The Commonwealth of Massachusetts Executive Office of
Health and Human Services Department of Public Health
Bureau of Health Professions Licensure

**Board of Registration in Pharmacy**
**250 Washington Street**
**Boston, MA 02108-4619**
pharmacy.admin@mass.gov
*(800) 414-0168 (office) / 617-973-0980 (fax) / (617) 973-0895 (TTY)*

# APPLICATION FOR REGISTRATION TO MANAGE AND OPERATE A NEW COMMUNITY PHARMACY WITHIN MASSACHUSETTS*

**Instructions:**

Use this application to be issued a permit to manage and operate a pharmacy. The Massachusetts registered pharmacist who is responsible for the management and operation of the pharmacy must complete this application for registration to manage and operate a pharmacy and submit it to the Board before the pharmacy can operate.

*Non-resident pharmacy licensure is not yet available.

The forms and documents listed below must accompany each application.

**Checklist:**

_____ A completed checklist and application form, fully and properly completed and signed by the pharmacist who is to manage and operate the pharmacy.

_____ A statement of the scheduled hours during which the pharmacy is to remain open, including the time of opening and closing during regular business hours for each day of the week.

_____ The new pharmacy fee of **$525** payable by check or money order to the *Commonwealth of Massachusetts* NOTE: Cash or foreign currency is not accepted. **This fee is non-refundable and non-transferable.**

_____ An application for a Massachusetts controlled substance registration. Include a check or money order payable to the *Commonwealth of Massachusetts* for **$225**. Cash or foreign currency is not accepted. **This fee is non-refundable and non-transferable.**

_____ Blueprint or architectural drawing: see below for Requirements for Certified Blueprints/Architectural Drawings

_____ 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.

_____ A copy of the corporation's Articles of Organization signed and sealed by the Secretary of State if the corporation is incorporated in the Commonwealth.

_____ If the corporation in incorporated is in another state, submit a copy of the corporation's Foreign Corporation Certificate, signed and sealed by the Secretary of State pursuant to M.G.L. c.181, § 4.

_____ A statement of the name and address of each officer and director of the corporation and the position held.

_____ The d/b/a name of the business.

_____ If the corporation is not publicly owned, list the total amount and type of stock issued to each stockholder and the names and addresses of said stockholder(s).

For complete information regarding registration of a new pharmacy, please refer to 247 CMR 6.00. All Board regulations may be found at https://www.mass.gov/law-library/247-cmr

**All fees are non-refundable and non-transferable.**

**Please be advised that no pharmacy shall begin to operate until the application has been approved by the Board and:**

1) **The pharmacist Manager of Record has received from the Board a permit number to manage and operate the pharmacy.**
2) **The pharmacy has received a controlled substances registration number.**

To obtain a DEA number, please contact the Drug Enforcement Administration (DEA) office for an application:

J.F.K. Federal Building
Drug Enforcement Administration
Room E400
15 New Sudbury Court
Boston, MA 02203-0131
(617) 557-2200

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# APPLICATION TO MANAGE AND OPERATE A NEW COMMUNITYPHARMACY IN MASSACHUSETTS

***TO BE COMPLETED BY BOARD***

CHECK/M.O. $_____ DATE_____

CHECK/M.O. NO._____RECEIPT NO._____APP NO._____

I hereby apply for a permit to operate a store for the transaction of retail drug business in accordance with the provisions of Chapter 112, General Laws.

**$525.00 licensure / application fee**. Make check or money order payable to the *Commonwealth of Massachusetts*. **This fee is non-refundable and non-transferable.**

1. Legal Name of Business._____

2. Full Business Address (Street Address, City, State and Zip)._____
_____

3. Area Code and Telephone Number._____

4. All trade or business names ("D.B.A." names) used by same Corporation or by License._____
_____
_____

5. E-mail address for this community pharmacy: _____

6. Type of ownership or operation (i.e., sole proprietorship, partnership, corporation)._____
_____
If corporation, please submit articles of corporation signed and sealed by the Secretary of State if the corporation is incorporated in the Commonwealth; if the corporation in incorporated is in another state, please submit the corporation name, website and phone number.

