



MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

newsletter to promote pharmacy and drug law compliance

The Board Has Moved!

In December 2021, the Department of Public Health's Bureau of Health Professions Licensure, including the Massachusetts Board of Registration in Pharmacy, relocated from 239 Causeway Street to 250 Washington Street in Boston, MA. The Board's main phone number and staff phone numbers have not changed. Additional information will be posted on the Board website as needed, including any changes to application submissions and Board meeting locations. For any questions, please contact the Board staff member with whom you typically work, or email pharmacy.admin@mass.gov.

See below for the Board's new mailing address:

Department of Public Health
Bureau of Health Professions Licensure
Board of Registration in Pharmacy
250 Washington Street
Boston, MA 02108

Preparing for an Inspection

A pharmacist's day is filled with many activities, including answering phones, filling prescriptions, consulting prescribers, and counseling patients. How can you continue to care for your patients and still manage a compliance inspection from the Board? The easiest answer is to always be prepared!

Being prepared for a Board of Pharmacy compliance inspection takes some time and effort up front but will save you time and trouble during an unannounced inspection. A good place to start is to understand what the pharmacy investigators will be inspecting. Use the [inspection templates](#) as your guide. There are separate templates for retail, United States Pharmacopeia (USP) Chapter <795> nonsterile compounding, and USP Chapter <797> sterile compounding. These are the very

same forms that the investigator will utilize during the inspection, so you have all the “questions on the exam” and just need to provide the answers – like an open-book test!

The inspection templates are broken down into sections, each covering a different aspect of pharmacy practice with each line item’s regulatory reference. It is highly recommended to do a self-inspection using these tools to help you gather what will be needed during the inspection.

Some inspection items are easily observed by the investigator before they even approach the pharmacy. The investigator can observe the required signage and determine pharmacist-to-ancillary staff ratio before announcing themselves and entering the pharmacy. However, any documents that the pharmacy investigator is required to review will have to be provided by the pharmacy. Examples of these documents would include controlled substance records, invoices, and compounding records. A good practice is to have these documents organized into some type of filing or binder system, so they are readily retrievable.

Being prepared and organized will make the inspection process easier and faster. Make sure that all members of the pharmacy team are aware of the location of the necessary documents should the inspection occur when the manager of record is not on site. The investigators do not want to interrupt your workflow any more than necessary, and being well prepared can expedite the process.

Should a deficiency be discovered during a compliance inspection, you may have the opportunity to rectify it during the inspection, or you may have to provide a [plan of correction](#) to address and correct the deficiency going forward. The goal of the pharmacy investigators is to ensure that your pharmacy complies with all the rules and regulations set forth by the Board and that you continue to provide safe care for your patients.

Nonresident Pharmacy Requirements

Although licensing will soon be required, the Board does not currently offer any out-of-state licenses, except for Food and Drug Administration-registered [outsourcing facilities](#). However, the Board has no plans to offer nonresident licensure to wholesalers, third-party logistics providers, or device manufacturers.

Until licensure is available, a nonresident pharmacy may continue to ship medications into Massachusetts if the pharmacy is licensed and in good standing in the state where it is located, but must submit prescription information for Schedules II-V, as well as gabapentin, to the [Massachusetts Prescription Monitoring Program](#).

At least one designated pharmacist will be required to hold a Massachusetts license. Since the Board expects nonresident pharmacy licensure to go into effect soon, it strongly recommends that those pharmacists apply for [reciprocal licenses](#) as soon as possible.

Reporting information such as change of manager, address, or discipline does not need to be submitted to the Board until after the pharmacy is licensed.

Based on the pharmacy's business model, the Board will also have certain inspectional requirements for licensure. Typical **nonresident retail drugstores** will be required to report the most recent inspection, which must have been conducted within two years of the application submission date. Acceptable inspections include those that have been conducted by:

1. the National Association of Boards of Pharmacy® (NABP®) as part of NABP's **Verified Pharmacy Program® (VPP®)** utilizing its Universal Inspection Form;
2. a resident state inspector utilizing the NABP Universal Inspection Form; or
3. a resident state inspector utilizing that state's inspection form.

Nonresident sterile compounding pharmacies will have slightly different requirements, including a recent inspection that must have been conducted within one year of the application submission. Suitable inspections include:

1. a satisfactory VPP inspection utilizing the NABP Universal Inspection Form, including the Sterile Compounding Module; or
2. for pharmacies in a NABP-approved Multistate Pharmacy Inspection Blueprint state, a satisfactory inspection conducted by a resident state inspector utilizing:
 - a. the NABP Universal Inspection Form, including the Sterile Compounding Module; or
 - b. the state's NABP-approved sterile compounding inspection form.

Complex nonsterile compounding is defined by state law as the compounding of drug preparations that require "special training, a special environment or special facilities or equipment or the use of compounding techniques and procedures that may present an elevated risk to the compounder or the patient." **Nonresident complex nonsterile compounding pharmacies** will be required to provide their most recent inspection report conducted within one year of the application submission date. One acceptable inspection would be a satisfactory VPP inspection utilizing the NABP Universal Inspection Form that includes the Nonsterile Compounding Module.

Nonsterile Compounding

The Board's **advisory** on nonsterile compounding reviews the various aspects of this type of compounding. Some of the topics include the requirement for patient-specific prescriptions, when essentially a copy of a commercially available product may be compounded, and veterinarian emergency compounds.

As you may be aware, the revisions to USP Chapter <795> propose the elimination of the levels of nonsterile compounding. Even if this occurs, **Massachusetts State law** will still recognize complex

nonsterile compounding and mandates a specialty license that will be available soon. Examples of these complex nonsterile preparations include hazardous drug-containing preparations, capsules, suppositories, modified-release preparations, as well as others.

Did You Know?

- Under the same rules as outlined below, Massachusetts pharmacies may now fill **Schedule II prescriptions from any nonresident practitioners** (eg, nurse practitioners, dentists) who are authorized to prescribe in the state where they are located. There have been no other changes to out-of-state Schedule II prescription validity:
 - All Schedule II prescriptions issued from out of state are only valid for five days from the date of issuance.
 - Schedule II **nonnarcotic** prescriptions may be filled from any state.
 - Schedule II **narcotic** prescriptions may only be filled if issued from states contiguous to Massachusetts (Connecticut, New Hampshire, New York, Rhode Island, and Vermont) and Maine.
- Otherwise valid prescriptions from certain prescribers who require supervision (eg, nurse practitioner, nurse anesthetist) may be filled as written even if a **supervisor's name** is not on it.
- Even though **e-prescribing** is required for federally controlled substances, a pharmacist receiving an otherwise valid written or oral prescription for **any** legend drug may dispense it without having to verify that a waiver has been granted or that an exception applies. Essentially, there has been no change to this aspect of pharmacy practice!
- Paper reminder notices regarding license renewal will no longer be provided. The Board will soon move to email reminders, so please keep your **email address updated**.
- If you have not already done so, consider being added to the Board's email list for any new updates the Board may have to share. Simply **email** the Board and ask to be placed on the distribution list!

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