

MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

newsletter to promote pharmacy and drug law compliance

Pharmacy Technician Vaccination Authorization

Even though the federal Public Readiness and Emergency Preparedness Act is ending on May 11, 2023, updates to the Massachusetts Department of Public Health regulations now allow trained pharmacy technicians (PTs) to continue to administer certain vaccinations and emergency medications under the direct supervision of an immunizing pharmacist.

Pharmacists, interns, and trained PTs are all authorized to administer vaccines included in the latest recommended immunizations for adults and children as approved by the Advisory Committee on Immunization Practices (ACIP) to individuals five years of age and older.

In addition, any Food and Drug Administration (FDA)-approved, authorized, cleared, or licensed coronavirus disease 2019 (COVID-19) vaccines, regardless of whether or not they appear on the ACIP list, may be administered, but only in accordance with FDA's guidance and manufacturerapproved labeling.

As with pharmacists and pharmacy interns, training must be approved by the Accreditation Council for Pharmacy Education (ACPE) and current CPR certification must be maintained; however, PTs must also meet the following additional requirements before administering vaccines. They must be licensed as PTs and either be nationally certified (ie, the Exam for the Certification of Pharmacy

Technicians or the Pharmacy Technician Certification Exam) or have worked at least 500 hours after being licensed as a PT. Pharmacy technician trainees may not vaccinate.

Please review the Board's Vaccination Administration policy for complete details.

National Pharmacy Compliance News

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

COVID-19 Control Measures

COVID-19 control measures are defined by state law as a COVID-19 drug, COVID-19 test, or other COVID-19 diagnostic device approved or otherwise authorized by FDA.

Pharmacists and interns may dispense, or dispense by administration (administer), COVID-19 control measures under certain circumstances. One requirement is to complete an ACPE-accredited training program on COVID-19 drugs that includes contraindications with commonly prescribed medications, recommendations for clinical monitoring, and appropriate recommendations for follow-up with a medical practitioner. Please be aware that there may be additional training required by the product's FDA approval or authorization.

Under a pharmacy's standing order for COVID-19 control measures, a reasonable effort must be made to obtain the purchaser's insurance coverage and submit a claim, unless the purchaser requests to pay out of pocket.

Medications for the treatment or prevention of COVID-19 may be administered, but only in accordance with FDA approval or authorization, and only subcutaneously or intramuscularly. No other routes, including intravenous, are permitted. If needed, appropriate private space based on the nature of administration (eg, gluteal injection) must be provided, as well as any required post-injection observation (eg, one hour) or clinical monitoring.

If performing COVID-19 tests on site at a pharmacy, use appropriate areas (eg, segregated area, drive-through) and take precautions when consulting with COVID-19-positive patients in order to reduce the risk of transmission. No aspects of testing (including machine-processing of specimens), may be conducted within a pharmacy's licensed prescription area, including the service counter.

Complete information regarding COVID-19 control measures can be found in the Massachusetts Board of Registration in Pharmacy's policy.

Implementation of New and Revised USP Chapters

The revised United States Pharmacopeia (USP) <795>, <797>, <800>, and <825> Chapters will become compendially applicable on November 1, 2023, and there have been several inquiries on the Board's stance regarding enforcement.

Enforcement of USP <795>, <797>, and <825> will be done through education and coaching during inspections to ensure compliance as of November 1, 2023.

However, USP <800> became official on December 1, 2019, and on October 3, 2019, the Board voted to inspect pharmacies on these standards with the intention of directing pharmacies to develop an action plan to work toward compliance. Pharmacies not yet in compliance with USP <800> will be issued a plan of correction.

Renovations

When a Board-licensed pharmacy is planning for renovations including remodeling, change in configuration, or change in square footage, an application must be submitted to the Board prior to beginning the work. To avoid delays, remember to include all requested information such as a complete description of the work to be done, certified blueprints with the current layout outlined in blue and proposed layout outlined in red, square footage, containment strategy/risk mitigation plan, and a written plan to maintain security of controlled substances.

If the Board-licensed pharmacy is located within any health care facility, documentation of approval from the facility's licensing body(s) must also be provided.

