Massachusetts Board of Registration in Pharmacy

Frequently Asked Questions

Institutional Sterile Compounding

Issued July 2017

1. When will hospital pharmacies be licensed by the Board of Pharmacy and what licenses are needed?

Institutions must apply for Institutional Sterile Compounding Pharmacy Licenses once amendments to 247 CMR 6.00 are promulgated.

Please note, the Board will not license or oversee pharmacy areas that do not perform sterile compounding. See proposed revision to 247 CMR 6.00:
http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/alerts/247-cmr-6-6-25-15.pdf

2. What will the licensing process be like?

After amendments to 247 CMR 6.00 are promulgated, each institutional sterile compounding pharmacy will complete an application for an institutional sterile compounding pharmacy license. The application form will require the institution to describe its sterile compounding facility and operations. Board staff will review the information in order to determine whether the facility is in substantial compliance with USP and Board regulations. If the institutional sterile compounding pharmacy appears to be in substantial compliance based on the paperwork, the Board will issue a "provisional" license effective for one year or until the pharmacy achieves a successful Board inspection, whichever period is shorter. Upon successful inspection, the facility will be granted a full institutional sterile compounding license.

3. Will waivers be allowed?

An institutional sterile compounding pharmacy may apply for a waiver of Board regulations in accordance with 247 CMR 14.00. Please note the Board is not able to grant waivers for statutory requirements. For instance, the requirement to follow all chapters of USP is in state law and cannot be waived by the Board of Pharmacy. See M.G.L. c. 112, § 39I.

4. Since the Board does not issue compounding licenses yet, how do I get my clean room design plan approved?

Until Board of Pharmacy licensure occurs, the Bureau of Health Care Safety and Quality will continue to approve all plans. The Bureau of Health Care Safety and Quality currently seeks Board of Pharmacy input as needed. If the facility has questions about future Board of Pharmacy requirements, Board staff are available to provide guidance.

5. Where can I find an updated copy of the proposed sterile compounding regulations?

The draft of 247 CMR 17.00 may be found at the following link:
http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/draft-regulations.html

6. When will 247 CMR 17.00 be finalized?

247 CMR 17.00 is expected to be offered for public comment sometime in the fall of 2017. Final promulgation will not occur until after the Board considers all comments, makes any changes, and takes a final vote.

7. Must we comply with 247 CMR 17.00 now?

Board regulation 247 CMR 17.00 has not been promulgated and is therefore not in effect. At this time, sterile compounders must be in compliance with all current chapters of USP. The Board suggests pharmacies use the draft 247 CMR 17.00 as guidance. Board of Registration in Pharmacy staff are available to provide guidance on proposed renovation projects in relation to the proposed regulations.

8. Please address the room size requirement in 247 CMR 17.00.

Board staff are aware of space constraints in institutions. If this standard is finalized in the regulation, the Board will consider waivers of square footage as long as the pharmacy maintains policies and procedures to mitigate risk to the compounded sterile products.

9. Where can pass-throughs be located?

As it exists in the current draft of 247 CMR 17.00, pass-throughs are only permitted from:

ISO Class 7 buffer room to ISO Class 8 area or better; or

ISO Class 8 area to unclassified space or better; or

ISO Class 7 ante room to unclassified space or better.

If this standard is finalized in the regulation, the Board may consider waivers if the pharmacy maintains policies and procedures to mitigate risk to the compounded sterile products.

10. What is a DCR (dedicated compounding room)?

As proposed in the current draft of 247 CMR 17.00, a DCR is an ISO 8 classified room permitted only in institutions, where non-hazardous, low risk level compounded sterile products may be prepared. This

differs from a segregated compounding area as defined in USP <797> since a DCR would be classified as ISO 8 or better and a segregated compounding area space would be unclassified space.

11. How will the Board of Pharmacy reduce duplication with the Bureau of Health Care Safety and Quality?

Pharmacy Board staff are collaborating with Bureau of Health Care Safety and Quality to streamline reporting requirements as well as inspectional roles. Massachusetts General Law requires Board staff to inspect each sterile compounding pharmacy it licenses at least once yearly. See M.G.L. c. 112, § 39I.

12. Do I need to submit forms such as the *Sterile Compounding Reporting Form* and the *Above Action Level Reporting Forms?*

Until institutional sterile compounding pharmacies receive a license issued by the Board of Pharmacy, these forms do not need to be submitted.

13. How can I prepare for a Board of Pharmacy inspection?

The current inspection forms are posted on the website and are available for your review. Scrutiny of the tool will show you what inspectors will be looking for as well as which documents you should have available. The USP <797> Inspection Tool can be found here:
http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/dhpl/pharmacy/pharmacy-practice/