Massachusetts Board of Registration in Pharmacy
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(617) 973-0960

# Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage

**Pharmacy Name** _____MA License Number_____
Pharmacy Address _____
City/Town _____State_____ Zip Code _____
Pharmacy Tel. No. _____Pharmacy Fax No._____
Pharmacy E-mail _____
Name of Manager of Record (MOR) (print)_____
MOR MA License Number_____
MOR Email_____

***Please contact the Board with any questions.**

## This application is required for pharmacy modifications involving:

1. remodeling or change in 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 unlicensed pharmacy areas (e.g. immunization room, counseling room, etc.); and
3. moving, removing, adding, modifying, or replacing of any secondary engineering control in a compounding pharmacy.

## This application is not needed for work, repairs, and/or service if:

1. done in response to an urgently needed repair or service (e.g. damage from a broken pipe, storm-related repairs, HVAC system malfunction, etc.) and the Board is notified by email as soon as possible;
2. done in response to a deficiency cited during an inspection and has been detailed in a submitted plan of correction;
3. the work, repairs, and/or service do not require an application as outlined in the section above; and
4. all related documentation is maintained in the pharmacy's records and available for Board inspection.

## What are the projected start and completion dates?

## Describe all proposed changes including any square footage changes.

Attach additional sheets as needed and applicable documents as below.

☐ **Retail Pharmacies (Drug Stores) must submit:**

- □ Blueprints or architectural drawing depicting (electronic format only):
  a. current layout outlined in blue and proposed pharmacy layout outlined in red, including square footage of the licensed space;
  b. prescription area;
  c. counseling area;
  d. a legend explaining all abbreviations; and
  e. other pertinent details.
- □ Containment strategy / risk mitigation plan.
- □ A written plan to maintain security of controlled substances.

☐ **Sterile Compounding Pharmacies must submit:**

- □ Certified blueprints depicting (electronic format only):
  a. current layout outlined in blue and proposed pharmacy layout outlined in red, including square footage of each room;
  b. a legend explaining all abbreviations;
  c. location and ISO classification of each primary and secondary engineering control;
  d. air flow;
  e. room pressurization;
  f. HVAC details;
  g. location of any pass-throughs; and
  h. other pertinent details.
- □ Containment strategy / risk mitigation plan.
- □ Environmental monitoring plan.
- □ Plan to recertify primary and secondary engineering controls.
- □ Continuity of care plan.

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

- □ Certified blueprints depicting (electronic format only):
  a. current layout outlined in blue and proposed pharmacy layout outlined in red, including square footage of each room;
  b. a legend explaining all abbreviations;
  c. placement of containment hood(s), as applicable;
  d. room pressurization, as applicable;
  e. HVAC details, as applicable; and

f. other pertinent details.

□ Containment strategy / risk mitigation plan.
□ Plan to recertify any containment hoods.
□ Continuity of care plan.

☐ **Nuclear Pharmacies must submit:**

□ Certified blueprints depicting (electronic format only):
a. current layout outlined in blue and proposed pharmacy layout outlined in red, including square footage of each room;
b. a legend explaining all abbreviations;
c. location and ISO classification of each primary and secondary engineering control in the sterile compounding areas;
d. placement of containment hood(s) in the non-sterile compounding area(s), as applicable;
e. air flow;
f. room pressurization;
g. HVAC details;
h. location of any pass-throughs in the sterile compounding areas; and
i. other pertinent details.

□ 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.

**As the MOR, I understand and attest that:**

1. The work cannot begin until approved by the Board of Registration in Pharmacy.
2. Any changes to the approved application require approval by the Board of Registration in Pharmacy.
3. It is my responsibility to assure that adequate measures are in place to maintain the security of all controlled substances at all times during the work.
4. It is my responsibility to comply with all state / local building codes as they relate to this pharmacy.
5. It is my responsibility to assure that primary and secondary engineering controls are properly tested and recertified prior to reengaging in compounding activities, as applicable.
6. I will notify the Board when the work will be completed or if it will not be completed within the estimated timeline.

7. All related documentation will be maintained in the pharmacy's records and available for Board inspection.

**MOR Name (print): _____**

**MOR Signature: _____ Date: _____**