

**STATE OF RHODE ISLAND
AND PROVIDENCE PLANTATIONS**

**DEPARTMENT OF HEALTH
HEALTH SERVICES REGULATION
BOARD OF PHARMACY**

**IN THE MATTER OF:
BAYVIEW PHARMACY
License Number PHA00373
Complaint Numbers C12-056(a) and (b)**

CONSENT ORDER

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

1. Respondent is licensed as a retail pharmacy in the State of Rhode Island; license #PHA00373 and Controlled Substances Registration Number CPH00373, pursuant to R.I. Gen. Laws §§ 5-19.1-8 and -9.
2. Respondent operates as Bayview Pharmacy located at 3045 Towerhill Road, Saunderstown, Rhode Island.
3. On November 13, 2012, inspectors for the Board of Pharmacy performed an inspection of Respondent pharmacy.
4. Inspectors on November 13, 2012, viewed two prescription bottles containing Tylan powder dispensed by a veterinarian. Inspectors informed Respondent's owner/pharmacist in charge that his receiving the product from the veterinarian without protocol to verify the source of the powder, its potency, storage, handling and

identity of the product is a violation of governing pharmacy rules and regulations and must be discontinued forthwith. Inspection of pharmacy records revealed this practice occurred from May 2, 2012, to the date of this inspection. .

5. Respondent possessed and distributed misbranded items in violation of R.I. Gen. Laws §§ 21-31-3 and -15, and 21 U.S.C. § 352.
6. Bayview Pharmacy is not licensed as a manufacturer or wholesale drug distributor pursuant to R.I. Gen. Laws §§ 5-19.1-12 and -13.
7. Bayview Pharmacy is engaged in the compounding of high, medium, and low risk sterile preparations, and permissibly non-sterile 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."
8. On at least two occasions, based on pharmacy records, a pharmacist at Bayview Pharmacy used expired powder to compound a permissibly non-sterile topical preparation, rendering it misbranded in civil violation of R.I. Gen. Laws § 21-31-15.
9. On or about May 21, 2012, Respondent's owner and pharmacist in charge compounded and dispensed Oxycodone ER 60 mg a commercially available product. The compounded product contained mannitol as an inert ingredient, which distinguishes it from the commercially available product. Respondent states the brand name product was

reformulated and the patient is allergic to the inactive ingredients in the reformulated commercially available product.

10. Compounding and dispensing of a commercially available controlled substance is a violation of R5-19.1-PHAR-19.1.
11. On or about June 29, 2012, and on or about July 5, 2012, Respondent partially filled a schedule II controlled substance for greater than seventy-two (72) hours.
12. Respondent partially filled a compounded prescription for Oxycodone IR 80 mg despite the absence of indication that the patient was a "long term care resident," "terminally ill," or a "Hospice patient."
13. Respondent partially filled a prescription with one hundred (100) tablets on or about June 29, 2012; with one hundred (100) tablets on or about July 5, 2012; and with two dispensations of two hundred (200) and three hundred twenty (320) tablets on or about July 11, 2012.
14. Such partial filling of controlled substances is in civil violation of R.I. Gen. Laws § 21-28-3.18(j).
15. A media fill test is required on a semi-annual basis for pharmacies that conduct high-risk sterile compounding, and a written plan and schedule for environmental monitoring procedures for viable micro-organisms need to be established, and to be followed with weekly evaluation, per R5-19.1-PHAR-19.28.
16. When inspectors requested a copy of the media fill plate tests for the past six months, Respondent stated that he could not locate them because all environmental cleaning logs and results were delegated to another staff pharmacist who was out of the country at the time. Respondent told inspectors that media plate and fingertip testing

had been done sporadically in the preceding few months, and that there were no failing results even though he was unable to provide records.