Regulations and Public Hearings

The process of adopting, amending, or repealing regulations includes many steps:

- draft the updated regulations;
- schedule a public hearing;
- · review public comments and make revisions, if applicable;
- · receive approval of finalized draft; and
- publish and implement.

As part of the administrative process, the public will have an opportunity to provide testimony regarding proposed regulatory changes at a public hearing. Hearing testimonies may be presented orally or in writing. However, a written copy of any oral testimony will be requested. Written testimony can be submitted via email or mail, as detailed in the hearing announcements.

The Board takes all comments offered by the public into account when reviewing the proposed regulatory changes and may adjust accordingly.

For more information on the regulatory process, the Secretary of State's Regulations Manual is an excellent resource. The Board's drafted regulations may be found here.

Getting to Know the Board Staff - Richard Geaney, Jr

As one of the Board's pharmacy investigators, Richard "Rick" Geaney, Jr, may have inspected your pharmacy at some point. Rick has always focused his practice on being compliant with rules, regulations, and laws in the retail setting; and when a pharmacy investigator opportunity arose, it was a perfect fit.

Before Rick attended Massachusetts College of Pharmacy and Health Sciences to become a pharmacist, he worked at Osco Drug as a stock boy. One day, after wandering into the pharmacy area to deliver supplies, he struck up a conversation with the pharmacist. With his interest piqued, he started his career and love of pharmacy.

Rick feels that the best part of inspecting pharmacies is working directly with the pharmacy staff to discuss his observations and provide education. Rarely are his observations a surprise when he points them out. While some violations are minor and can be resolved while he is still on site, others may require some work and follow-up. The goal is to help pharmacies become compliant.

Rick wants licensees to know that all the inspection templates are available on the Board's website in order to help you prepare for upcoming inspections. In addition, pharmacy investigators, as well as members of the Board staff, are all here to assist with questions to help you be compliant.

Rick's advice to pharmacy interns is to "Always let your supervisor / boss / coworkers know where you want your pharmacy career to go. If you are not vocal about what you want your future to hold, no one else will know what you want to achieve."

When he is not inspecting pharmacies, Rick spends his free time with his most valued thing: his family. His blessings include a beautiful, amazing wife (also a pharmacist) and two outstanding girls.

Did You Know?

- The Board is in the process of restructuring and reorganizing its website. Please be patient as
 we make it more user-friendly.
- All interns, technicians, and pharmacists must have a valid Massachusetts license whenever they work or intern in a Massachusetts-located pharmacy. Out-of-state registrations or licenses are not sufficient.
- Last year, MassHealth changed prescription drug days supply limitations. Pharmacists are
 permitted to make quantity changes for drugs that do not require prescription monitoring
 program (PMP) reporting in accordance with Board policy.
- Please visit this web page for a statewide emergency contraception standing order and frequently asked questions.
- Most Massachusetts insurance plans, including MassHealth, Group Insurance Commission, and private insurers, are required to cover a 12-month supply of birth control pills to be dispensed all at once. Check with the insurer for any questions. Be aware that pharmacists are permitted to make quantity changes for drugs that do not require PMP reporting in accordance with Board policy.
- Suspected fraudulent e-prescriptions should be directly reported to Surescripts at support@ surescripts.com or 866/797-3239. Although this is the general support line, these reports will be immediately forwarded to the anti-fraud team. To date, fraudulent scripts have been the result of identity theft, providing approved access to register with an electronic prescription for controlled substances system. To their knowledge, the system has not been hacked.

- As a reminder, veterinary prescriptions for Schedule VI drugs do not require a Drug
 Enforcement Administration number. If needed, contact your IT Department/Help Desk to walk
 you through the data entry process without it. Please note that Schedule VI prescriptions only
 require the prescriber's Massachusetts Controlled Substances Registration number.
- Please review the updated Data Submission Guide for Dispensers for acceptable identification and dispensing procedures for when identification is not available.
- When the **manager of record** of a pharmacy changes, a new pharmacy license is sent to the store in about two to three weeks. If it is not received, please **email** the Board.

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