# The Commonwealth of Massachusetts

Executive Office of Health and Human Services
Department of Public Health
100 Cambridge Street, 19th floor, Boston, MA 02114-2509

## Pharmacy Application Checklist

Requirements below apply to both resident and non-resident pharmacies unless otherwise noted. Retain a copy of the completed checklist, applications, and supporting documents for your records. Submitted applications are only valid for 1 year**.**

**Application(s) and all required documents must be fully complete with no outstanding issues and received no later than 14 calendar days prior to a Board meeting in order for the application(s) to be considered at that meeting.** Please direct any questions to: Pharmacy.Admin@mass.gov

## Ownership Changes

Ownership changes are defined as a change in any direct owner(s) or parent company owner(s) of the current licensee **or** when there is a change in the Internal Revenue Service (IRS)-issued employer identification number (FEIN or EIN). Changes in ownership not meeting this definition may require reporting in accordance with 247 CMR 20.00.

**Ownership changes require the closing of the current pharmacy license and a new pharmacy application for the pharmacy with the new owner(s)**.

The **outgoing licensee** must notify the Board of the proposed ownership change of a licensed pharmacy at least 14 days prior to the change 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) as outlined in 247 CMR 6.00.

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

Any **MassHealth enrolled pharmacy** must speak with MassHealth to update their enrollment after an ownership change, relocation, etc.

## Retail Pharmacy

☐ A completed Retail Pharmacy Application fully and properly completed and signed by the Manager of Record (MOR) or Designated Pharmacist-in-Charge (PIC). A Massachusetts-licensed pharmacist is required in order to apply for a pharmacy license.
(The "Designated Pharmacist-in-Charge" is responsible for assuring non-resident pharmacy compliance with all Massachusetts laws and regulations pertaining to the practice of pharmacy and does not have to be the pharmacy's pharmacist-in-charge.)

**** A non-dispensing pharmacy license is not available.***

***** A Controlled Substance Registration is not required for non-resident pharmacies.***

☐ Applicable fee. **Fees are non-refundable and non-transferable.**
$750 - resident pharmacies
$825 - non-resident pharmacies

☐ Pharmacy hours during which the pharmacy is to remain open, including the opening and closing times for each day of the week. (**Resident pharmacies only.)**

☐ A copy of the Business Entity Summary. (**Resident pharmacies only.)**

☐ Architectural drawing or certified blueprint. See *Architectural Drawing / Certified Blueprint Requirements* on pages 6-7. (**Resident pharmacies only.)**

☐ If a Retail 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 will be located in the exact same space.) (**Resident pharmacies only.)**

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

☐ An Inspection Report. See *Non-Resident Pharmacy Inspection Requirements* on pages 11-13. **(Non-resident pharmacies only.)**

☐ If applicable, a documented plan of correction for inspectional deficiencies. See *Non-Resident Pharmacy Inspection Requirements* on pages 11-13. **(Non-resident pharmacies only.)**

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

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

## Sterile Compounding

☐ Applicable fee. (**This fee is IN ADDITION to the Retail Pharmacy fee.)**
$4,525 - resident pharmacies
$1,825 - non-resident pharmacies

☐ A completed Sterile Compounding Application fully and properly completed and signed by the Manager of Record (MOR) or Designated Pharmacist-in-Charge (PIC) who is to manage and operate the pharmacy. *Do not send certification reports or policies unless requested.*

☐ Architectural drawing or certified blueprint. See *Architectural Drawing / Certified Blueprint Requirements* on pages 6-7.

☐ An Inspection Report from a satisfactory sterile compounding inspection. See *Non-Resident Pharmacy Inspection Requirements* on pages 11-13. **(Non-resident pharmacies only.)**

☐ If applicable, a documented plan of correction for inspectional deficiencies. See *Non-Resident Pharmacy Inspection Requirements* on pages 11-13. **(Non-resident pharmacies only.)**

☐ Compliance Checklist for DRAFT sterile compounding regulations 247 CMR 17.00 on pages 8-10.

☐ Each additional, unconnected sterile compounding pharmacy area must be separately licensed. Use the Sterile Compounding License Additional Compounding Area License - New Application if needed. There is no fee for this license.