17. A review of the November 2012 cleaning logs of the sterile hoods revealed that no cleanings had occurred between November 1 and 13, 2012.
18. Respondent admitted to inspectors that non-viable and viable air/surface testing had not been conducted in the past.
19. Respondent is in civil violation of R.I. Gen. Laws §§ 21-31-3 and -14 and 21 U.S.C. § 351 for possessing potentially adulterated drugs. Compounding sterile preparations with sterile air is required by USP-NF Chapter 797 standards.
20. On September 7, 2012 during an initial inspection, inspectors asked Respondent to explain why 2520 milliliters of hydrocodone/acetaminophen syrup was dispensed to Patient A, *alias*. Respondent told inspectors that the ratio of the two ingredients prescribed by Patient A's physician is not available on the market and must be compounded. The pharmacy has letters on file with the diagnosis for which the prescriber based the dosing order; however there is no manufacturer data available for such high dosing. The pharmacist in charge/owner said that he never questioned the dosing because he spoke to the provider about the individual patient's needs and the basis for the dosing amounts and that Patient A presents with normal appearance when picking up the medication.
21. Respondent was the dispensing pharmacist for multiple prescriptions in which 2520 mL of the schedule III controlled substance Hydrocodone/APAP was compounded and distributed by Bayview Pharmacy.
22. Respondent is in civil violation of R.I. Gen. Laws §§ 21-28-3.18(m)(1) for

- dispensing schedule III controlled substances in quantities exceeding the maximum allowed.
23. Respondent partially filled a compounded prescription for Oxycodone IR 80 despite the absence of indication that the patient was a "long term care resident," "terminally ill," or a "Hospice patient."
 24. Inspectors on November 13, 2012, found in the dispensable inventory a bottle of injectable Fluorouracil injection which appeared opened and used and did not have a "date/time opened" label. The manufacturer's packaging insert requires that the unused portion of the drug should be discarded within four hours of initial entry.
 25. During their inspection on November 13, 2012, Inspectors found a bottle of Vancomycin® dry powder which had no "date/time opened" indicator, and whose manufacturer packaging insert instructed to discard within four hours after initial use.
 26. Respondent possessed and distributed misbranded items in civil violation of R.I. Gen. Laws §§ 21-31-3 and -15, and 21 U.S.C. § 352.
 27. Inspectors on November 13, 2012, found Respondent's dispensable inventory contained bulk powders from B & B Pharmaceuticals of 17200 East Ohio Drive, Aurora, Colorado, 80017 (hereinafter "B & B"), which is not licensed in Rhode Island.
 28. Respondent possessed and distributed medications from a distributor not licensed in Rhode Island.
 29. On September 7, 2012, inspectors for the Board of Pharmacy found Respondent's refrigerator and freezer did not have thermometers, and they discarded products that were expired or without expiration dates.

30. Inspectors on November 13, 2012, found Respondent's drug refrigerators and found no alarms or method of tracking or monitoring temperature changes on days when the business is closed.
31. Inspectors on November 13, 2012, found Respondent's freezer contained multiple compounded items, including a high-risk sterile compound with an expiration date of no more than 45 days under freezing conditions without additional sterility testing per R5-19.1-PHAR-19.14.1.
32. Respondent permitted the compounding of a misbranded product by permitting use of Morphine Sulfate powder that expired nine months prior to the compounding date. The product used to compound a topical prescription expired May 1, 2011. Respondent did provide evidence to the Board that the product was 99.5% active when assayed on 9/20/12. Respondent further stated that they followed current practice standards related to the use of bulk powders.
33. Respondent is in civil violation of R.I. Gen. Laws §§ 21-31-3 and -14 for possessing potentially adulterated drugs.
34. Respondent possessed and distributed misbranded items in violation of R.I. Gen. Laws §§ 21-31-3 and -15, and 21 U.S.C. § 352.
35. Respondent was acting as an unlicensed manufacturer and distributor of sterile injectable medications to residents and nonresidents of Rhode Island, some of whom were licensed practitioners who were using the product as office stock.
36. Respondent's 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.

