The Commonwealth of Massachusetts
Board of Registration in Pharmacy
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Pharmacy Application Checklist

Pharmacy applications must be approved by the Board of Registration in Pharmacy (Board), and the pharmacy must have received a satisfactory inspection before a license to operate may be issued. Retain a copy of the completed checklist, applications, and supporting documents for your records. Submitted applications are only valid for 1 year.

Transfer of Ownership:

Transfer of ownership occurs when pharmacy ownership will change to a person or entity other than the person or entity who was listed on the initial registration application. The Board views a transfer of ownership as the closing of one pharmacy and the opening of a new pharmacy.

The **outgoing licensee** must notify the Board of the proposed transfer of ownership of a licensed pharmacy at least 14 days prior to the transfer using the closing of a pharmacy form in the licensing system. The outgoing licensee must comply with transfer of ownership and pharmacy closure requirements (including the distribution of controlled substances) outlined in 247 CMR 6.00.

The **proposed new licensee** must apply for a new pharmacy license at least 14 days prior to the transfer of ownership, however the application should be submitted at least 45 days in advance to allow for timely review.

Drug Store Pharmacy:

☐ A completed Drug Store Pharmacy Application fully and properly completed and signed by the Manager of Record (MOR) who is to manage and operate the pharmacy.

☐ The $750 fee. **NOTE**: **Fees are non-refundable and non-transferable.**

☐ Pharmacy hours during which the pharmacy is to remain open, including the time of opening and closing for each day of the week.

☐ A copy of the Articles of Organization.

Pharmacy Name: _____

☐ Blueprint or architectural drawing. See *Requirements for Certified Blueprints/Architectural Drawings* on pages 4-5.

☐ If a Drug Store pharmacy is proposing to locate within any healthcare facility, documentation of approval from the facility's licensing body(s) must be attached. (Not required if an existing retail pharmacy is transferring ownership but will continue to operate as a retail pharmacy using a similar business model and must be located in the exact same space.)

☐ If applicable, a completed Petition for a Waiver for each regulation and section the pharmacy is requesting to be waived. Waivers are not transferable. New petitions for waivers must be submitted in the case of transfer of ownership.

☐ If applicable, items from the Sterile Compounding Pharmacy Checklist below.

☐ If applicable, items from the Complex Non-Sterile Compounding Pharmacy Checklist below.

Sterile Compounding Pharmacy:

☐ All items listed from the Drug Store Pharmacy Checklist above.

☐ Attestation of Intent to Conduct Sterile Compounding completed and signed by the Manager of Record.

☐ Certified blueprint. See *Requirements for Certified Blueprints / Architectural Drawings* on pages 4-5.

☐ Detailed description of the HVAC system.

☐ Compliance Checklist for DRAFT sterile compounding regulations 247 CMR 17.00 on pages 6-8.

Complex Non-Sterile Compounding Pharmacy:

☐ All items listed from the Drug Store Pharmacy Checklist above.

☐ Attestation of Intent to Conduct Complex Non-Sterile Compounding completed and signed by the Manager of Record.

☐ Certified blueprint. See *Requirements for Certified Blueprints / Architectural Drawings* on pages 4-5.

☐ Detailed description of the HVAC system to include temperature, humidity, and pressurization, as applicable.

☐ Review DRAFT non-sterile compounding regulations 247 CMR 18.00.

Nuclear Pharmacy:

☐ A completed Nuclear Pharmacy Application fully and properly completed and signed by the Manager of Record (MOR) who is to manage and operate the pharmacy.

☐ The $750 fee. **NOTE**: **Fees are non-refundable and non-transferable.**

☐ Pharmacy hours during which the pharmacy is to remain open, including the time of opening and closing for each day of the week.

☐ A copy of the Articles of Organization.

☐ If proposing to locate within any healthcare facility, documentation of approval from the facility's licensing body(s) must be attached.

☐ If applicable, a completed Petition for a Waiver for each regulation and section the pharmacy is requesting to be waived. Waivers are not transferable. New petitions for waivers must be submitted in the case of transfer of ownership.

☐ Copy of DPH Radiation Control Program (RCP) license.

☐ Certified blueprint. See *Requirements for Certified Blueprints / Architectural Drawings* on page 5.

☐ Detailed description of the HVAC system. Include non-sterile compounding room(s), as applicable.

Requirements for Certified Blueprints/Architectural Drawings

Blueprints not meeting the requirements below will not be accepted.

Drug Store Pharmacy	**A blueprint/architectural drawing with the proposed prescription area outlined in RED, drawn to scale with the following items clearly labeled:** 1. prescription area (proposed licensed area) 2. square footage* 3. legend explaining all abbreviations 4. patient consultation area 5. drop off and pickup windows 6. pick-up bins 7. refrigerator 8. safe 9. sink 10. designated non-sterile compounding area (draft 247 CMR 18.00) will require 10 square feet of counter space for non-sterile compounding) 11. other pertinent details *** DO NOT include areas such as consultation/immunization rooms, front store area, offices, or restrooms in the proposed licensed square footage total.**
Complex Non-Sterile Compounding Pharmacy	**A certified blueprint** with the proposed prescription area outlined in RED, drawn to scale with the following items clearly labeled:** 1. all requirements listed above for Drug Store Pharmacy 2. designated non-sterile compounding area, if applicable 3. dedicated compounding room(s), including placement of containment hood(s), as applicable, and sink(s) 4. detailed HVAC design plan, as applicable 5. hazardous drug storage area, if applicable 6. other pertinent details
Sterile Compounding Pharmacy	**A certified blueprint** with the proposed prescription area outlined in RED, drawn to scale with the following items clearly labeled:** 1. all requirements listed above for Drug Store Pharmacy 2. proposed pharmacy layout, including square footage of each room 3. location and ISO classification of each primary and secondary engineering control 4. detailed HVAC design plan 5. air flow 6. room pressurization 7. sink 8. any exposed plumbing system pipes within ISO classified areas 9. any pass-throughs 10. hazardous drug storage area, if applicable 11. other pertinent details

Pharmacy Name: _____

Nuclear Pharmacy	**A <u>certified blueprint</u>** with the proposed prescription area outlined in RED, drawn to scale with the following items clearly labeled:** 1. proposed pharmacy layout, including square footage of each room (DO NOT include areas such as offices or restrooms in the proposed licensed area) 2. non-sterile compounding room, including placement of containment / fume hood(s), as applicable 3. legend explaining all abbreviations 4. refrigerator, if applicable 5. safe, if applicable 6. location and ISO classification of each primary and secondary engineering control 7. detailed HVAC design plan (include non-sterile compounding room(s), as applicable) 8. air flow 9. room pressurization 10. sink(s) 11. any exposed plumbing system pipes within ISO classified areas 12. any pass-throughs 13. drug storage area 14. other pertinent details

**** A certified blueprint must be stamped with an architect's seal along with the architect's signature.**

Compliance Checklist

If the proposed design of the sterile compounding area(s) 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 "NA".

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 least one meter away from the buffer room door.	17.07(3)(b)		
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 ingress of less clean air or contaminants from adjacent areas.	17.05(5)		
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)		