

# MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

*Newsletter to Promote Pharmacy  
and Drug Law Compliance.*

## New Regulations

Many Massachusetts Board of Registration in Pharmacy **regulations** have been updated and are now final and official. The affected sections include 247 Code of Massachusetts Regulations (CMR) 6.00 Licensure of Pharmacies, 247 CMR 9.00 Professional Practice Standards, 247 CMR 15.00 Continuous Quality Improvement Program, and 247 CMR 20.00 Reporting. Some important changes of note include the following:

- Counseling must be provided for each new drug therapy and each drug therapy that the pharmacist deems necessary for the health and safety of the patient.
- Pharmacies must transfer a prescription to another pharmacy in a timely manner at the request of a patient or their agent.
- Schedule V prescriptions are only valid for six months or five refills.
- Schedule VI prescriptions are only valid for one year.
- Managers of record (MOR) must work an average of at least 30 hours per week at the pharmacy they manage.
- Additional compounding licenses are required for pharmacies that perform sterile and/or complex nonsterile compounding.

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## Waivers

With the new regulatory updates, the citations for many common waivers have changed. Pharmacies with these existing waivers will not have to change the citations until they

apply for renewal waivers once they expire. A list of **waiver conversions** to the new regulatory citations can be found on the Board's website.

## Nonresident Licensure

Regulations implementing the requirement for nonresident licensure have been promulgated, and on **January 1, 2025**, the Board will begin accepting **applications**. To avoid any delays, ensure that the application is complete with all necessary information and documents.

To apply, at least one pharmacist at each nonresident pharmacy must hold a Massachusetts pharmacist license (this pharmacist does not have to be the store's pharmacist-in-charge (PIC)). This designated PIC is responsible for ensuring nonresident pharmacy compliance with all Massachusetts laws and regulations pertaining to the practice of pharmacy.

A recent inspection will also be required. Please review the Board's **frequently asked questions document** for acceptable inspections and details.

**In addition to a retail pharmacy license ("non-resident drug store"), pharmacies that engage in sterile and/or complex nonsterile compounding will require additional licensure.**

The Board has no plans to offer nonresident licensure for non-dispensing pharmacies, wholesalers, distributors, third-party logistics providers, or manufacturers. Nonresident nuclear pharmacy licensing is not yet available.

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 the proper license(s) to dispense prescription products into Massachusetts. Please note that any prescription dispensed into Massachusetts must be pursuant to a valid patient-specific prescription. Pharmacies are **not permitted** to provide office stock.

**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.**



## Institutional Sterile Compounding Pharmacy Licensure

An institutional sterile compounding pharmacy includes any sterile compounding pharmacy located within a health care facility (including but not limited to hospitals, health maintenance organizations, and clinics) that holds either a **Hospital or Clinic Massachusetts Controlled Substances Registration (MCSR)**.

A separate Institutional Sterile Compounding Pharmacy license will be required for each unique Hospital or Clinic MCSR (ie, each different physical address). Any additional sterile compounding pharmacy area(s) under the same MCSR number will also require licensure.

Institutional nuclear medicine departments are not required to obtain Board licensure since they are not institutional pharmacies as defined by **Massachusetts General Laws (MGL) c.112, §39D**.

The Board will begin accepting **applications** from **January 1, 2025, through March 31, 2025**. After the application has been reviewed, an investigator will contact the pharmacy to arrange the initial on-site inspection to minimize any impact on daily operations.