## Complex Non-Sterile Compounding

☐ A completed Complex Non-Sterile Compounding Application fully and properly completed and signed by the Manager of Record (MOR) or Designated Pharmacist-in-Charge (PIC) who is to manage and operate the pharmacy. *Do not send certification reports or policies unless requested.*

☐ Applicable fee. (**This fee is IN ADDITION to the Retail Pharmacy fee.)**
$2,900 - resident pharmacies
$1,625 - non-resident pharmacies

☐ Architectural drawing or certified blueprint. See *Architectural Drawing / Certified Blueprint Requirements* on pages 6-7.

☐ An Inspection Report from a satisfactory complex non-sterile compounding inspection. See *Non-Resident Pharmacy Inspection Requirements* on pages 11-13. **(Non-resident pharmacies only.)**

☐ If applicable, a documented plan of correction for inspectional deficiencies. See *Non-Resident Pharmacy Inspection Requirements* on pages 11-13. **(Non-resident pharmacies only.)**

☐ Review DRAFT non-sterile compounding regulations 247 CMR 18.00 and the Board's Non-Sterile Compounding Policy. **(No submission required.)**

## 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.

** Non-resident nuclear pharmacy licensing is not yet available. There is no need to apply for any non-resident licensure at this time.*

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

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

☐ A copy of the Business Entity Summary.

☐ 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 Waiver Petition for each regulation / policy and section the pharmacy is requesting to be waived. Waivers are not transferable. New petitions for waiver must be submitted in the case of transfer of ownership.

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

☐ Architectural drawing or certified blueprint. See *Architectural Drawing / Certified Blueprint Requirements* on pages 6-7.

## Institutional Sterile Compounding Pharmacy

☐ A completed Institutional Sterile Compounding Pharmacy Application for EACH sterile compounding pharmacy area, that is fully and properly completed and signed by the Manager of Record (MOR). *Do not send certification reports or policies unless requested.*

*Each additional, unconnected sterile compounding pharmacy area must be separately licensed. Use the Institutional Sterile Compounding Pharmacy Additional Compounding Area License - New Application if needed. There is no fee for this license.

☐ Hospital MCSR number or Clinic MCSR number. MCSR is the Massachusetts Controlled Substances Registration number from DPH and is unique to each physical address. Any additional sterile compounding pharmacy area(s) under the same MCSR number will require a separate application for licensure.

☐ Name of Manager of Record (MOR). This is the on-site pharmacist who is responsible for the operation of all sterile compounding pharmacy areas under the same MCSR.

☐ Name of supervising pharmacist who is on-site at EACH sterile compounding area, as applicable.

☐ Applicable fees. **Fees are non-refundable and non-transferable.**

$4,525 - primary sterile compounding area
$4,475 - EACH additional sterile compounding area

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

☐ Architectural drawing or certified blueprint. See *Architectural Drawing / Certified Blueprint Requirements* on pages 6-7.

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

☐ Compliance Checklist for DRAFT sterile compounding regulations 247 CMR 17.00 on pages 8-10.

☐ Completed Sterile Compounding Pharmacy Inspection Template for EACH sterile compounding area.

## 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.

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

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

## Sterile Compounding 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 |
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| **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:<br>a. have an interlocking door design; and<br>b. are not refrigerator units. | 17.04(1) | | |

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| 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:<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;<br>iii. minimize splashing and dripping of water;<br>iv. be designed to prevent standing water; and<br>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) | | |

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| 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) | | |

# Non-Resident Pharmacy Inspection Requirements

The Massachusetts Board of Registration in Pharmacy (Board) adopts these requirements for non-resident pharmacy inspections as summarized below. Both the inspection form and a separate plan of correction (if applicable) must be provided.

A "**satisfactory inspection**" for non-resident pharmacies is defined as an on-site, Board-approved pharmacy inspection (as outlined in the chart below) revealing substantial compliance with required standards, provided that any identified deficiencies do not have an impact on patient safety and there is a documented plan of correction.

A "**plan of correction**" for any identified deficiencies must be developed by the non-resident pharmacy and include the regulatory violation, observation / explanation of the deficiency, correction plan, date corrected, on-going compliance plan, and Massachusetts license number of the Designated Pharmacist-in-Charge.

If a **blueprint state inspection** is completed using the state's sterile compounding inspection template, then it must have been cross-walked with NABP's current version that reflects the November 2023 updates to USP <797>. If not, an additional inspection by a Massachusetts Board-approved inspector will be required.

