

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

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

v.

RHODE ISLAND VILLAGE PHARMACY
License #PHA00328/CPHA00328
#PHA00519/CPHA00519

SUMMARY SUSPENSION

The Rhode Island Board of Pharmacy (hereinafter "Board") has investigated a complaint regarding the professional pharmacy operations of Rhode Island Village Pharmacy (hereinafter "Respondent"), a licensed retail pharmacy in the State of Rhode Island.

The Office of the Director of Health makes the following:

Findings of Fact and Conclusions of Law

1. Respondent is a licensed retail pharmacy in the State of Rhode Island and holds license numbers and RI controlled substances registrations, PHA00328/CPHA00328 & PHA00519/CPHA00519.
2. Respondent has a registered location of 1 Commerce Street, Lincoln, RI.
3. Respondent has operated as a retail pharmacy during all relevant times outlined below.
4. The Board conducted an inspection of Rhode Island Village Pharmacy on February 25, 26, and 27, 2013 and determined the following:

- Respondent holds two retail pharmacy licenses with the State of Rhode Island and, as such, is required to designate a Pharmacist-In-Charge who shall be administratively responsible for any and all operations and activities for each license. Respondent pharmacy license #PHA00328/CPHA00328 designated a Pharmacist in Charge on or about 8/14/2002 and maintained the same Pharmacist-In-Charge at all times prior to and during the time of inspection. A pharmacist at Respondent pharmacy informed Board investigators that the Pharmacist-In-Charge of license #PHA00328/CPHA00328 died on or about January 18, 2013. Respondent pharmacy failed to inform the Board of Pharmacy of this event and failed to designate a new Pharmacist-In-Charge. Respondent pharmacy continued to dispense pharmaceuticals and engage in the

practice as a retail pharmacy during this period of no Pharmacist-In-Charge.

- Respondent 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 license as a non-resident retail pharmacy, non resident drug manufacturer, or non resident drug wholesaler with the State of Rhode Island. Respondent pharmacy 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.
- Respondent pharmacy 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, the pharmacist at Respondent pharmacy admitted to Board investigators that Respondent pharmacy did engage in low risk sterile compounding before and after the date Respondent pharmacy's affidavit was submitted to the Board.
- Respondent pharmacy 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 pharmacy engaged in 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 pharmacy 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 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.
- Respondent 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 5-19.1-8, RIGL 5-19.1-18 & RIGL 21-28-3.18(h).
- Respondent pharmacy failed to maintain a biennial inventory at the pharmacy in violation of RIGL 21-28-3.16.

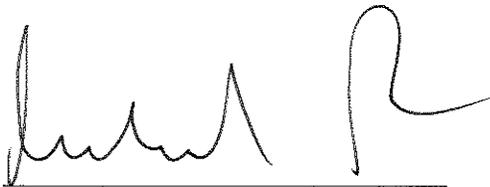
- Respondent pharmacy failed to have video surveillance cameras covering drug stock in violation of R5-19.1-PHAR-13.2.3.
- Respondent pharmacy failed to post names of the Pharmacist-In-Charge in violation of R5-19.1-PHAR-11.3.1.
- Respondent pharmacy failed to have technicians wear name badges denoting title in violation of R5-19.1-PHAR-24.7.

ORDER

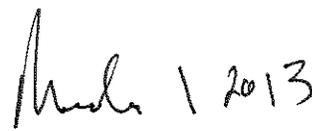
After considering the findings of the Board of Pharmacy regarding Rhode Island Village Pharmacy it has been determined that the continuation of Respondent's licenses to operate as a retail pharmacy would constitute an immediate danger to the public. Accordingly, the retail pharmacy licenses and corresponding controlled substances registrations of Rhode Island Village Pharmacy are hereby suspended until further Order of the Department of Health.

Respondent shall continue to be responsible for providing continuity of care for patients seeking to transfer prescriptions to other pharmacies, patients seeking to obtain prescription records, or patients seeking information or assistance in regards to the voluntary recall issued by Village Fertility Pharmacy located at 335 Bear Hill Road, Waltham, MA.

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



Date

CERTIFICATION

I hereby certify that a copy of this ORDER was hand-delivered to Elise Varkonyi, RPh on this 1st day of March, 2013 at the following address:

Rhode Island Village Pharmacy
c/o Elise Varkonyi, RPh
1 Commerce Street
Lincoln, RI 02865