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MEMORANDUM

TO: All Massachusetts Institutional Sterile Compounding Pharmacies

FROM: Massachusetts Board of Registration in Pharmacy (Board)
Bureau of Health Care Safety and Quality (BHCSQ)

DATE: November 19, 2024

SUBJECT: Institutional Sterile Compounding Pharmacy Licensure – Hospital and Clinic

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This memorandum is intended to inform all Massachusetts Institutional Sterile Compounding Pharmacies that the Department of Public Health's Massachusetts Board of Registration in Pharmacy (Board) is preparing to promulgate amendments to 247 CMR 6.00 (*Licensure of Pharmacies*), requiring Board licensure for all **institutional sterile compounding pharmacies**, pursuant to M.G.L. c.112, § 39I. Promulgation is expected in December, 2024, and the Board will begin accepting applications on **January 1, 2025**. The application must be submitted by **March 31, 2025.**

Once the Board has reviewed the application, an inspector will be in contact to arrange the initial on-site inspection(s). Please review the list of requirements below that will be necessary for the application and inspection processes.

An **Institutional Sterile Compounding Pharmacy** includes any sterile compounding pharmacy located within a healthcare facility (including, but not limited to hospitals, health maintenance organizations, and clinics) that holds either a **Hospital** or **Clinic MCSR** (Massachusetts Controlled Substances Registration). A separate Institutional Sterile Compounding Pharmacy license will be required for each unique Hospital or Clinic MCSR (i.e., each different physical address). Any other sterile compounding pharmacy area(s) under the same MCSR number will also require additional licensure.

Institutional nuclear medicine departments are not required to obtain Board licensure as they are not institutional pharmacies as defined by M.G.L. c.112, § 39D.

Please review the requirements below that will be necessary for the application and inspection processes, so that you can begin to collect and prepare these materials:

1. Hospital MCSR number or Clinic MCSR number.

2. Name of Manager of Record (MOR). This is the on-site pharmacist who is responsible for the operation of all sterile compounding pharmacy areas under the same MCSR.

3. Name of supervising pharmacist who is on-site at EACH sterile compounding area, as applicable.

4. List of all individuals who physically compound or directly supervise sterile compounding.

5. Certified blueprint/architectural drawing of EACH sterile compounding area.

6. Sterile Compounding Compliance Checklist for DRAFT sterile compounding regulations 247 CMR 17.00 for EACH sterile compounding area.

7. Completed Sterile Compounding Pharmacy Inspection Template for EACH sterile compounding area.

8. List of documents needed for inspection.

The initial on-site inspection will be announced and coordinated with each pharmacy to minimize impact on daily operations.

Please direct any questions to: Pharmacy.Admin@mass.gov