



**STATE OF RHODE ISLAND  
RHODE ISLAND DEPARTMENT OF HEALTH**

**NICOLE ALEXANDER-SCOTT, M.D., M.P.H.,  
IN HER CAPACITY AS DIRECTOR OF THE  
RHODE ISLAND DEPARTMENT OF HEALTH**

**IN THE MATTER OF:  
STEPHEN PETTERUTI, D.O.  
License Number DO 00413**

**NOTICE OF VIOLATION AND COMPLIANCE ORDER**

Now comes the Director (the "Director") of the Rhode Island Department of Health ("RIDOH") and, pursuant to R.I. Gen. Laws § 23-1-20, determines there are reasonable grounds to believe Stephen Petteruti, D.O. ("Respondent") is in violation of law and or rule or regulation administered by her, and provides notice thereof.

**REASONABLE GROUNDS FOR DETERMINATION OF VIOLATION**

1. Respondent operates I.M. 120 and a "Drip Bar" which utilizes compounded sterile products as treatment for patients.
2. On May 14, 2019, pursuant to the May 2, 2019 Consent Agreement between Respondent and RIDOH, an investigator for the RIDOH Board of Pharmacy Investigator ("Investigator") conducted an unscheduled inspection of Respondent.
3. In the course of the inspection, the Investigator identified two deficiencies. First, the Investigator observed a vial of Human Chorionic Gonadotropin ("HCG"), a scheduled III-controlled substance, which had been compounded by Bayview Pharmacy, and which was clearly labeled "Discard after 7/28/2017," more than one year and 9 months prior to the date of inspection. This vial was found in a refrigerator, co-mingled with non-expired medications.

The Investigator noted in his report relative to the inspection, *"This is a violation of RI Pharmacy regulation 1.5.5.A.6 (d)," which requires "that the expiration dates of the pharmaceutical stock are periodically checked to ensure that no expired medications are dispensed."*

4. Respondent has failed to appropriately discard a schedule-III injectable controlled substance, storing it in the same area as current medications.
5. The second deficiency identified by the Investigator pursuant to the inspection relates to an individual patient vial of HCG, compounded by Wells Pharmacy of Ocala, Florida, and dispensed on January 4, 2019. The vial of was a multi-dose vial with a concentration of 1,000 units/ml. There was no date on the vial indicating when it was opened nor a beyond use date ("BUD").
6. In his report relative to the inspection, the Investigator reported, *"According to USP 797 once a multi-dose vial has been punctured, the beyond use date becomes 28 days maximum from date of opening. Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see Table 1) air quality (see immediate-Use CSPs), and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 (see Table 1) or cleaner air may be used up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see Antimicrobial Effectiveness Testing 51) unless otherwise specified by the manufacturer. These Compounded Sterile Products need to have a 28 beyond use date placed onto the vial after puncturing."*
7. Additionally, RIDOH cites the CDC published *Guide to Infection Prevention For*

*Outpatient Settings: Minimum Expectations for Safe Care* (version 2.3 September 2016, page 33), which states in relevant part, "Multi-dose vials are dated by HCP ["health care professional"] when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. Note this is different from the expiration date printed in the vial."

8. Respondent did not date the vial upon opening and did not indicate a beyond use date on the vial.

#### **ALLEGED VIOLATION(S)**

Based upon the foregoing, Respondent alleged to have:

1. Committed unprofessional conduct, as defined in violation of R.I. Gen. Laws § 5-37-5.1(19), which states in relevant part that "unprofessional conduct" includes "[i]ncompetent, negligent, or willful misconduct in the practice of medicine which includes the rendering of medically unnecessary services, and any departure from, or the failure to conform to, the minimal standards of acceptable and prevailing medical practice in his or her area of expertise as is determined by the board;" and
2. Violated 216-RICR-40-15-1, Pharmacists, Pharmacies, and Manufacturers, Wholesalers and Distributors 1.5.5.A.6 (d), which requires "that the expiration dates of the pharmaceutical stock are periodically checked to ensure that no expired medications are dispensed."

#### **ORDER**

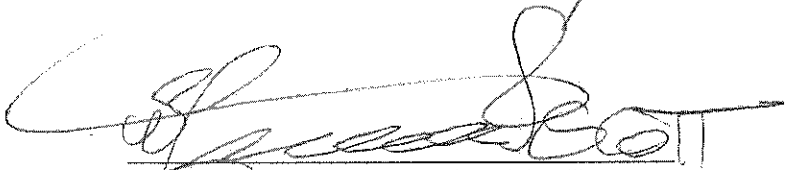
Upon determinations as set forth above, on or before tenth (10th) day from service of this Notice of Violation and Compliance Order, Respondent shall remedy the above-cited violations and come into full compliance with applicable law by, at a minimum, fulfilling the conditions set forth below:

1. Respondent shall appropriately discard all expired and/or out of date medications,

following applicable state and federal law for appropriate disposal.

2. Respondent shall date every multi-dose vial as soon as it is opened and prior to giving any medication in that vial to a patient.
3. Respondent shall discard every multi-dose vial appropriately, following applicable state and federal law for disposal of any multi-dose vial, that is beyond 28 days.
4. Respondent shall adhere to the *Guide to Infection Prevention For Outpatient Settings: Minimum Expectations for Safe Care* (version 2.3 September 2016), for all matters pertaining to infection prevention, which is a recognized standard, as determined by the Board.

Entered this 16<sup>th</sup> day of May, 2019



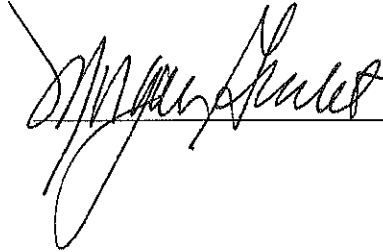
Nicole Alexander-Scott, M.D., M.P.H.  
Director  
Rhode Island Department of Health  
Cannon Building, Room 401  
Three Capitol Hill  
Providence, RI 02908

A written request for a hearing may be filed with the Director within ten (10) days of this Notice of Violation and Compliance Order.

**CERTIFICATION OF SERVICE**

A copy of the within Notice of Violation and Compliance Order was served on Respondent by certified mail at the address listed below and by email to his attorney, Dennis Grieco, at DGrieco@grieco-law.com, on this 10<sup>th</sup> day of May, 2019;

Stephen Petteruti, D.O.  
Unit 10, 250 Centerville Road, BLDG E  
Warwick, Rhode Island 02886



A handwritten signature in black ink, appearing to read "Stephen Petteruti", is written over a horizontal line.