



**In the Matter of:**

**In the Matter of: Women and Infants Hospital of Rhode Island  
LICENSE #PHB00020**

### **NOTICE OF VIOLATIONS AND COMPLIANCE ORDER**

**NOW COMES** the Director (“Director”) of the Rhode Island Department of Health (“RIDOH”) and, pursuant to R. I. Gen. Laws § 23-1-20, RIGL § 5-19.1, *et seq.* and 216-RICR-40-15-1, *et seq.*, determines there are reasonable grounds to believe that Women and Infants Hospital of Rhode Island (hereafter “Respondent” or “Respondent Facility”) is in partial violation of its agreement with the Rhode Island Department of Health, Board (“RIDOH”) of Pharmacy dated June 16, 2022, and provides notice thereof.

### **GROUND FOR DETERMINATION OF VIOLATIONS**

1. That Respondent is a duly licensed hospital pharmacy in the State of Rhode Island and holds license #PHB00020.
2. On or around January 13, 2022, and January 14, 2022, RIDOH, the Board of Pharmacy investigators conducted an inspection of the Respondent’s sterile compounding pharmacy suites (one located in the main pharmacy and the other located in a nearby wing of the hospital) which revealed that numerous conditions were out of compliance with RIGL § 5-19.1, *et seq.* and 216-RICR-40-15-1, *et seq.*,
3. On February 7, 2022, the Board of Pharmacy issued a complaint to Respondent and, subsequently, the Board of Pharmacy Investigatory Committee made a finding of unprofessional conduct based on the conditions of two pharmacy suites.
4. On June 13, 2022, Respondent waived its right to a hearing to challenge the findings and, instead, entered into a Consent Order & Agreement (Exhibit A – hereafter “Agreement”) and immediately undertook steps to cooperate with RIDOH and the Board of Pharmacy to remedy the cited conditions.
5. The Agreement required that Respondent thoroughly clean the pharmacy suites, implement and show proof of cleaning logs, replace outdated equipment, hire a third-party monitor at its own expense for a period of one year (ending no earlier than June 16, 2023), and remodel and renovate both pharmacy suites (or condense the suites and remodel the remaining one) as stipulated in item 13 of the Agreement.

6. Pursuant to the terms of the Agreement, Respondent remains on probation for a period of one (1) year ending June 16, 2023, or until all conditions of the Agreement are satisfied as stipulated in item 22 of the Agreement.
7. Respondent has violated item 22 of the Agreement because it failed to commence work to timely remodel and renovate the pharmacy suite(s) as agreed.

**BASED ON THE FOREGOING, IT IS HEREBY ORDERED**

**(Modified Remodel and Renovation Schedule)**

8. The Respondent will promptly comply with the following steps and deadlines to complete the renovation of the pharmacy compounding suites:
  - a) 3/1/24 Equipment Design/Existing – in process
  - b) 6/21/24 Equipment Acquisition
  - c) 4/5/24 Relocation of staff
  - d) 5/31/24 Storage space complete
  - e) 6/14/24 Relocation of storage, C2 and refrigeration
  - f) 2/28/25 Completion date for main pharmacy area
  - g) 4/25/25 Run Time, commissioning, and certificate of completion.
9. Any and all remodel and renovation work will be done in compliance with building and safety requirements set forth in the Professional Licensing & Facility Regulations, 216-RICR-40-10-4, *et. seq.* and in compliance with certificate of need requirements set forth in the Professional Licensing and Facility Regulations, 216 RICR 40-10-22, *et. seq.*

**(Extended Monitoring)**

10. Respondent shall be monitored by Health Quality Assurance Advisor Group (“HQAA”), an independent pharmacy monitoring service, or other Department-approved vendor(s), which shall be paid for by Respondent.
11. The Monitor will provide quarterly reports to RIDOH detailing compliance with the above renovation schedule, beginning no later than three (3) months after the issuance of this Order.
12. The monitor will remain in place until such time as the remodel and renovation steps are substantially complete, as determined by the Monitor and RIDOH. If the Respondent seeks to discontinue the services of the Monitor prior to completion of the remodel and renovation, it must first seek permission from RIDOH/Board of Pharmacy.

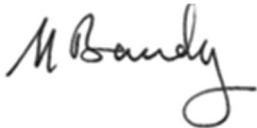
**(Reinspection)**

13. Upon completion of the renovations (or at such time that is recommended by the Monitor), the Respondent's pharmacy suite(s) are subject to inspection by RIDOH and by the National Association of Boards of Pharmacy ('NABP) for verification of its sterile compounding suites, which shall be paid for by Respondent.

**(Extended Probation)**

14. The Respondent will remain under probation by the RIDOH Board of Pharmacy until such time as the renovations are completed.

Entered this 19th day of March 2024



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Utpala Bandy, M.D., M.P.H.  
Interim Director of Health  
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 Order by submitting a request to:**

**Utpala Bandy, M.D., M.P.H., Interim Director of Health  
Rhode Island Department of Health  
3 Capitol Hill  
Providence, RI 02908  
c/o Legal Department, Rm 401 and by  
electronic mail: [Juliawyman@ohhs.ri.gov](mailto:Juliawyman@ohhs.ri.gov)**

**CERTIFICATION OF SERVICE**

Per the consent of the parties, a copy of this Notice and accompanying exhibits was delivered to Respondent via Electronic Mail to: Stacy Vaeth, PharmD – Pharmacy Director

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