

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 in violation of R5-19.1-PHAR-19.28.
9. 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:

1. 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.

3. 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:
 - b. Respondent shall not serve as a Pharmacist-In-Charge during her probationary period;
 - c. 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 Exhibit 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 23rd day of May 2013.

Stephen Zubrygo, Esq.
One Ciberus Farm
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