STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS PROVIDENCE, SC.

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

v.

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

Rhode Island Department of Health

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