7. Name and phone number of the contact person for questions regarding this application

_____

8. Names(s) and Social Security Number(s) of the owner(s) and/or operator(s) of the licensee. *Please indicate type of ownership - Partnerships: the name of each partner and name address of partnership; Corporations: the name and title of each corporate officer and director, the corporate names, name and address of parent company, if any, and the State of incorporation; Sole Proprietorship: the name of the sole proprietor and the address of the business entity*

_____

_____

**Name of registered pharmacist charged with the management of the pharmacy (MOR)**_____

License/Registration number of MOR_____

Has the proposed MOR met all the continuing education requirements of the MA Board of Registration in Pharmacy for the last two years? YES NO (circle one)

NABP ID:_____

Name(s) and registration number(s) of staff pharmacist(s) employed at pharmacy._____

_____

_____

9. (a) Have any of the applicant(s) and/or managers-in-charge had: 1) any convictions related to the distribution of drugs (including samples); 2) any felony convictions; 3) any suspension(s) or revocation(s) or other sanction(s) by federal, state or local governmental agency of any license or registration currently or previously held by the applicant or license for the manufacture, distribution, or dispensing of any drugs, including controlled substances?
Yes_____No _____

If yes, provide a full explanation. (Attach additional sheets if necessary)

_____

_____

(b) Have any applications for licensure been denied by any federal or state agency including any state board of pharmacy? List and explain. (Attach additional sheets if necessary)

_____

_____

10. The applicant/licensee must notify the Board in writing of any changes in ownership or management within thirty (30) days of such change(s).

11. Social Security Number of the Pharmacy Manager (**Mandatory**)._____
Pursuant to M.G.L. c. 62C, § 47A, the Bureau of Health Professions Licensure is required to obtain your social security number and forward it to the Department of Revenue. The Department of Revenue will use your social security number to ascertain whether you are in compliance with the tax laws of the Commonwealth.

12. List any licenses/certifications held by the Pharmacy Manager in the United States or any country or foreign jurisdiction and the state/jurisdiction from which the license/certification was originally issued. Please include a certificate of standing from each state or jurisdiction in which you are licensed/certified in a signed sealed envelope. The verification must indicate the status of your license and any relevant disciplinary information. (Attach additional sheets if necessary)_____

13. Has any disciplinary action been taken against you by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes_____ No_____ If yes, please state the details (Attach additional sheets if necessary)

14. Are you the subject of pending disciplinary actions by a licensing/certification board located in the United States or any country or foreign jurisdiction? Yes_____No _____

If yes, please state the details (Attach additional sheets if necessary)_____

15. Have you ever voluntarily surrendered or resigned a professional license to a licensing/certification board in the United States or in any country or foreign jurisdiction? Yes_____No _____

If yes, please state the details (Attach additional sheets if necessary)_____

16. Have you ever applied for and been denied a professional license in the United States or any country or foreign jurisdiction? Yes_____No _____

If yes, please state the details (Attach additional sheets if necessary)_____

17. Pursuant to Board Regulations at 247CMR 6.01(3), **The Board shall not register nor permit ownership of a pharmacy by a practitioner with prescriptive privileges**. By signing this application, the applicant certifies that none of the owners, directors or officers has prescriptive privileges.

## AFFIDAVIT (MUST BE COMPLETED AND NOTARIZED)

Pursuant to M.G.L. c. 62C, § 49A, I certify under the penalties of perjury that I, to the best of my knowledge and belief, have filed all state tax returns and paid all state taxes required under law.

The applicant certifies that each person employed in any prescription drug distribution activity has the education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety, and security will at all times be maintained as required by law.

I hereby state that I am the person authorized to sign this application for all licensure; that all statements are true and correct in all respects and are made under the penalties of perjury.

