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TO: Institutional Sterile Compounding Pharmacies

FROM: Drug Control Program
Division of Health Care Facility Licensure and Certification
Board of Registration in Pharmacy

DATE: December 18, 2024

SUBJECT: Continuity of Care Guidance

The Massachusetts Department of Public Health, through the Board of Registration in Pharmacy (Board), Drug Control Program (DCP), and Division of Health Care Facility Licensure and Certification (DHCFLC) adopts this joint guidance to address options available when a specific institutional sterile compounding pharmacy temporarily cannot meet the compounded sterile preparation (CSP) needs of their patients. Such temporary incapacity can include, but is not limited to, clean room renovations, HVAC failure, gross contamination, etc.

All licensees must maintain full compliance with all federal and state laws, regulations, and policies, including, but not limited to 105 CMR 700.00, 247 CMR 2.00, *et seq.*, United States Pharmacopeia (USP), and M.G.L. c.94C and 112.

I. Definitions

- A. An **institutional sterile compounding pharmacy** is defined as a sterile compounding pharmacy located in a health care facility and is licensed pursuant to [M.G.L. c. 112 § 39I](#).
- B. A **health care facility** includes, but is not limited to, a Massachusetts-located hospital, health maintenance organization, or outpatient clinic licensed by DHCFLC.

II. Utilizing the Sterile Compounding Pharmacy of Another Health Care Facility

Unless otherwise authorized or prohibited, a health care facility's use of another health care facility's sterile compounding pharmacy may be permitted as a temporary continuity of care plan under the following conditions:

- A. A health care facility (renter) wishing to utilize the sterile compounding pharmacy in another health care facility (host) must implement a contract / agreement to use their compounding area and staff, as applicable. The contract / agreement shall address, at a minimum:
 - 1. Estimated time the renter will need use of the space. The maximum duration shall not exceed six (6) months.
 - 2. Each pharmacy's responsibilities for cleaning, environmental monitoring, etc.
 - 3. If the host allows access for the renter's staff to enter their pharmacy, address the times it is allowed as well as security measures.
 - 4. Renter staff responsibilities for glove/fingertip testing, media fill, etc.
 - 5. Transport of medications and the finished CSPs, including temperature monitoring / controls.
- B. In the scenario where the host's pharmacy staff compound for the renter, the contract/agreement between renter and host must ensure that they become agents of the renter for those purposes. Procedures must be in place so that the host's pharmacy staff person clearly understands when they are working either for the host or the renter.
- C. Procedures must be implemented to track and keep the renter's drugs, components, and CSPs physically and visually separated. Consider a separate storage space, separate refrigerated space, color coding, labeling, etc.

Please direct any questions to:

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[Division of Health Care Facility Licensure and Certification](#)