



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

**NICOLE ALEXANDER-SCOTT, MD, MPH,  
IN HER CAPACITY AS DIRECTOR OF THE  
RHODE ISLAND DEPARTMENT OF HEALTH**

**IN THE MATTER OF:  
Toll Gate Apothecary  
License #: PHA00663  
176 Toll Gate Road, Suite 302  
Warwick, RI 02886**

*E. J. Jones  
10/11/19*

**IMMEDIATE COMPLIANCE ORDER**

Now comes the Director (“Director”) of the Rhode Island Department of Health (“RIDOH”) and, pursuant to R. I. Gen. Laws § 23-1-21, after initial investigation of Toll Gate Apothecary (“Respondent”) pertaining to an inspection of Respondent’s premises located at 176 Toll Gate Rd, Suite 302, Warwick, RI 02886 by the Rhode Island Board of Pharmacy (the “Board”) and the Board Inspector (the “Board Inspector”) on October 4, 2019, makes the following

**FINDINGS OF FACT AND CONCLUSIONS OF LAW**

1. Respondent is a “pharmacy,” as defined in R.I. Gen. Laws § 5-19.1-2(s), duly licensed by RIDOH as a Pharmacy, License No. PHA00663.
2. Respondent is under the jurisdiction of the Board.
3. Respondent prepares compounded sterile preparations (“CSPs”).

4. Section 1.7(B) of the Rhode Island Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors (216-RICR-40-15-1) sets forth the general requirements for all risk levels of sterile compounding, and provides that “[a]ll CSPs shall be prepared in a manner that maintains sterility and minimizes the introduction of particulate matter,” which is to be accomplished as outlined in current United States Pharmacopeia (“USP”) standards.

5. The applicable USP standards for the preparation of CSPs are set forth in USP General Chapter 797 *Pharmaceutical Compounding – Sterile Preparations* (“USP 797”). In Section 1.7(B) of the Rhode Island Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors, the Board has adopted USP 797 as the minimum standards for preparing compounded sterile drugs, as provided in the paragraph above.

6. According to USP 797, CSPs must be prepared in an environment that conforms, at least, to the requirements of International Organization for Standardization (“ISO”) Class 5.

7. Section 1.3(A)(3) of the Rhode Island Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors defines the “Code of Professional Conduct” as including “[a] pharmacist-in-charge, registered pharmacist, pharmacy or anyone acting on behalf of a pharmacy or pharmacy department shall observe the standards of the current United States Pharmacopoeia (“USP”) in addition to state laws and regulations.”

8. On October 4, 2019, the Board Inspector performed an inspection of Respondent relative to its preparation of CSPs.

9. Pursuant to the results of that inspection, the Board Inspector observed that the ISO Class 5 barrier isolator was labeled with an expired certification sticker, issued by B&V Testing, a National Sanitation Foundation (“NSF”) accredited certifier. The ISO Class 5 barrier isolator is part of the environment where the sterile compounded products are prepared at this pharmacy.

10. Noting that the stated purpose of USP 797 is to “minimize harm, including death, to . . . patients that could result from,” among other things, microbial or fungal contamination (non-sterility), the Board Inspector opined that Respondent’s failure to prepare CSPs that could be demonstrated to comply with current certification standards that meet ISO Class 5 environment was cause for safety concerns about any product prepared in that environment. At that time, the Board Inspector verbally asked Respondent to cease all sterile compounding immediately, with which Respondent verbally agreed.

11. Moreover, the Rhode Island Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors at Section 1.7(E)(4) require monthly environmental monitoring for sterile compounding areas used for low and medium risk preparations. For high risk preparations, a weekly evaluation is required.

12. The Board Inspector observed no records that demonstrated monthly environmental monitoring was occurring for this sterile compounding ISO 5 equipment (i.e. primary engineering control). Respondent confirmed to the Board Inspector that monthly environmental inspections had not been completed for at least the past year.

13. Section 1.3(A)(1) of the Rhode Island Rules and Regulations for Pharmacists, Pharmacies, and Manufacturers, Wholesalers, and Distributors requires that a Pharmacy or Pharmacy Department shall, at all times, comply “with federal, state and municipal laws, ordinances, and/or regulations, including the regulations of the Board.”

### ALLEGED VIOLATIONS

1. Respondent is in violation of 216-RICR-40-15-1.3 (A)(1).
2. Respondent is in violation of 216-RICR-40-15-1.3 (A)(3).
3. Respondent is in violation of 216-RICR-40-15-1.7(B).
4. Respondent is in violation of 216-RICR-40-15-1.7(E)(1).
5. Respondent is in violation of 216-RICR-40-15-1.7(E)(4).


### ORDER

Based on the foregoing, the Director has determined that the failure to prepare CSPs in an ISO Class 5 sterile, certified environment constitutes an immediate threat to the health, welfare and safety of the public.

Effective upon service of this Immediate Compliance Order, Respondent shall immediately cease the preparation of all compounded sterile preparations [CSPs] until such time as the Director determines the Respondent has reached compliance with the aforementioned regulations in this Order.

Failure to strictly comply with this Immediate Compliance Order without written consent from the Director could result in disciplinary action, including summary suspension of license.

Entered this 11 day of October, 2019.

  
\_\_\_\_\_  
Nicole Alexander-Scott, MD, MPH  
Director  
Rhode Island Department of Health  
Cannon Building, Room 401  
Three Capitol Hill  
Providence, RI 02908

**CERTIFICATION OF SERVICE**

A copy of this Immediate Compliance Order was served upon Respondent by certified U.S. Mail and personal service on this 11 day of October, 2019, as follows:

Eileen Wynne  
Pharmacist  
Toll Gate Apothecary  
176 Toll Gate Road, Suite 302  
Warwick, RI 02886  
Pharmacy License No. PHA00663

Peter J. Zagosta 10/11/2019

STATE RHODE ISLAND AND PROVIDENCE PLANTATIONS

Providence, SC.

RETURN OF SERVICE

I served this subpoena on the within named by TOLLGATE APOTHECARY  
176 TOLLGATE RD  
WARWICK, RI 02886

by delivering a copy to h\_\_, and tendering to h\_\_ \$ \_\_\_\_\_ as fees for one day's attendance and mileage.

Date of Service 10/11/2019

Miles Traveled \_\_\_\_\_

Robert John Mai #6211 Constable  
Signature of Server

Subscribed and sworn to before me this 11 day of October 2019.

Bernadette E Dimais  
Notary Public  
# 755622 8/1/21  
BERNADETTE E. DIMAIO  
NOTARY PUBLIC OF RHODE ISLAND  
Comm. # 755622  
My Commission Expires 8/1/2021

NOTE: Affidavit required only if service made by a person other than a sheriff or his deputy or a police officer.

ACKNOWLEDGMENT

Due and legal service is hereby acknowledged, and the receipt of legal fees for travel and one day's attendance.