

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

Tel: 617-973-0800
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www.mass.gov/dph/boards

Board of Registration in Pharmacy

Non-Resident Facility Licensure FAQs

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

Yes. Regulatory information can be found here:

<https://www.mass.gov/regulations/247-CMR-2100-registration-of-outsourcing-facilities> and the application here:

<https://www.mass.gov/how-to/apply-for-a-non-resident-outsourcing-registration>

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

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

3. Is a Massachusetts pharmacy license required for out-of-state pharmacies at this time?

The Board does not currently issue licenses to non-resident pharmacies. A non-resident pharmacy may deliver or ship medications into Massachusetts as long as the pharmacy is licensed and in good standing in the state where it is located.

4. Will non-resident pharmacy licensure be offered in the future?

Yes, we will soon have regulations in place to require licensure. Consider e-mailing us at Pharmacy.admin@mass.gov and ask to be added to the email distribution list so you can be notified of when licensing becomes available.

5. Will the pharmacist-in-charge (PIC) need a Massachusetts pharmacist license?

Each non-resident pharmacy will be required to have a designated pharmacist hold a Massachusetts pharmacist license. 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.

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

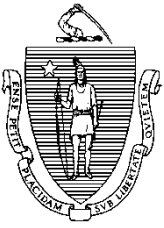
Yes. See pages 3-5 for acceptable inspections.

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

Since non-resident pharmacies are not yet licensed, there is no need to report things such as change of PIC or address. However, information for Schedules II - V and gabapentin prescriptions that are delivered or shipped into Massachusetts must be reported to the Prescription Monitoring Program (PMP):

<https://www.mass.gov/service-details/pharmacy-reporting-and-data-submission>

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



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Policy 2019-03: Non-Resident Pharmacy Inspection Requirements for Licensure

The Massachusetts Board of Registration in Pharmacy (“Board”) adopts these requirements for non-resident pharmacy inspections as summarized below.

Massachusetts License Type	Initial Licensure	Renewal
Non-Resident Drug Store Pharmacy (Retail)	<p>Most recent inspection report conducted within two (2) years of the application submission date.</p> <p>Acceptable inspections include:</p> <ul style="list-style-type: none">a. An inspection conducted by NABP as part of NABP’s Verified Pharmacy Program (VPP) utilizing the NABP Universal Pharmacy Inspection Form, or;b. An inspection conducted by a resident state inspector utilizing the NABP Universal Pharmacy Inspection Form, or;c. An inspection conducted by a resident state inspector utilizing that state’s inspection form, or;d. An inspection conducted by a Board-approved inspector utilizing a Board-approved inspection form.	<p>See 247 CMR 6.09(1)(c) and 247 CMR 20.07 for reporting requirements pertaining to inspections.</p>

<p>Non-Resident Complex Non-Sterile Compounding</p>	<p>Most recent inspection report conducted within one (1) year of the application submission date.</p> <p>Acceptable inspections include:</p> <ul style="list-style-type: none"> a. A satisfactory inspection conducted by NABP as part of NABP's Verified Pharmacy Program (VPP) utilizing the NABP Universal Pharmacy Inspection Form including the Nonsterile Compounding Module, or; b. A satisfactory inspection conducted by a Board-approved inspector utilizing a Board-approved inspection form. 	<p>Most recent inspection report conducted within one (1) year of the renewal application submission date.</p> <p>Acceptable inspections include:</p> <ul style="list-style-type: none"> a. A satisfactory inspection conducted by NABP as part of NABP's Verified Pharmacy Program (VPP) utilizing the NABP Universal Pharmacy Inspection Form including the Nonsterile Compounding Module, or; b. A satisfactory inspection conducted by a Board-approved inspector utilizing a Board-approved inspection form.
<p>Non-Resident Sterile Compounding</p>	<p>Most recent inspection report conducted within one (1) year of the application submission date.</p> <p>Acceptable inspections include:</p> <ul style="list-style-type: none"> a. A satisfactory inspection conducted by NABP as part of NABP's Verified Pharmacy Program (VPP) utilizing the NABP Universal Pharmacy Inspection Form including the Sterile Compounding Module or; b. In an NABP-approved Multistate Pharmacy Inspection Blueprint state, a satisfactory inspection conducted by a resident state inspector utilizing: <ul style="list-style-type: none"> 1. NABP Universal Pharmacy Inspection Form including the Sterile Compounding Module; or 	<p>Most recent inspection report conducted within one (1) year of the renewal application submission date.</p> <p>Acceptable inspections include:</p> <ul style="list-style-type: none"> a. A satisfactory inspection conducted by NABP as part of NABP's Verified Pharmacy Program (VPP) utilizing the NABP Universal Pharmacy Inspection Form including the Sterile Compounding Module or; b. In an NABP-approved Multistate Pharmacy Inspection Blueprint state, a satisfactory inspection conducted by a resident state inspector utilizing: <ul style="list-style-type: none"> 1. NABP Universal Pharmacy Inspection Form including the Sterile

	<p>2. The state's NABP-approved sterile compounding inspection form or;</p> <p>c. A satisfactory inspection conducted by a Board-approved inspector utilizing a Board-approved inspection form.</p>	<p>Compounding Module; or</p> <p>2. The state's NABP-approved sterile compounding inspection form;</p> <p>c. A satisfactory inspection conducted by a Board-approved inspector utilizing a Board-approved inspection form.</p>
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