STATE OF RHODE ISLAND

DEPARTMENT OF HEALTH
DIVISION OF CUSTOMER SERVICES

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

CONSENT ORDER & AGREEMENT

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 charging Women & Infants Hospital of Rhode Island (hereinafter "Respondent"), with violations of RIGL § 5-19.1, et seq. and 216-RICR-40-15-1, et seq. of the Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers and Distributors ("Rules"). 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 hospital pharmacy in the State of Rhode Island and holds license #PHB00020.

2. Pursuant to § 5-19.1-21 the following facts constitute unprofessional conduct in the State of Rhode Island.

3. That on or around January 13, 2022 and January 14, 2022, the Board conducted an unannounced inspection of the sterile compounding suites (the Main and South Pavilion, collectively "the suites") located at Women & Infants Hospital.


5. That on or around January 13, 2022 and January 14, 2022, the Board inspector discovered dust, dirt, and grime in several areas in both compounding suites. This was in violation of 216-RICR-40-15-1.7(A)(9).

6. That on or around January 13, 2022 and January 14, 2022 the Board inspector discovered multiple dates on the cleaning log for both sterile
compounding suites were not completed in a timely manner as required pursuant to 216-RICR-40-15-1.7(E)(6).

7. That on or around January 13, 2022 and January 14, 2022 the Board inspector was provided with sterility test results which showed that Respondent had identified several organisms in their sterile compounding environment in violation of 216-RICR-40-15-1.7(E)(7), and 40-15-1.7(E)(8).

8. That on or around January 13, 2022 and January 14, 2022 the Board inspector discovered that both compounding suites were outdated in design and materials, in need of maintenance in several areas, and not in conformity with 216-RICR-40-15-1.7(C)(2). Remodeling and updating was discovered to be needed in both rooms. Respondent has taken steps to correct the problems identified while the renovation and/or remodeling is planned.

9. That on or around January 13, 2022 and January 14, 2022 the Board inspector discovered that hoods used in both pharmacy suites were older models, and despite passing tests and certifications conducted by third-party inspectors were determined to be not in conformity with 216-RICR-40-15-1.7(C)(2).

10. That on or around January 13, 2022 and January 14, 2022 the Board inspector discovered unlabeled syringes left by compounding personnel in the non-hazardous hood in the Main compounding suite in violation of 216-RICR-40-15-1.7(C)(4)(a)(3).

11. That on or around January 13, 2022 and January 14, 2022 the Board inspector discovered several particle-generating materials, items, and equipment in the anterooms of both sterile compounding suites such as computers, wooden shelving, paperwork, refrigerators, file cabinets, printers, books, wooden doors, office furniture, and a rolling medication delivery tower in violation of 216-RICR-40-15-1.7(B)(1)(d).

Based on these findings, the Respondent agrees to the following conditions of this Consent Order:
12. Respondent has conducted an immediate cleaning and organization of both compounding suites. Respondent shall ensure that these activities are ongoing and consistent.

13. Respondent shall conduct a complete remodel and renovation of all compounding suites. Respondent shall follow current industry standards for hospital pharmacies. Respondent expects to begin work on the remodel and renovation on or before December, 2022. Respondent agrees to inform the Board if any reasonable delays arise due to construction contingencies, supply chain issues, or for any other reason.

14. As part of the remodel, Respondent shall replace old and outdated equipment including but not limited to hoods, furniture, carts, tables, shelving, and pass-through windows.

15. Respondent shall follow its policies regarding inspections of the pharmacy suites to identify and remove expired drugs in any areas of the hospital pharmacy.

16. Respondent shall ensure that cleaning logs are completed in a timely manner following each cleaning that takes place in all compounding suites.

17. Respondent shall ensure that no unnecessary and extraneous items that could be considered particle generating are present in any areas of the compounding suites.

18. Respondent shall be monitored every three (3) months for a period of one (1) year by Health Quality Assurance Advisor Group ("HQAA") an independent pharmacy monitoring service, or other Department-approved vendors, which shall be paid for by Respondent.

19. Respondent shall be inspected by the National Association of Boards of Pharmacy ("NABP") for verification of its sterile compounding suites upon completion of the final quarterly monitoring by HQAA, which shall be paid for by Respondent. This NABP inspection shall not be required to take place until after the remodel and/or renovations of the suites are complete.

20. The Respondent shall receive a copy of each HQAA, or other Department-approved vendor, monitoring report.
21. The Board shall receive a copy of each HQAA, or other Department-approved vendor, monitoring report.

22. Respondent shall ensure compliance with all reasonable recommendations resulting from the monitoring reports. Respondent shall remain on probation for a period of one (1) year to commence upon ratification of this consent order and which may continue beyond 1 year if the respondent fails to comply with the stipulations of this Consent Order, including compliance with reasonable recommendations resulting from HQAA inspection reports. Within sixty (60) days of the end of the 1 year probationary period, Respondent may contact the Board and ask for relief from probation. This contact may be via email to Peter Ragosta at Peter.Ragosta@health.ri.gov. Upon receipt of such a request, the Board shall place Respondent’s request on the agenda for its next regularly scheduled meeting. To the extent that the Board is considering an extension of the one-year probationary period, the Board shall provide Respondent with reasonable notice of the reasons for the proposed continuation of the probationary period and shall give Respondent a reasonable amount of time within which to correct any issues identified.

Based on the foregoing, the parties agree as follows:

23. Respondent is a hospital pharmacy and is able to conduct business under and by virtue of the laws of the State of Rhode Island.

24. Respondent admits to the jurisdiction of the Department and hereby agrees to remain under the jurisdiction of the Department.

25. Respondent has read this Consent Order and understands that it is a proposal of the Board 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.

26. Respondent has begun to undertake measures to comply with this Agreement. It is acknowledged that Respondent had taken steps to address the items referenced above.
Respondent represents that it has always taken, and will continue to take, steps to ensure that its compounded drugs are safe, and that its practices ensure the safety of its patients.

Respondent has also undertaken repairs to the pharmacy suites and sealed pass-through windows. Respondent has taken steps to reduce/remove particle generating materials from the ante rooms of its compounding suites. Respondent has also engaged in training of staff and has implemented policies to prevent the recurrence of the issues identified in this order. Respondent is actively engaged in the process of planning remodeling of the pharmacy suites at Women & Infants Hospital.

27. Respondent hereby acknowledges and waives:
   a) The right to appear personally or by counsel or both before the Board;
   b) The right to produce witnesses and evidence on its behalf at a hearing;
   c) The right to cross-examine witnesses;
   d) The right to have subpoenas issued by the Board and or 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 Board 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.

28. 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.

29. Acceptance by the Respondent and approval by the Department of this Consent Order constitutes an admission of the facts contained herein.

30. Respondent hereby agrees to a Formal Reprimand of its hospital pharmacy license.

31. That should Respondent violate the terms of this Consent Order, Respondent shall be subject to further disciplinary sanctions.

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Date

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Signature of Pharmacist-In-Charge
Women & Infants Hospital of RI
License # PHB00020
Michaels Smith, Pharm.D, BCPS, CACP

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Date

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Chairperson
Stacey Ramacci, BPharm, RPh
Rhode Island Board of Pharmacy

Ratified on this _16_ day of _June_, 2022.