_____

Signature of pharmacist who is to manage the pharmacy

Date Sworn and subscribed before me this___day of _____

Notary Public signature ____

*Notary Seal*

My commission expires ____

# Requirements for Certified Blueprints/Architectural Drawings

| | |
|---|---|
| **Retail Drugs Store Simple and Moderate compounding only** | **A <u>certified blueprint/architectural floor plan**</u>with the pharmacy outlined in RED, drawn to scale with the following items clearly labeled:**<br>**1. square footage***<br>**2. prescription area**<br>**3. patient consultation area**<br>**4. drop off and pickup windows**<br>**5. pick-up bins**<br>**6. refrigerator**<br>**7. safe**<br>**8. sink**<br>**9. non-sterile compounding counter** |
| **Complex Non-Sterile** | **A <u>certified blueprint/architectural floor plan**</u> with the pharmacy outlined in RED, drawn to scale with the following items clearly labeled:**<br>**1. square footage***<br>**2. prescription area**<br>**3. patient consultation area**<br>**4. drop off and pickup windows**<br>**5. pick-up bins**<br>**6. refrigerator**<br>**7. safe**<br>**8. sink**<br>**9. non-sterile compounding counter and**<br>**10. hazardous drug storage, if applicable**<br>**11. the designated dedicated compounding room, including placement of containment hood(s)**<br>**12. detailed HVAC design plan and written description** |
| **Sterile Compounding** | **A <u>certified blueprint/architectural floor plan</u>** with the pharmacy outlined in RED, drawn to scale with the following items clearly labeled.**<br>**1. square footage***<br>**2. prescription area**<br>**3. patient consultation area**<br>**4. drop off and pickup windows**<br>**5. pick-up bins**<br>**6. refrigerator**<br>**7. safe**<br>**8. sink**<br>**9. non-sterile compounding counter**<br>**10. hazardous drug storage, if applicable**<br>**11. proposed pharmacy layout outlined in red, include square footage of each room**<br>**12. a legend explaining all abbreviations**<br>**13. location and ISO classification of each primary and secondary engineering control**<br>**14. air flow**<br>**15. room pressurization**<br>**16. HVAC details**<br>**17. location of any pass-throughs**<br>**18. other pertinent details** |

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

**** A Certified Blueprint/Architectural floor plan must be stamped with a architect's seal along with the architects signature.**

**MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY**

**All pharmacies are expected to engage in non-sterile compounding (except complex level) to meet the needs of the community to be served.**

**If a pharmacy does NOT plan to engage in non-sterile compounding, a petition for waiver must be submitted for the Board's consideration.**

## Attestation of Intent to Conduct COMPLEX Non-Sterile Compounding

All pharmacies licensed by the Massachusetts Board of Registration in Pharmacy (Board) that perform **complex non-sterile compounding** are required to prepare and dispense medications in compliance with state and federal laws and regulations, and all chapters of the United States Pharmacopeia (USP) including <795>, Pharmaceutical Compounding – Nonsterile Preparations and <800>, Hazardous Drugs – Handling in Healthcare Settings.

**Pharmacies applying to perform Complex Non-Sterile Compounding are required to submit this completed Attestation of Intent to Conduct Complex Non-Sterile Compounding as part of a complete application.**

**Complex non-sterile compounding**: compounding of drug preparations which requires special training, special environment, special facilities or equipment, or the use of compounding techniques and procedures that may present an elevated risk to the compounder or the patient.

https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section39D

For more information on non-sterile compounding and examples of complex non-sterile compounds, please review the Board's *Advisory on Levels of Non-Sterile Compounding*:

https://www.mass.gov/lists/pharmacy-practice-resources

As Manager of Record, I understand and attest under the pains and penalties of perjury that:

1. Employees engaged in or overseeing complex non-sterile compounding will be / have been trained in LEAN concepts, which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency, before a Complex Non-Sterile Compounding Pharmacy license or Non-Resident Complex Non-Sterile Compounding pharmacy license may be renewed.