37. Respondent's records found by inspectors indicate that the pharmacy has sent sterile injectable medications to practitioners in Indiana and other states.
38. Such unlicensed manufacturing and distributing is in violation of R.I. Gen. Laws §§ 5-19.1-12 and -13.
39. Respondent is in civil violation of R.I. Gen. Laws § 5-19.1-21(2), (6) and (11).
40. Pursuant to § 5-19.1-21, this conduct constitutes unprofessional conduct in the State of Rhode Island.
41. During the pendency of this matter and prior to receipt of this Consent Order, Respondent voluntarily completed 50 contact hours of continuing education ACPE #0012-0000-12-225-L04-P, 20-342454 Essential Elements of Compounded Sterile Preparations- Live Component; 0012-0000-12-114-H04P, 20-343453 Essential Elements of Compounded Sterile Preparations- Home Component; 0012-0000-12-113-H01-P, 20-342452 Aseptic Manipulations & Techniques for Compounded Sterile Preparations; 0012-0000-12-112-H04P, 20-342451 Sterile Environments for Compounded Sterile Preparations. All programs were completed in April 2013. (Copies of Certificate of Attendance attached.)
42. Additionally, Respondent voluntarily completed the continuing education course entitled: Pharmacists' Responsibility in Appropriate Controlled Substance Dispensing in 2013.
43. During the pendency of this matter and prior to receipt of this Consent Order, it is of import to note that the pharmacist in charge/owner voluntarily implemented the following changes/protocol as soon as possible for all pharmacists and personnel following the hearing on this matter in December 2012:
 - a. Media fill plate test are conducted semi-annually along with weekly environmental testing. The pharmacy conducts samples on 5 sites per week with agar plates and they monitor for growth. For increased assurance, a positive control is used.

- b. Bayview has also contracted for monthly environmental testing by Microtest which tests for viable and non-viable air samples in addition to contact plates. A trending chart has been maintained. Bayview Pharmacy has not had any trending at an action level.
- c. Microtest provides monthly non-viable particulate sampling results, TSA plate testing for the pharmacy's 150 Class 5, 7, and 8 environments.
- d. The pharmacy performs personal touch plate testing weekly in addition to 5 sites and positive and negative controls.
- e. Bayview also contracted with Nano Clean to perform monthly cleaning which is in addition to the in house daily cleaning and cleaning agents are rotated monthly per 797 guidelines.
- f. No partial fills in excess of 72 hours are allowed for any controlled substances.
- g. Providers are required to indicate on the face of the prescription why a compound is required for a particular patient.
- h. Bayview Pharmacy now has stickers on all injectable products indicating date received and date opened and all are discarded according to manufacturer guidelines or USP 797.
- i. Bayview Pharmacy no longer compounds with 5FU.
- j. Compounds made with a sterile powder for a non-sterile use are labeled with a label "FOR USE IN NON-STERILE PREPARATIONS ONLY".
- k. Bayview no longer does business with B & B despite their acquiring the proper licensing.
- l. Both pharmacy refrigerators and freezers have been equipped with Fisher Scientific Traceable digital thermometers. A daily refrigerator and freezer monitoring log is recorded by the pharmacist each day. Additionally the

pharmacy has initiated using the WarmMark® Time-Temp tag which indicates exposure of product to temperatures 10 degrees centigrade.

- m. The pharmacy has also instituted new policies regarding its Bi-Mix/Tri-Mix compounds by performing stability testing and applying a 60 day beyond use date from the lab results when refrigerated.
- n. All chemicals to be used in compounding are logged into the pharmacy's computer system and a log sheet cannot be printed with an expired product on it.
- o. Bayview no longer dispenses outside of RI, MA or CT.
- p. Bayview no longer dispenses for "office use."