**There are four current "Board-approved inspectors" that may provide Board-approved pharmacy inspections:**

Accreditation Commission for Health Care (ACHC)
Gates Healthcare Associates, Inc.
National Association of Boards of Pharmacy (NABP®)
Real Solutions Group (RSG)

| Massachusetts License Type | Initial Licensure | Renewal |
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| **Retail Pharmacy** | Most recent inspection report conducted within two (2) years of the application submission date.<br><br>Acceptable inspections include:<br>a. An inspection conducted by a resident state inspector utilizing the NABP Universal | In connection with an application to renew a non-resident Retail Pharmacy license, a licensee shall submit copies of all reports or correspondence pertaining to all inspections by any state or federal agency, or any entity inspecting on behalf of a state or |

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| | Inspection Form, General Pharmacy Inspection; or<br>b. An inspection conducted by a resident state inspector utilizing that state's general pharmacy compliance inspection form; or<br>c. An inspection conducted by a Massachusetts Board-approved inspector (see above) utilizing their approved general pharmacy compliance inspection form. | federal agency, occurring within the pending licensing period. |
| **Non-Resident Complex Non-Sterile Compounding** | Most recent inspection report conducted within one (1) year of the application submission date. Inspection of USP <800> standards must also occur if the pharmacy is engaged in the compounding of hazardous (HD) drugs.<br><br>Acceptable inspections include:<br>a. A satisfactory inspection conducted by a resident state inspector utilizing the NABP Universal Inspection Forms: Nonsterile Compounding Inspection for USP <795>, and Hazardous Drugs - Handling in Health Care Settings USP <800> inspection form, if applicable; or;<br>b. A satisfactory inspection conducted by a Massachusetts Board-approved inspector (see above) utilizing their approved nonsterile compounding inspection form and USP <800> inspection form, if applicable.<br><br>* a Non-Resident Retail Pharmacy inspection is also required | Most recent inspection report conducted within one (1) year of the renewal application submission date. Inspection of USP <800> standards must also occur if the pharmacy is engaged in the compounding of hazardous (HD) drugs.<br><br>Acceptable inspections include:<br>a. A satisfactory inspection conducted by a resident state inspector utilizing the NABP Universal Inspection Forms: Nonsterile Compounding Inspection for USP <795>, and Hazardous Drugs - Handling in Health Care Settings USP <800> inspection form, if applicable; or<br>b. A satisfactory inspection conducted by a Massachusetts Board-approved inspector (see above) utilizing their approved nonsterile compounding inspection form and USP <800> inspection form, if applicable. |

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| **Non-Resident Sterile Compounding** | Most recent inspection report conducted within one (1) year of the application submission date. Inspection of USP <800> standards must also occur if the pharmacy is engaged in the compounding of hazardous (HD) drugs.<br><br>Acceptable inspections include:<br>a. If the state is part of NABP's Multistate Pharmacy Inspection Blueprint Program, a satisfactory inspection conducted by a resident state inspector utilizing:<br>1. NABP's Universal Inspection Forms: Inspection for USP <797>, and Hazardous Drugs – Handling in Health Care Settings USP <800> inspection form, if applicable; or<br>2. The state's NABP-approved sterile compounding inspection form, and USP <800> inspection form, if applicable; or<br>b. A satisfactory inspection conducted by a Massachusetts Board-approved inspector (see above) utilizing their approved sterile compounding inspection form and USP <800> inspection form, if applicable.<br><br>* a Non-Resident Retail Pharmacy inspection is also required | Most recent inspection report conducted within one (1) year of the renewal application submission date. Inspection of USP <800> standards must also occur if the pharmacy is engaged in the compounding of hazardous (HD) drugs.<br><br>Acceptable inspections include:<br>a. If the state is part of NABP's Multistate Pharmacy Inspection Blueprint Program, a satisfactory inspection conducted by a resident state inspector utilizing:<br>1. NABP's Universal Inspection Forms: Inspection for USP <797>, and Hazardous Drugs - Handling in Health Care Settings USP <800> inspection form, if applicable; or<br>2. The state's NABP-approved sterile compounding inspection form, and USP <800> inspection form, if applicable; or<br>b. A satisfactory inspection conducted by a Massachusetts Board-approved inspector (see above) utilizing their approved sterile compounding inspection form and USP <800> inspection form, if applicable. |