2. I have completed continuing education requirements for complex non-sterile compounding in accordance with 247 CMR 4.03(4)(c) and that all pharmacy staff engaged in or overseeing complex non-sterile compounding have received the appropriate training and education required by law and regulation before engaging in compounding.

3. The pharmacy will only dispense medication pursuant to a valid prescription as defined in

M.G.L. c. 94C, §19 for a single patient for any medications dispensed into or from Massachusetts.

4. If the pharmacy knows or should have reason to know that a compounded drug preparation dispensed into or from Massachusetts by the pharmacy is or may be defective in any way, the pharmacy shall immediately recall the drug preparation in accordance with M.G.L. c. 112, § 39D(e).

5. The pharmacy shall comply with all Massachusetts and federal laws and regulations governing the practice of pharmacy and USP <795> and USP <800>.

Print Name of Manager of Record (MOR): _____

Signature of MOR: _____

MA Pharmacist License #_____

MOR E-mail _____

Date: _____

# Attestation of Intent to Conduct STERILE Compounding

All pharmacies licensed by the Massachusetts Board of Registration in Pharmacy (Board) that perform **sterile compounding** are required to prepare and dispense medications in compliance with state and federal laws and regulations, and all chapters of the United States Pharmacopeia (USP) including <797>, Pharmaceutical Compounding – Sterile Preparations, and <800>, Hazardous Drugs – Handling in Healthcare Settings.

**Pharmacies applying to perform Sterile Compounding are required to complete and submit this Attestation of Intent to Conduct Sterile Compounding as part of a complete application.**

M.G.L. c. 112, § 39D defines **sterile compounding** as the engagement in the compounding of a sterile drug preparation. A sterile drug preparation is a compounded biologic, diagnostic, drug, nutrient or radiopharmaceutical, which under chapter <797> of the USP must be compounded using aseptic techniques. Sterile drug preparations may include, but are not limited to, implants, injectables, parenteral nutrition solutions, irrigation solutions, inhalation solutions, intravenous solutions and ophthalmic preparations.
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section39D

**Will the pharmacy engage in non-sterile to sterile (i.e. high risk) sterile compounding?**

☐Yes ☐No

***Please note that if any ingredient or component of a CSP was originally non-sterile, the final product must be considered high risk.

Please review the Sterile Compounding Pharmacy DRAFT 247 CMR 17.00 Checklist found on p. 13 prior to application submission.

As Manager of Record, I understand and attest under the pains and penalties of perjury that:

1. Employees engaged in or overseeing sterile compounding will be / have been trained in LEAN concepts, which are tools that assist in the identification and steady elimination of waste and promote continuous improvement in quality and efficiency, before a Sterile Compounding Pharmacy license, Non-Resident Sterile Compounding license, or Institutional Sterile Compounding license may be renewed.

2. I have completed continuing education requirements for sterile compounding in accordance with 247 CMR 4.03(4)(c) and that all pharmacy staff engaged in or overseeing sterile compounding have received the appropriate training and education required by law and regulation before engaging in compounding.

3. The pharmacy will only dispense medication pursuant to a valid prescription as defined in M.G.L. c. 94C, §19 for a single patient for any medications dispensed into, within, or from Massachusetts.

4. If the pharmacy knows or should have reason to know that a compounded drug preparation dispensed into or from Massachusetts by the pharmacy is or may be defective in any way, the pharmacy shall immediately recall the drug preparation in accordance with M.G.L. c. 112, § 39D(e).

5. The pharmacy shall comply with all Massachusetts and federal laws and regulations governingthe practice of pharmacy and USP <797> and USP <800>, as applicable.