Please review the list of requirements below that will be

# Institutional Sterile Compounding Pharmacy Licensure (cont)

necessary for the application and inspection processes:

- 1) Hospital MCSR number or Clinic MCSR number.
- 2) Name of MOR. This is the on-site pharmacist who is responsible for the operation of all sterile compounding pharmacy areas under the same MCSR.
- 3) Name of supervising pharmacist who is on-site at **each** sterile compounding area, as applicable.
- 4) List of all individuals who physically compound or directly supervise sterile compounding
- 5) **Certified blueprints/architectural drawings** of **each** sterile compounding area.
- 6) **Sterile Compounding Compliance Checklist** for **draft** sterile compounding regulations 247 CMR 17.00 for **each** sterile compounding area.
- 7) Completed **Sterile Compounding Pharmacy Inspection Template** for **each** sterile compounding area.
- 8) **Sterile compounding documents required for inspection.**



## Compounding Pharmacies

All retail **sterile** and **complex nonsterile** compounding pharmacies located in Massachusetts must obtain an additional license(s) from the Board to continue compounding and dispensing any sterile or complex nonsterile compounded preparations.

As with the other new license types (ie, nonresident, institutional),

the Board will begin accepting **applications** on **January 1, 2025**, which must be received by **March 31, 2025**.

**Beginning May 1, 2025, any compounding pharmacy must hold the appropriate additional license(s) to continue dispensing compounded prescription products.**

## Pharmacist License Renewal Reminders

Pharmacist licenses expire on December 31, 2024, so **you should renew now!** All licensing activities, including renewals, have transitioned to the new **eLicensing system**. If you have not already done so, you must create a new account. Simply click the “Create Account” button

located below the “Sign In” button on the new eLicensing system web page. After creating your account, follow the prompts and link your license to avoid delays in the renewal process. In addition to linking your pharmacist license, you should also link any other existing **Department**

**of Public Health (DPH) licenses** you may hold. This will help streamline your renewal process and house all your Massachusetts professional credentials in one place.

To assist with this transition, video tutorials have been provided that offer step-by-step instructions on

# Pharmacist License Renewal Reminders

(continued)

creating, linking, and renewing licenses, as well as managing forgotten usernames or passwords. These can be found in the online [Licensing System User Guide](#), which is conveniently linked in the banner on the eLicensing system web page. Additional assistance can be obtained by contacting the Help

Desk at 800/414-0168 or submitting an [eLicensing Support Request](#).

As a reminder, paper renewal forms are no longer issued. Instead, electronic notifications are sent via email, so make sure that your email address is always current in the eLicensing system.

And, as always, do not forget to complete your continuing education (CE)! General CE guidance is available in the Board's [CE policy](#). Please remember that at least five contact hours must be "live" each calendar year.



## Schedule II and III Supply Limits

MGL 94C §23(d) was [updated](#) on July 29, 2024, to allow certain Schedule II and III prescriptions to be written and filled for a 90-day supply:

- 1) Drugs for the treatment of opioid use disorder (buprenorphine-containing products, etc).
- 2) **Any** non-opioids in Schedules II and III (stimulants, testosterone, etc).

**Note:** It is no longer necessary to verify diagnoses for narcolepsy,

attention-deficit disorder, or attention-deficit/hyperactivity disorder.

- 3) Implantable infusion pumps.

All other Schedule II and III medications (methadone, oxycodone, etc) may only be filled for a maximum 30-day supply.

This change applies to all pharmacies that dispense into, within, or from Massachusetts.

Drug Enforcement Administration still allows the issuance of multiple prescriptions for all Schedule II

medications to provide up to a 90-day supply, so prescribers may continue to follow this practice, especially since stimulant medications are still in shortage. As outlined in [federal regulations](#), the prescriptions must be dated with the actual date written in addition to the "do not fill before" date. When verifying the validity from a timing perspective, use the "do not fill before" date as the "issue date."

## Did You Know?

- Remember to submit required **reports** on time to remain in compliance.
- Please take advantage of a free, one-credit CE program offered by DPH, titled *Responsive Practice: Providing Health Care and Screenings to Individuals with Disabilities*.
- Certificates of Achievement for the American Pharmacists Association's (APhA's) *Pharmacy-Based Immunization Administration By Pharmacy Technicians* training program expires after three years. There is a two-hour APhA home study program that **immunizing pharmacy technicians** can take to receive an updated certificate.

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