



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
250 Washington Street, Boston, MA 02108-4619

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MEMORANDUM

TO: Non-Resident Pharmacies

FROM: Massachusetts Board of Registration in Pharmacy (Board)

DATE: November 19, 2024

SUBJECT: Massachusetts Licensing of Non-Resident Pharmacies

In accordance with Massachusetts law, all pharmacies located outside Massachusetts must obtain a license from the Board in order to dispense any prescription products into Massachusetts. M.G.L. c. 112, § 39 G, H, and J.

Regulations implementing the requirement for non-resident licensure will be promulgated in December, 2024, and on **January 1, 2025**, the Board will begin accepting [applications](#). Frequently asked questions can be found on page 2.

In addition to a retail pharmacy license (non-resident drug store), pharmacies that engage in [sterile](#) and [complex non-sterile compounding](#) will require additional licensure.

In order to comply with the new licensing regulations, a grace period has been established through **March 31, 2025** to apply for the required license(s).

Beginning May 1, 2025, any pharmacy located outside of Massachusetts must hold a license in order to dispense prescription products into Massachusetts. Please note that any prescription dispensed into Massachusetts must be pursuant to a valid patient-specific prescription.

Any pharmacy without a license that dispenses prescription products into Massachusetts on or after May 1, 2025 will be subject to prosecution and penalties for unlawful distribution as provided by law.

Please direct any questions to: Pharmacy.Admin@mass.gov



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Bureau of Health Professions Licensure
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Board of Registration in Pharmacy

Non-Resident Facility Licensure FAQs

1. Does the pharmacist-in-charge (PIC) need a Massachusetts pharmacist license?

At least one pharmacist at each non-resident pharmacy must hold a Massachusetts pharmacist license. (This pharmacist does not have to be the store's pharmacist-in-charge.) This "Designated Pharmacist-in-Charge" is responsible for assuring non-resident pharmacy compliance with all Massachusetts laws and regulations pertaining to the practice of pharmacy. It is recommended to have more than one Massachusetts licensed pharmacist in the event that the Designated Pharmacist-in-Charge is no longer able to continue in this capacity.

Applications and instructions for pharmacist licensure can be found [here](#). Be aware that the process can take 30-60 days.

2. Will an inspection of my pharmacy be required for licensure?

Yes. See pages 3-5 for acceptable inspections.

3. What does a non-resident pharmacy have to report?

Information for Schedules II - V and gabapentin prescriptions that are dispensed into Massachusetts must be reported to the [Prescription Monitoring Program \(PMP\)](#). Other reporting requirements will be in effect upon licensure and can be found [here](#).

4. Will non-resident licensure be offered for non-dispensing pharmacies, wholesalers, distributors, 3PLs, or manufacturers?

The Board has no plans to offer non-resident licensure for these facilities.

5. Is non-resident registration offered for 503B outsourcing facilities?

Yes. See [regulatory information](#) and [application details](#).



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Board of Registration in Pharmacy

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.

There are two current “Board-approved inspectors” that may provide Board-approved pharmacy inspections:

Gates Healthcare Associates, Inc.
ernie.gates@gatesconsult.com
1 Meeting House Square
Middleton, MA 01949
Phone: 978-646-0091

National Association of Boards of Pharmacy (NABP®)
inspections@nabp.pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056-6014

Massachusetts License Type	Initial Licensure	Renewal
Retail Pharmacy	Most recent inspection report conducted within two (2) years of the application submission date. Acceptable inspections include: a. An inspection conducted by a resident state inspector utilizing	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

	<p>the NABP Universal Inspection Form, General Pharmacy Inspection; or</p> <p>b. An inspection conducted by a resident state inspector utilizing that state's general pharmacy compliance inspection form; or</p> <p>c. An inspection conducted by a Massachusetts Board-approved inspector (see above) utilizing their approved general pharmacy compliance inspection form.</p>	<p>federal agency, occurring within the pending licensing period.</p>
<p>Non-Resident Complex Non-Sterile Compounding</p>	<p>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.</p> <p>Acceptable inspections include:</p> <p>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;</p> <p>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.</p> <p>* a Non-Resident Retail Pharmacy inspection is also required</p>	<p>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.</p> <p>Acceptable inspections include:</p> <p>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</p> <p>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.</p>

<p>Non-Resident Sterile Compounding</p>	<p>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.</p> <p>Acceptable inspections include:</p> <ul style="list-style-type: none"> a. If the state is part of NABP's Multistate Pharmacy Inspection Blueprint Program, a satisfactory inspection conducted by a resident state inspector utilizing: <ul style="list-style-type: none"> 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 2. The state's NABP-approved sterile compounding inspection form, and USP <800> inspection form, if applicable; or 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. <p>* a Non-Resident Retail Pharmacy inspection is also required</p>	<p>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.</p> <p>Acceptable inspections include:</p> <ul style="list-style-type: none"> a. If the state is part of NABP's Multistate Pharmacy Inspection Blueprint Program, a satisfactory inspection conducted by a resident state inspector utilizing: <ul style="list-style-type: none"> 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 2. The state's NABP-approved sterile compounding inspection form, and USP <800> inspection form, if applicable; or 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.
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