Print Name of Manager of Record (MOR): _____

Signature of MOR: _____

MA Pharmacist License #_____

MOR E-mail _____

Date: _____

**MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY**
**250 Washington Street**
**Boston, MA 02108-4619**

# Controlled Substance Registration (CSR) Application

***TO BE COMPLETED BY BOARD***

***CHECK/M.O.$_____*** ***DATE_____***

***CHECK/M.O. No._____*** ***RECEIPT No._____APP No._____***

I hereby apply for a Controlled Substances Registration in accordance with M.G.L. c. 94C, § 7:

Name of Corporation/Applicant _____

Street Address _____

City/Town_____State_____Zip Code _____

Tel. No._____Fax No. _____

E-mail_____

FEIN Number: _____

**Registration Classification**:

☐ Drug Store Pharmacy

☐ Complex Non-Sterile Compounding Pharmacy ☐ Sterile Compounding Pharmacy

**Please check applicable controlled substance(s):**

☐Schedule II ☐Schedule III ☐Schedule IV ☐Schedule V ☐Schedule VI**

**** Schedule VI: This substance is a prescription drug that has not already been included in Schedules I-V.**

Signature of Applicant: _____
(Owner of facility must sign application)

Printed Name of Applicant whose signature appears above: _____

Date_____

**MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY**
**250 Washington Street**
**Boston, MA 02108-4619**

## PHARMACY HOURS

Name of Pharmacy_____

Street Address _____

City/Town_____State_____Zip Code _____

Tel. No._____Fax No. _____

Pharmacy E-mail _____

| Days | Open | Close | Hours |
|---|---|---|---|
| Monday | | | |
| Tuesday | | | |
| Wednesday | | | |
| Thursday | | | |
| Friday | | | |
| Saturday | | | |
| Sunday | | | |
| **Total per week** | | | |

**Please describe how a patient may contact a pharmacist for questions or refill their prescriptions when the pharmacy is closed.**

_____**License No**_____
**Signature of Manager of Record or Duly Authorized Representative**

_____**Date**_____
**Print Full Name**

**MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY**
**250 Washington Street**
**Boston, MA 02108-4619**

# Sterile Compounding Pharmacy
# DRAFT 247 CMR 17.00 Checklist

Although this is not an all-inclusive list of proposed standards in DRAFT 247 CMR 17.00, sterile compounding pharmacy applicants are encouraged to utilize and include this checklist with the application. 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.

If the applicant's proposed design meets the listed requirement, please indicate by placing "Y" (yes) in the space. If not, please indicate "N" (no) and include comments as to the reason for the non-compliance and plans to mitigate. If not applicable, indicate with "NA".

| Draft 247 CMR 17.00 | Citation | Y/N | Comments |
|---|---|---|---|
| A newly constructed ante room shall be at least 72 square feet. | 17.11(3)(f) | | |
| A newly constructed non-HD buffer room shall be at least 100 square feet. (non-hazardous only) | 17.11(2)(b) | | |
| A newly constructed HD buffer room shall be at least 72 square feet. | 17.11(2)(c) | | |
| An ante room must precede any ISO Class 7 buffer room. | 17.11(3)(b) | | |
| Each newly constructed Secondary Engineering Control (SEC) shall allow for visual observation from the outside through windows or technology. | 17.11(1)(a) | | |
| A pharmacy shall have a dedicated changing area for sterile compounding personnel that is not a restroom. | 17.08(4) | | |
| Buffer room doors shall be hands-free. | 17.11(2)(e) | | |
| Each SEC shall be physically separated by fixed walls and doors. | 17.11(1)(b) | | |
| The doors leading into and between ISO Classified areas shall be constructed with an active or passive interlocking design. | 17.11(1)(d) | | |
| Unless prohibited by local building or fire code, an SEC may not have more than one door to immediately adjacent areas. | 17.11(1)(c) | | |
| Upon new construction, remodeling, or change in configuration or square footage of any SEC, a pass-through, if utilized shall:<br>a. have an interlocking door design; and<br>b. not be a refrigerator unit. | 17.08(3) | | |
| Walls shall be made of solid surface, locking sealed panels, or epoxy-coated gypsum board and shall be impervious, cleanable, and non-shedding. | 17.11(1)(n) | | |
| Walls may not contain windows to the outdoors. | 17.11(1)(o) | | |
| Ceiling surfaces shall be impervious and hydrophobic. | 17.11(1)(k) | | |

