

**STATE OF RHODE ISLAND AND
PROVIDENCE PLANTATIONS**

**RHODE ISLAND
DEPARTMENT OF HEALTH**

**MICHAEL FINE, M.D., IN HIS CAPACITY
AS DIRECTOR OF HEALTH,
STATE OF RHODE ISLAND**

**In the Matter of:
BAYVIEW PHARMACY (LICENSE #PHA00373, CPHA00373)**

IMMEDIATE COMPLIANCE ORDER

Now comes the Director of Health of the State of Rhode Island and, pursuant to Rhode Island General Laws §§ 23-1-21 and 5-19.1-7, -8, -12, -13, makes the following Findings of Fact and Order regarding:

FINDINGS OF FACTS

1. On November 13, 2012, Board of Pharmacy inspectors arrived at Bayview Pharmacy, 3045 Tower Hill Road, Saunderstown, Rhode Island, for a follow-up inspection after concerns were found during a September 7, 2012, inspection.
2. Bayview Pharmacy is licensed as a retail pharmacy, license number PHA00373 and Controlled Substances Registration Number CPHA00373, pursuant to Rhode Island General Laws §§ 5-19.1-8 and -9.
3. Bayview Pharmacy is not licensed as a manufacturer or wholesale drug distributor pursuant to Rhode Island General Laws § 5-19.1-12 or -13.
4. Bayview Pharmacy is engaged in the compounding of high-, medium- and low-risk sterile preparations, and permissibly nonsterile topical and oral preparations, that are prescribed by licensed prescribers for specific patients. "Compounding" is defined by the Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers and Distributors Regulation 1.22 as "the act of combining two (2) or more ingredients as a result of a practitioner's prescription or medication order occurring in the course of professional practice based upon the individual needs of a patient and a relationship between the practitioner,

patient, and pharmacist. Compounding does not mean the routine preparation, mixing or assembling of drug products that are essentially copies of a commercially available product.”

5. The most recent two inspections of Bayview Pharmacy have revealed that it is acting as an unlicensed manufacturer and distributor of sterile injectable medications to Rhode Island residents and out-of-state nonresidents, some of whom were licensed practitioners who were using the product as office stock. As one of numerous examples, Bayview records indicated that it manufactured and distributed 1.25 liters of sterile injectable Lidocaine, an anesthetic, to a practitioner in Illinois for general office use on multiple occasions. Bayview records found by inspectors indicate that the pharmacy has sent sterile injectable medications to practitioners in Indiana and other states. Such unlicensed manufacturing and distributing is a civil violation of Rhode Island General Laws §§ 5-19.1-12 and -13.
6. On at least two occasions, based on pharmacy records, a pharmacist at Bayview used expired powders to compound a permissibly nonsterile topical preparation, rendering it misbranded in civil violation of Rhode Island General Laws § 21-31-3.
7. The sterile room for compounding is required to have media fill plate testing every six months, and upon inspection, Bayview was unable to produce to inspectors their testing results for the past two years despite their claim that they were done.
8. The sterile room for compounding is required to be cleaned on a weekly basis as a condition of the compounding of high-risk sterile compounds. Bayview was unable to produce adequate record that cleaning occurred between November 1 and 13, 2012, despite their claim that it was done.
9. Bayview is required to have a written plan and schedule for the environmental monitoring for viable and non-viable microorganisms on a weekly basis as a condition of high-risk sterile compounding. Bayview has not conducted such testing, or proven such testing, as required under the Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers and Distributors.
10. Board of Pharmacy inspectors had observed on September 7, 2012, cages, bedding, food, and water dishes for pets that were all located in a cubicle adjacent to the pharmacy compounding area, which have since been removed from the pharmacy.
11. Upon survey of Bayview stock of compounding powders, Board of Pharmacy inspectors observed that Bayview utilizes compounding powders from a

manufacturer and distributor which is not licensed in Rhode Island in accordance to Rhode Island General Laws § 5-19.1-8.

12. Bayview retained in stock a quantity of powder that it had obtained from a prescriber who was not authorized to provide such powder.
13. Based on the foregoing, there exists a civil violation of Rhode Island statutes and regulations within the jurisdiction of the Director of the Department of Health that requires immediate action to protect the health, welfare or safety of the public.

ORDER

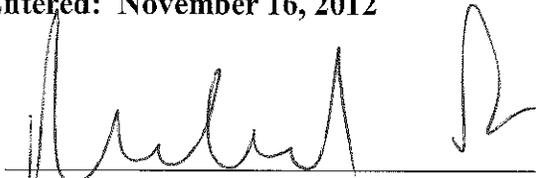
After consideration of the above findings and a review of Department of Health records that demonstrate the accuracy of the above findings, it is hereby ordered that:

1. Bayview Pharmacy and its owners and employees shall cease and desist the manufacturing, distributing, and/or wholesaling of any medication in or outside of Rhode Island; but this Order shall not prohibit the lawful dispensing of medications that Bayview is otherwise currently licensed to dispense pursuant to its retail pharmacy license.
2. Bayview Pharmacy and its owners and employees shall cease and desist the use or dispensing of any medication obtained by any manufacturer, wholesaler, and/or distributor that is not licensed in Rhode Island as such.
3. Bayview Pharmacy and its owners and employees shall cease and desist the compounding and dispensing of any sterile medication.
4. Bayview Pharmacy and its owners and employees shall cease and desist the use or dispensing of any medication that is expired.
5. Bayview Pharmacy and its owners and employees shall cease and desist the practice of accepting any products from any outside source, including patients or prescribers, for the purpose of subsequent compounding.
6. Bayview Pharmacy and its owners and employees shall cease and desist the allowance of any animals, other than service animals, in the pharmacy area of the store.
7. Bayview Pharmacy shall produce to any Board of Pharmacy inspector a sample of compound powder and/or medications obtained or made from any unlicensed manufacturer, distributor, and/or wholesaler that is currently on the premises of the pharmacy. All remaining powders and medications obtained or made from any unlicensed manufacturer, distributor, and/or wholesaler that is currently on the

premises of the pharmacy shall be embargoed until further Order of the Director of the Department of Health or his agents.

8. Bayview Pharmacy and its owners and employees shall complete the following prior to any request for rescission or vacation of this Order:
 - a. Produce records of satisfactory media fill plate testing for the past two (2) years from the date of this Order;
 - b. Produce a current report generated by an external, independent environmental cleaning and/or monitoring entity – approved by the Department beforehand – that demonstrates that viable and nonviable microorganism surface and air testing was conducted of the sterile compounding area that shows compliance with acceptable standards outlined in the Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers and Distributors;
 - c. Hire at its own expense an external, independent environmental cleaning and/or monitoring entity – approved by the Department beforehand – to perform cleaning of the pharmacy area that is in compliance with acceptable standards outlined in the Rhode Island Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers and Distributors;
 - d. Produce a written attestation by the external, independent environmental cleaning and/or monitoring entity that avers that such cleaning and testing was done.

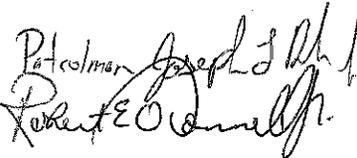
Date Entered: November 16, 2012

By: 

Michael Fine, M.D.
Director
Rhode Island Department of Health

CERTIFICATION OF SERVICE

A copy of the within Immediate Compliance Order was delivered to Bayview Pharmacy and Ryan Dyer, R.Ph., Pharmacist in Charge, 3045 Tower Hill Road, Saunderstown, Rhode Island, by the undersigned on this 16th day of November, 2012.

Witness  #37 SICPD