratified as an Order of the Board of Pharmacy on this \_\_\_\_\_ day of \_\_\_\_\_2013.

I hereby certify that the within Consent Order was mailed by certified mail to on this 23 day of 42013.

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