The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
100 Cambridge Street, 19th floor, Boston, MA 02114-2509
https://www.mass.gov/orgs/board-of-registration-in-pharmacy

Board of Registration in Pharmacy

Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage

The Renovation Amendment application is required for **all resident pharmacies and non-resident sterile compounding pharmacies** and must be submitted at least 30 days prior to the anticipated start date of the proposed modifications.

The application is required for pharmacy modifications involving:

1. construction that remodels or changes the configuration or square footage of any licensed pharmacy areas (includes the addition of any access points such as a door);
2. addition of contiguous or non-contiguous pharmacy areas (e.g., immunization room, Automated Pharmacy System, counseling room, etc.); and
3. moving, removing, adding, modifying, or replacing of any secondary engineering control in a compounding pharmacy.

The application is not needed if work is done in response to an urgently needed repair or service (e.g., damage from a broken pipe, storm-related repairs, HVAC system malfunction, etc.). However, the Board must be notified by email as soon as possible.

This application is not needed for work, repairs, and/or service if the work, repairs, and/or service do not require an application as outlined in the section above and all related documentation is maintained in the pharmacy's records and available for Board inspection.

Institutional Sterile Compounding Pharmacies must submit the renovation application to the Board. Renovations must comply with any municipal / state code requirements as well as the FGI *Guidelines for Design and Construction*.

If the proposed renovation will impact any licensed space beyond the Board-licensed Institutional Sterile Compounding Pharmacy area, then DPH Plan Review is also required. For renovations requiring DPH Plan Review, the Plan Review Unit will communicate their approval to the institution. Final approval will be issued by the Board, but only after the Plan Review Unit has issued their approval.

For the application, you will need:

- projected start and completion dates
- narrative of all proposed changes including any square footage changes
- if renovating/expanding within in any healthcare facility, documentation of approval from the facility's licensing body(s)
- documentation as required below

☐ **Retail Pharmacies must submit:**

□ Architectural drawing or certified blueprint (*see page 3 for details*).
□ Containment strategy / risk mitigation plan.
□ A written plan to maintain security of controlled substances.

☐ **Sterile Compounding (including institutional) must submit:**

□ Architectural drawing or certified blueprint (*see page 4 for details*).
□ Sterile Compounding Pharmacy Compliance checklist (*pages 5 - 8*).
□ Containment strategy / risk mitigation plan.
□ Environmental monitoring plan.
□ Plan to recertify primary and secondary engineering controls.
□ Continuity of care plan.

☐ **Complex Non-Sterile Compounding must submit:**

□ Architectural drawing or certified blueprint (*see page 3 for details*).
□ Containment strategy / risk mitigation plan.
□ Plan to recertify any containment hoods.
□ Continuity of care plan.

☐ **Nuclear Pharmacies must submit:**

□ Architectural drawing or certified blueprint (*see page 4 for applicable details*).
□ Sterile Compounding Pharmacy Compliance checklist (*pages 5 - 8*).
□ Containment strategy / risk mitigation plan.
□ Environmental monitoring plan for sterile compounding areas.
□ Plan to recertify any primary and secondary engineering controls including any containment hood(s).
□ Continuity of care plan.

Architectural Drawing / Certified Blueprint Requirements

Architectural drawings / certified blueprints not meeting these requirements will not be accepted.

***** A certified blueprint is one that has been signed and sealed by the architect.

**** DO NOT** include areas such as consultation/immunization rooms, front store area, offices, or restrooms in the proposed licensed square footage total.

Retail Pharmacy	**Outline the current layout in BLUE and proposed pharmacy layout outlined in RED, drawn to scale with the following items clearly labeled on the document.** 1. prescription area (proposed licensed area) 2. square footage [at least 325 square feet as required by 247 CMR 9.19(2)] 3. patient consultation area 4. Automated Pharmacy System (APS) location, if applicable; 5. drop off and pickup windows 6. pick-up bins 7. refrigerator 8. sink 9. designated non-sterile compounding area (draft 247 CMR 18.00 proposes to require 10 square feet of counter space for non-sterile compounding) 10. legend explaining all abbreviations 11. other pertinent details
Complex Non-Sterile Compounding	**Outline the current layout in BLUE and proposed pharmacy layout outlined in RED, drawn to scale with the following items clearly labeled on the document.** 1. proposed pharmacy layout, including square footage of each room 2. designated non-sterile compounding area and/or dedicated compounding room(s) 3. location of containment hood(s), as applicable 4. sink(s) 5. HVAC details (ACPH, negative pressure, externally vented, etc.), as applicable for hazardous compounding area(s) in compliance with USP <800> 6. hazardous drug storage area, as applicable 7. legend explaining all abbreviations 8. any other pertinent details

