

# Massachusetts Implements Long-Awaited Licensing Regime for Out-of-State Pharmacies

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Until recently, Massachusetts was the only state that did not maintain a licensing regime for nonresident pharmacies (*i.e.*, out-of-state pharmacies shipping drugs into the state). On December 6, 2024, the Massachusetts Board of Registration in Pharmacy promulgated [regulations](#), effectuating the licensure process first required under [Massachusetts law in 2015](#) and requiring that pharmacies located outside of Massachusetts obtain a nonresident drug store pharmacy license in order to dispense or ship any prescription drugs into the Commonwealth. Nonresident pharmacies dispensing sterile compounded or complex nonsterile compounded preparations to Massachusetts-located patients also must obtain special approval for such activities as part of the licensure process.

- The Board will begin accepting applications for nonresident drug store pharmacy licenses and compounding licenses on January 1, 2025.
- For pharmacies currently shipping into Massachusetts, the Board has established a grace period extending through March 31, 2025, to allow these facilities to apply for new licensure.
- After May 1, 2025, all nonresident pharmacies shipping into Massachusetts must hold a license or they will be subject to prosecution and penalties for unlawful distribution.

Because of the impending deadlines, pharmacies shipping prescription drugs (including controlled substances), sterile compounded preparations, or complex nonsterile compounded preparations to patients located in Massachusetts should begin to consider the applicability of these new requirements and what steps can be taken to ensure compliance. Nonresident pharmacies should submit applications well in advance of the deadline to account for potential delays in the application process.

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## In Depth

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The Board will begin accepting applications on January 1, 2025, in accordance with the requirements set forth in [247 CMR 6.00](#), as described below. The Board does not intend to offer nonresident licensure to wholesalers, distributors, third-party logistics services providers, or manufacturers and has not yet developed a procedure for nonresident pharmacies that dispense radiopharmaceutical drugs.

### APPLICATION REQUIREMENTS

Like resident pharmacy applicants, applicants for nonresident drug store pharmacy licensure may seek waiver from [specific regulatory requirements](#) by submitting a petition for waiver form to the Board, explaining why the requirement is unduly burdensome or otherwise not applicable to the applicant's operations and attending a Board hearing to review the petition. . Nonresident pharmacies are automatically exempt from compliance with certain practice standards (*e.g.*, pharmacy signage and minimum square footage of prescription area). As a result, applicants will not need to seek waiver from the subset of regulations enumerated at [247 CMR 9.19\(23\)](#).

The Board will use the same form of [application](#) for resident and nonresident pharmacies, with the following additional requirements for nonresident applicants:

- At least one pharmacist at each nonresident pharmacy must hold a Massachusetts pharmacist license and be designated as responsible for ensuring the nonresident pharmacy's compliance with all Massachusetts laws and regulations pertinent to the practice of pharmacy (Massachusetts-licensed designated pharmacist in charge).

The Massachusetts-licensed designated pharmacist in charge need not be the pharmacist in charge named on the pharmacy's home-state license (*i.e.*, the pharmacist in charge does not need to be dually licensed in Massachusetts *and* the home state to satisfy this requirement).

The Board typically allocates 30 to 60 days to process applications for individual pharmacist licensure. Nonresident pharmacies that do not currently employ a pharmacist licensed in Massachusetts should immediately begin to consider this requirement and complete the pharmacist licensure process as soon as possible.

In terms of ongoing reporting obligations, a change of the Massachusetts licensed designated pharmacist in charge will trigger the need for a new application. The nonresident pharmacy must notify the Board within 14 days of the resignation, termination, or change of the Massachusetts licensed designated pharmacist in charge and must submit the new application for facility licensure within 90 days of the change.

- Inspection will be required for any nonresident pharmacy seeking licensure. The requirements for such inspection vary depending on the type of pharmacy.

Nonresident pharmacies must provide a copy of the inspection report from a Board-approved inspector, and the inspection must be conducted within two years of the application date. An inspection conducted by a home-state inspector according to home-state pharmacy standards of

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operation is sufficient.

Nonresident pharmacy applicants that perform sterile compounding and/or complex nonsterile compounding must achieve a “satisfactory Board inspection” prior to the issuance of a license. Details regarding what constitutes a “satisfactory Board inspection” for nonresident applicants performing sterile compounding and complex nonsterile compounding are detailed in an [FAQ memorandum published by the Board on November 19, 2024](#). Generally, an inspection conducted within one year of the application by a resident-state inspector utilizing the applicable National Association of Boards of Pharmacy standards is sufficient.

## **OTHER REQUIREMENTS**

Applicants for nonresident pharmacy licensure must report ownership information, including the name and title of each corporate officer and director of the entity to hold the license, and the name and address of the applicant’s parent entity. The nonresident pharmacy also will be required to provide blueprints or architectural drawings depicting the pharmacy layout. The Board may require representatives from the applicant to personally appear before the Board to answer questions about the application (and about petitions for waiver, if requested by the applicant).

Nonresident pharmacies must also apply to the Board for a Massachusetts controlled substances registration (MCSR) if dispensing any drugs classified as controlled substances (Schedules I – V) by the US Drug Enforcement Agency. The application for a Board MCSR is incorporated into the nonresident pharmacy licensure process, which is administered on the [Health Professions Licensing Portal](#). There is no separate application for a Board MCSR.

## **COMPOUNDING**

Any applicant for nonresident pharmacy licensure conducting sterile compounding or complex nonsterile compounding must complete all components of the application for nonresident drug store pharmacy licensure, plus certain additional requirements in the application to obtain special approval for the compounding activities:

- Certified blueprints of the compounding areas.
- A detailed HVAC design plan and written description of the HVAC design.
- An attestation of intent to engage in compounding, signed by the Massachusetts-licensed designated pharmacist in charge.

## **REPORTING**

Newly licensed nonresident pharmacies should be prepared to comply with various ongoing reporting requirements under [247 CMR 20.00](#), including but not limited to:

- Reporting to the Board any improper dispensing into Massachusetts of a prescription drug that results in a serious injury or death, within seven days of discovery.
- Notifying the Board of any change to information reported on the initial application for licensure (e.g., change in name, contact information, termination, or resignation of manager of record or Massachusetts-licensed designated pharmacist in charge) within 14 days of the change.
- With respect to nonresident pharmacies dispensing controlled substances in Schedules II – V,

submitting information required in accordance with the [Prescription Monitoring Program](#).

- With respect to nonresident pharmacies performing sterile compounding and complex nonsterile compounding:
  - Providing to the Board, on an annual basis, a list of sterile and complex nonsterile prescriptions dispensed within and outside of Massachusetts, as well as the volume of such prescriptions.
  - Reporting to the Board any defective compounded sterile preparation dispensed into Massachusetts within seven days of discovery.

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