Based on the foregoing, the parties agree as follows:

- 1. Respondent is a registered pharmacist and is able to conduct business under 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 has read this Consent Order and understands that it is a proposal of the Department and is subject to the final ratification by the Department. This Consent Order and the contents thereof are not binding on Respondent until final ratification 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 evidence in her 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 the Department reviewing this Consent Order may be the same as the hearing committee presiding over this matter should it later be brought to an administrative hearing; and
 - j) Any objection to the fact that potential bias against the 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 and accepted by the Department.
 6. Acceptance by the Respondent and approval by the Department of this Consent Order constitutes an admission of the facts contained herein.
 7. Respondent's pharmacy license shall be suspended for one (1) year, with said suspension being stayed pending Respondent's compliance with this Consent Order and Respondent being on probation for the one (1) year period of stayed suspension.
 8. That if Respondent complies with the laws and regulation governing the practice of pharmacy and this Consent Order during the one (1) year period of probation, said license shall be reinstated without restriction.
 9. Respondent shall arrange and pay for three (3) NABP Inspections: one to be completed by NABP within thirty (30) days of inspector availability; one twelve (12) months after the first inspection; and a third inspection twelve (12) months after the second inspection. Respondent shall notify the Board in advance of the three (3) inspections noted herein to inform them of the dates said inspections

shall occur, and further Respondent shall provide reports made by the NABP inspectors within ten (10) days of receipt of same.

10. During the period of stayed suspension/probation, Respondent shall not serve as preceptor of any pharmacy intern, after the effective date of ratification of this Order by the Board.
11. Respondent shall retain an independent monitor approved by the Board of Pharmacy. The monitor shall be paid by Bayview Pharmacy. Said monitor shall perform weekly monitoring of Bayview Pharmacy's operations and the practices of all pharmacist and paraprofessionals employed by Bayview Pharmacy. Said monitoring shall be required for one (1) year from the actual commencement of monitoring; however, Respondent may petition the Board in writing to terminate the monitoring requirement sooner. Said monitor shall perform said monitoring for no less than two (2) hours each week and shall be skilled in the practice of a compounding pharmacist sufficient to ensure Respondent, its employees and related paraprofessionals compliance with all governing laws, rules and regulations currently applicable to the practice of pharmacy in Rhode Island.
12. Respondent shall have 30 days from the effective date of ratification of this Order to notify the Board of the name and start date of the monitor in accordance with this Consent Order.
13. Respondent is to notify the Board forthwith if he encounters any problems securing a competent monitor to perform the duties proscribed by this Order.
14. So long as the provisions of Paragraphs 9 are implemented and the monitor referenced in Paragraph 11 herein is in place, Respondent may remain as pharmacist in charge of Bayview Pharmacy.
15. Respondent shall complete an additional five (5) hours of Continuing Education (0.5CEU) from a recognized provider in a subject matter pertaining to pharmacy or drug law and regulation within six (6) months of the ratification of this Order by the Department. These five (5) hours of Continuing Education shall be in addition to those already required under R5-19.1-PHAR-7.4 for Respondent's annual license renewal. Respondent shall submit copies of the five (5) hours of Continuing Education in pharmacy or drug law and regulation within six (6)

months of ratification of this Order and Respondent shall submit all other Continuing Education Credits required under R5-19.1-PHAR-7.4 for his annual license renewal to the Department no later than June 30, 2014.

16. Respondent hereby agrees to a Formal Reprimand of his registered pharmacist license.
17. That if Respondent violates the terms of this Consent Order, Respondent shall be subject to further disciplinary sanctions.

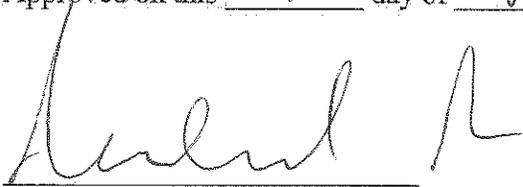
4/22/14
Date


RYAN DYER, RPh on behalf of Bayview
Pharmacy
License # RPH04568

5/15/14
Date


Kelly Orr, Pharm.D. RPh.
Chairperson
Rhode Island Board of Pharmacy

Approved on this 22 day of May, 2014.


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