| | | | |
|---|---|---|---|
| Ceiling panels, fixtures, and other penetrations through the ceiling or walls shall be smooth and sealed around the perimeter. | 17.11(1)(l) | | |
| Floors shall be cleanable and composed of wide sheet vinyl that is heat sealed at seams, or other solid, smooth surface. Floors shall be coved at the wall or appropriately sealed. | 17.11(1)(p) | | |
| A pharmacy shall utilize light fixtures designed for cleanrooms in all SECs and the exterior surface of ceiling lighting fixtures shall be smooth, mounted flush with the ceiling surface, and sealed. | 17.11(1)(j) | | |
| Sprinkler heads shall be recessed, covered, and easily cleanable. | 17.11(1)(m) | | |
| Countertops, work surfaces, doors, pass-throughs, racks, equipment, furniture, or other items in Secondary Engineering Controls ("SEC") must be:<br>a. constructed of a nonporous, smooth, non-shedding, impermeable material such as acrylic, polycarbonate or similar fiberglass-reinforced plastic, molded plastic, glass, or stainless steel;<br>b. free from cracks and crevices; and<br>c. cleanable and resistant to degradation by cleaning agents. | 17.08(2) | | |
| Newly constructed clean room suites shall utilize a closed loop ducted system, a sealed plenum system, or other similar contamination control system for Heating, Ventilation, and Air Conditioning ("HVAC") systems. | 17.09(1) | | |
| Supply air provided to classified area(s) shall be provided exclusively through high-efficiency particulate air ("HEPA") filters. | 17.09(2) | | |
| Each ISO Classified SEC shall have ducted air returns mounted low on the wall in order to create a general top-down dilution of room air with HEPA-filtered make-up air. | 17.09(5) | | |
| 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 spaces. | 17.09(6) | | |
| Air changes for each ISO Classified SEC shall come from ceiling mounted HEPA filters. | 17.09(4) | | |
| A buffer room shall be ISO Class 7 and maintain a minimum of 30 air changes per hour ("ACPH"). | 17.11(2)(f) | | |
| For newly constructed non-HD buffer rooms, any air exchanges supplied to the buffer room from the PEC must be in addition to the 30 ACPH. | 17.11(2)(g) | | |
| An ante room shall be at least ISO Class 8. However, an ante room adjacent to a negative pressure buffer room shall be at least ISO Class 7. | 17.11(3)(c) | | |
| An ISO Class 8 ante room shall maintain a minimum of 20 air changes per hour. | 17.11(3)(e) | | |
| An ISO Class 7 ante room shall maintain a minimum of 30 ACPH. | 17.11(3)(d) | | |