Sterile Compounding	**Outline the current layout in BLUE and proposed pharmacy layout outlined in RED, drawn to scale with the following items clearly labeled on the document. Do NOT send certification reports.** 1. proposed pharmacy layout, including square footage of each room 2. location and ISO classification of each primary and secondary engineering control (PEC and SEC) 3. HVAC details (ACPH, positive/negative pressure, etc.) in compliance with USP <797> and/or <800> location 4. differential pressures from most recent certification 5. sink(s) 6. any pass-throughs 7. hazardous drug storage area, as applicable 8. legend explaining all abbreviations 9. any other pertinent details
Nuclear Pharmacy	**Outline the current layout in BLUE and proposed pharmacy layout outlined in RED, drawn to scale with the following items clearly labeled on the document. Do NOT send certification reports.** 1. proposed pharmacy layout, including square footage of each room 2. non-sterile compounding room, including placement of containment / fume hood(s), as applicable 3. location and ISO classification of each primary and secondary engineering control (PEC and SEC) 4. HVAC details for compounding area(s) (ACPH, positive/negative pressure, etc.) in compliance with USP <825> 5. differential pressures from most recent certification 6. sink(s) 7. any pass-throughs 8. legend explaining all abbreviations 9. any other pertinent details

Sterile Compounding Pharmacy Compliance

If the proposed design meets the listed requirement, please indicate by placing "Y" (yes) or "N" (no) and include comments as to the reason for the non-compliance and plans to mitigate. If not applicable, indicate with "N/A".

Please note that this is not an all-inclusive list of proposed standards in Draft 247 CMR 17.00 or the requirements of USP. At a minimum, applicants are required to adhere to the standards set forth in the most recent version of USP <797> and USP <800>. It is the responsibility of the applicant to be familiar with the requirements set forth in USP chapters and the Board's regulations.

Draft 247 CMR 17.00	Citation	Y/N	Comments
Miscellaneous:			
A pharmacy may not compound non-sterile preparations in any Primary Engineering Control (PEC) or Secondary Engineering Control (SEC) used for sterile compounding.	17.03(8)		
A pharmacy shall have a dedicated changing area for sterile compounding personnel.	17.04(2)		
Primary Engineering Controls (PECs):			
A pharmacy shall utilize only commercially manufactured PECs.	17.06(1)		
All Secondary Engineering Controls (SECs):			
The doors leading into and between ISO Classified SECs shall be constructed with an interlocking design or utilize an alternative method to ensure that doors are not opened simultaneously.	17.07(1)(c)		
Unless prohibited by local building or fire code, an SEC may not have more than one door to immediately adjacent areas.	17.07(1)(b)		

Each newly constructed SEC shall allow for visual observation through windows or technology.	17.07(1)(a)		
SECs may not contain windows to the outdoors.	17.07(1)(k)		
A pharmacy shall ensure that any pass-through chambers: a. have an interlocking door design; and b. are not refrigerator units.	17.04(1)		
Walls shall be made of solid surface materials such as locking sealed panels or epoxy-coated gypsum board.	17.07(1)(j)		
Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter.	17.07(1)(h)		
SECs shall utilize light fixtures designed for sterile compounding areas (i.e., cleanroom grade) that have an exterior surface that is smooth, mounted flush with the ceiling, and sealed.	17.07(1)(g)		
Sprinkler heads shall be recessed, covered, and easily cleanable.	17.07(1)(i)		
Floors shall be composed of wide sheet vinyl that is heat sealed at the seams, or other solid, smooth surface, and coved at the wall or appropriately sealed.	17.07(1)(l)		
SECs may not contain floor drains.	17.07(1)(f)		
A pharmacy may not locate a refrigerator in any ISO Classified SEC.	17.07(1)(e)		
A pharmacy may not use ISO Classified areas for drug storage.	17.04(3)		
Ante Rooms:			
A newly constructed ante room shall be at least 72 square feet.	17.07(3)(a)		
For hand hygiene, an anteroom shall have a stainless-steel sink that is located on the clean side of the line of demarcation at	17.07(3)(b)		

least one meter away from the buffer room door.			
The stainless-steel sink shall: i. be equipped with hands-free controls for water and soap dispensing; ii. have proper depth and capacity for hand washing up to the elbows; iii. minimize splashing and dripping of water; iv. be designed to prevent standing water; and v. have a faucet that does not have an aerator mechanism on the nozzle.	17.07(3)(c)		
An ante room shall have low-lint, disposable towels located in close proximity to the sink.	17.07(3)(d)		
Buffer Rooms:			
A newly constructed **non-hazardous drug** buffer room shall be at least 100 square feet.	17.07(2)(a)		
A newly constructed **hazardous drug** buffer room shall be at least 72 square feet.	17.07(2)(b)		
Buffer room doors shall be hands-free.	17.07(2)(c)		
HVAC			
Newly constructed ISO Classified SECs shall utilize a closed loop ducted system, a sealed plenum system, or equivalent HVAC design.	17.05(1)		
Supply air provided for each ISO Classified SEC shall be provided exclusively through ceiling mounted HEPA filters.	17.05(3)		
Air returns in ISO Classified SECs shall be mounted low on the walls	17.05(4)		
If utilized, relief air vents shall be mounted low on the wall and designed to prevent the	17.05(5)		

ingress of less clean air or contaminants from adjacent areas.			
Temperature/Humidity			
A pharmacy shall have a system to continuously measure the temperature and humidity of each SEC. The quantitative results shall be reviewed and documented at least daily on all days the pharmacy is open.	17.10(3)		
SECs shall maintain a temperature of 68 degrees Fahrenheit (20 degrees Celsius) or lower.	17.10(1)		
SECs shall maintain relative humidity of 60% or lower.	17.10(2)		