STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH
HEALTH SERVICES REGULATION
BOARD OF PHARMACY

vs. Case No. C13-113

RHODE ISLAND VILLAGE PHARMACY
License No. PHA00328/CPHA00328
PHA00519/CPHA00519

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 Rhode Island Village Pharmacy (hereinafter "Respondent") with a violation of Chapter 5-19.1 of the Rules and Regulations.

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

1. Respondent is a licensed retail pharmacy in the State of Rhode Island, and holds license numbers and Rhode Island controlled substance registrations numbers PHA00328/CPHA00328 and PHA00519/CPHA00519.

2. Respondent has a registered location of 1 Commerce Street, Lincoln, RI.

3. Respondent has operated a retail pharmacy during all relevant times outlined.

4. 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 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.

5. 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 Section 21-31-3

6. 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.

7. Respondent pharmacy 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.

8. 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.

9. 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-.18, RIGL 5-19.1-1-18 & RIGL 21-28-3.18(h).

10. Respondent pharmacy failed to maintain a biennial inventory at the pharmacy In violation of RIGL-21-28-3.16.

11. Respondent pharmacy failed to have video surveillance cameras covering drug Stock in violation of R5-19.1-PHAR-13.2.3.

12. Respondent pharmacy failed to post names of the Pharmacist-In-Charge in Violation of R5-19.1-PHAR-24.7.

The parties agree as follows:

1. Respondent is a Pharmacy licensed in the State of Rhode Island.

2. Respondent admits to the jurisdiction of the Department and hereby agrees to remain under the jurisdiction of the Department.

3. Respondent has read this Consent Order and understands that it is a proposal of the Department and is subject to the final approval by the Department. This Consent Order and the contents thereof are not binding on Respondent until final approval by the Department.

4. 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 Department for consideration and review;

   h) Any objection to the fact that it will be necessary for the Department 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 to the Department.

5. This Consent Order shall become part of the public record of this proceeding once it is accepted by all parties.

6. The Respondent and the Board desire to settle and resolve this matter without administrative action. Acceptance by the Respondent and approval by the Board of this Consent Order does not constitute an admission of the facts contained herein or a violation of applicable law, except as provided below.

7. The Summary Suspension heretofore issued against Respondent will be vacated when the following conditions are met:

   a. Written Policies and Procedures relating to the operation of the Respondent's pharmacy generally have been submitted to and approved by the Department;

   b. A new Pharmacist in Charge has been identified to the Department.

8. Respondent shall voluntarily surrender its PHA PHA00328/CPHA00328 license and execute the Voluntary Surrender attached hereto as Exhibit A.

9. Respondent shall be on probation for a period of one year from the date of re-opening. As special conditions of the probation, Respondent agrees that it shall employ a Compliance Officer to ensure compliance with State and federal statutes and regulations.

PRESIDENT

Chairperson
Board of Pharmacy

Ratified as an Order of the Board of Pharmacy on this 16 day of ~~April~~ May, 2013 .

I hereby certify that the within Consent Order was mailed by certified mail to Stephen Zelinger, Esq. One Citizens Plaza, Suite 500 Providence, RI 02903 on this 23 day of ~~April~~ May, 2013.

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EXHIBIT A

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STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH
HEALTH SERVICES REGULATION
BOARD OF PHARMACY

IN THE MATTER OF:
RHODE ISLAND VILLAGE PHARMAC (LICENSE #PHA00328, CPHA00328)

VOLUNTARY SURRENDER

Pursuant to Rhode Island General Laws Section 5-19.1-21 and the Rules and Regulations promulgated thereunder, the Department of Health, Board of Pharmacy (hereinafter "Department") has investigated a complaint charging Rhode Island Village Pharmacy (hereinafter "Respondent"), with violations of RIGL § 5-19.1-21 and Section 27 of the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors*. After consideration by the Department, the following constitutes the Findings of Fact with respect to the professional performance of the Respondent.

1. Respondent is licensed as retail pharmacy and holds license number PHA00328 and RI Controlled Substances Registration number CPHA00328.

2. Respondent has a registered location of 1 Commerce Street, Lincoln, RI.

3. Respondent's license as a retail pharmacy was summarily suspended by the Department on March 1, 2013.

4. Respondent wishes to surrender its license and corresponding controlled substances registration.

The parties agree as follows:

1. Respondent is a retail pharmacy and is able to conduct business under and by virtue of the laws of the State of Rhode Island.

2. Respondent admits to the jurisdiction of the Department and hereby agrees to remain under the jurisdiction of the Department.

3. 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 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 Voluntary Surrender Order;

   g) Any objection to the fact that this Voluntary Surrender Order will be presented to the Department for consideration and review;

   h) Any objection to the fact that it will be necessary for the Department to become acquainted with all evidence pertaining to this matter in order to adequately review this Voluntary Surrender Order;

   i) Any objection to the fact that the Department reviewing this Voluntary Surrender Order may be the same as the hearing committee presiding over this matter should it later be brought to an administrative hearing.

   j) Any objection to the fact that potential bias against the Respondent may occur as a result of the presentation of this Voluntary Surrender Order to the Department.

4. This Voluntary Surrender Order shall become part of the public record of this proceeding once it is accepted by all parties and accepted by the Department.

5. Acceptance by the Respondent and approval by the Department of this Voluntary Surrender Order does not constitute an admission of the facts contained herein.

6. Effective upon the date of ratification of this order by the Department, the Summary Suspension issued against Respondent on March 1, 2013 shall be vacated, conditioned further upon Respondent surrendering its license and controlled substances registration in the State of Rhode Island.

7. Respondent hereby voluntarily surrenders its retail pharmacy license and controlled substances registration in the State of Rhode Island.

   a. Respondent shall turn in its wall certificate to the Department upon ratification of this order by the Department.

   b. Respondent shall be responsible for appropriately transferring or destroying its pharmaceutical stock in accordance with the *Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors* and shall keep documentation of said activity.

8. Respondent shall, in writing, request reinstatement of its license as a retail pharmacy in the event that Respondent desires to resume practice in the State of Rhode Island. Once Respondent's request is approved by the Department, Respondent shall submit a new application to the Department and fulfill any and all requirements and fees of the application.

9. In the event that Respondent applies or re-applies to the Department for licensure as a retail pharmacy in this State, Respondent understands that it may be subject to a disciplinary action which may arise when the facts contained herein are presented to the Board or delegated hearing officer upon submission of Respondent's application.

4/26/13
Date

Rhode Island Village Pharmacy
License # PHA00328 & CPHA00328

Approved on this 26 day of APRIL 2013

Jonathan M. Mundy, RPh
Chairperson
Rhode Island Board of Pharmacy