| | | | |
|---|---|---|---|
| An ante room shall have a line of demarcation that separates the less clean area from the more clean area. | 17.11(3)(g) | | |
| A pharmacy shall conduct sterile HD compounding in a containment primary engineering control ("C-PEC") in an ISO Class 7 negative pressure buffer room that is:<br>a. physically separated from the non-HD buffer room, as applicable;<br>b. preceded by an ISO Class 7 ante room;<br>c. externally vented; and<br>d. under a constant negative pressure in accordance with 247 CMR 17.13(2). | 17.05(2) | | |
| A C-PEC shall be externally vented. | 17.05(3) | | |
| A C-PEC may not serve as the sole source of exhaust for a negative pressure buffer room. | 17.05(4) | | |
| A pharmacy shall have a system to continuously measure pressure differentials utilizing a gauge or a continuous recording device. Results shall be reviewed and documented at least once daily. | 17.13(4) | | |
| For non-HD sterile compounding, there shall be a minimum differential positive pressure of 0.02 inches of water column between:<br>a. the buffer room and ante room;<br>b. the ante room and unclassified space; and<br>c. any ISO Class 8 area and unclassified space. | 17.13(1) | | |
| For HD sterile compounding, the buffer room shall be under a constant negative pressure between -0.01 and -0.03 inches of water column relative to the adjacent positive pressure ISO Class 7 ante room. | 17.13(2) | | |
| An ISO Class 7 ante room preceding an ISO Class 7 negative pressure buffer room shall have a minimum differential positive pressure of 0.02 inches of water column relative to adjacent space. | 17.13(3) | | |
| A pharmacy shall have a system to continuously measure the temperature and humidity of each SEC. Results shall be reviewed and documented at least once daily. | 17.14(3) | | |
| SECs shall not exceed a temperature of 68 degrees Fahrenheit (20 degrees Celsius). | 17.14(1) | | |
| SECs shall not exceed a relative humidity of 60%. | 17.14(2) | | |
| A buffer room may not contain any source of water. | 17.11(2)(d) | | |
| SECs may not contain a floor drain. | 17.11(1)(h) | | |
| An ante room shall have a stainless-steel sink located on the clean side of the line of demarcation at least one meter away from **any** buffer room door. | 17.11(3)(h) | | |
| The stainless-steel sink must:<br>i. be equipped with hands-free controls for water and soap dispensing;<br>ii. have proper depth and capacity for hand washing up to the elbows; | 17.11(3)(i) | | |

| | | | |
|---|---|---|---|
| iii. be designed to prevent standing water;<br>iv. minimize splashing and dripping of water on adjacent walls and floor; and<br>v. have a faucet that does not have an aerator mechanism on the nozzle. | | | |
| Exposed plumbing system pipes within the ante room shall be minimized and easily cleanable. | 17.11(3)(k) | | |
| An ante room shall have low-lint, disposable towels located in proximity to the sink to minimize dripping water. | 17.11(3)(j) | | |
| SECs may not contain automatic hand dryers. | 17.11(1)(i) | | |
| An Segregated Compounding Area (SCA) shall:<br>i. adhere to the requirements of an SEC (247 CMR 17.11(1))<br>ii. be a dedicated, closed room restricted to sterile compounding activities;<br>iii. be limited to one PEC;<br>iv. be equipped with a hands-free door;<br>v. be located away from unsealed windows, doors that connect to the outdoors, traffic flow, and any environmental control challenges such as restrooms, warehouses, or food preparation areas;<br>vi. have a dedicated sink that is located immediately outside of the room or outside of a defined perimeter within the room;<br>vii. have the sink located at least one meter away from the PEC;<br>viii. have a sink that conforms to the requirements outlined in 17.11(3)(i); and<br>ix. have low-lint, disposable towels located in proximity to the sink to minimize dripping water.<br><br>Note: SCA only allowed for facilities that hold an institutional sterile compounding pharmacy license. | 17.11(4)(b) | | |
| A pharmacy shall locate a PEC for non-HD compounding within a positive pressure ISO Class 7 buffer room or Segregated Compounding Area ("SCA"). | 17.10(1) | | |
| A pharmacy shall utilize only commercially manufactured PECs. | 17.10(4) | | |
| A pharmacy may not utilize any ISO Classified area for both sterile and non-sterile compounding. | 17.08(1) | | |
| A pharmacy may not store drugs in any ISO Classified area. | 17.08(6) | | |
| A pharmacy shall limit furniture, equipment, supplies, and activities in an SEC to those essential for sterile compounding related activities. | 17.11(1)(e) | | |
| A pharmacy may not locate a refrigerator, dishwasher, or incubator in an SEC. | 17.11(1)(f) | | |
| A pharmacy may not locate equipment utilized for terminal sterilization (e.g. dry heat oven or steam sterilizer) in an SEC. | 17.11(1)(g) | | |