



MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

newsletter to promote pharmacy and drug law compliance

Pharmacy Practice Updates

Now that the federal public health emergency (PHE) has ended, there have been some changes to **pharmacy practice** resulting from the activities that were allowed under the Public Readiness and Emergency Preparedness Act (PREP Act), as well as continued staffing shortages.

Coronavirus disease 2019 (COVID-19) control measures, including COVID-19 tests and Paxlovid™, may be dispensed or administered in accordance with **Policy 2023-03: COVID-19 Control Measures**. The COVID-19 over-the-counter diagnostic testing statewide standing order can be found [here](#).

As staffing shortages continue, the Massachusetts Board of Registration in Pharmacy does not intend to take enforcement action against pharmacies that perform and reconcile **perpetual inventory counts** at least every 15 days as long as back counts are performed after each prescription is filled.

Although **state regulations** have changed to allow pharmacists, pharmacy interns, and pharmacy technicians to administer certain **vaccines** to individuals five years of age and older, the **Eleventh Amendment** to the declaration under the federal PREP Act continues to allow administration to individuals three years of age and older. Because the PREP Act Declaration supersedes the state age limitations, pharmacy personnel may continue to administer vaccines to individuals three years of age and older until December 31, 2024, unless there are further amendments. See **Policy 2023-02: Vaccine Administration** for other vaccination requirements.

National Pharmacy Compliance News

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In response to the continued public health need for vaccinations, the Board will not be enforcing the **supervisory ratios** set out in [247 Code of Massachusetts Regulations 8.06\(3\)](#) at licensed pharmacies that are providing vaccination services, if the following conditions are met:

1. a maximum ratio of one pharmacist to six support staff is not exceeded; and
2. at least three of the support staff are interns and/or certified licensed pharmacy technicians.

Any pharmacies that do not administer vaccinations but would like the Board to consider their specific circumstances regarding supervisory ratios may contact the Board.

Prescriptions for ADD, ADHD, and Narcolepsy

Quantities for Schedule II and III medications are generally limited to a 30-day supply as required by [state law](#). However, a 60-day supply is allowed when indicated either for narcolepsy or “minimal brain dysfunction,” which includes attention-deficit disorder (ADD), attention-deficit/hyperactivity disorder (ADHD), or other accepted term for an inattention or impulsivity-hyperactivity disorder. Those medications eligible for a 60-day supply for these disease states include dextroamphetamine sulfate, methylphenidate hydrochloride, and any other mixed amphetamine salts or derivatives that are approved by Food and Drug Administration for the treatment of these conditions. See the Board’s [policy](#) for details.

Compounding Guidance

The Board has several policies and advisories to guide licensees with both sterile and nonsterile compounding activities. A few have been highlighted below, but the complete list can be found [here](#).

Defective Drug Preparation

[State law](#) requires all Board-licensed pharmacies to have a [defective drug preparation log](#) and recall procedures for any compounded drug preparation that is defective or thought to be defective. This is mandated for any defective compound, including those prepared in a typical retail setting (eg, magic mouthwash).

Nonsterile Compounding

This [policy](#) provides an overview and guidance for nonsterile compounding, including the addition of flavoring agents, labeling, compounding copies of commercially available drugs, splitting tablets, and compounding kits.

With its recent revision that will become effective on November 1, 2023, United States Pharmacopeia (USP) Chapter <795> will no longer acknowledge the category of “complex non-sterile compounding”, but because [Massachusetts State law](#) will continue to recognize it, a definition and examples are also provided.

Action Levels

When a sterile compounding environment exhibits action level contaminants as defined in USP Chapter <797>, there are certain reporting and remediation requirements outlined in Board [policy](#). At this time, hospital sterile compounding pharmacies are not required to comply with this policy since they are not yet licensed by the Board.

The Board also has an [advisory](#) that provides some helpful tips on how to evaluate the risk to sterile preparations, investigate the root cause, and implement appropriate remediation and action plans after an excursion.

Getting to Know Your Board Members – Rita Morelli

In her junior year of high school, Rita Morelli attended a health careers day at a hospital where she met a pharmacist who was instrumental in changing her career path. She had planned to pursue a nursing degree and had never considered pharmacy until that day. The pharmacist displayed intravenous solutions that he had prepared and offered her a brochure providing an overview of the role of a pharmacist. From that day forward, she decided that becoming a pharmacist was a better fit for her than being a nurse.

Rita attended Massachusetts College of Pharmacy and Health Sciences (MCPHS) for her bachelor of science degree and returned many years later to earn her doctor of pharmacy degree. She wanted to transition to a clinical pharmacist role after many years of working in community pharmacy and felt that a PharmD would give her the needed skills. Oddly enough, instead of clinical pharmacy, she wound up transitioning into academia.

After starting her position with MCPHS, Rita attended her first of many monthly Board meetings. She enjoyed them and learned a great deal about the regulatory process. One of her first meetings involved the New England Compounding Center (NECC) meningitis outbreak, which became the focus for many future meetings. She saw firsthand the challenges of NECC and all the regulatory changes that were required as a result. Because she wanted to participate in the process, Rita applied for the academic seat on the Board and was excited to be appointed as a member in November 2021.

The Board's mission is to protect and preserve the health and safety of the public, and the 13-member Board focuses on this during every meeting. Not only are the differences of opinion expected, but Rita also finds them to be valuable. It is through professional and respectful discussion – and sometimes debate – that the Board members approach various topics. Board staff also provides their expertise to aid the Board members in their decision making.

As a Board member, the valuable experience she has gained has helped her develop a new perspective on the regulatory process. It has also helped sharpen her collaboration skills, especially when interacting with other Board members.

Her advice for pharmacy students is that “no matter where you start your career as a pharmacist, involve yourself in continuous professional development and take advantage of networking opportunities. Always be ready for the next opportunity that may come your way.”

Rita’s career in pharmacy has offered her many opportunities and she has met many great colleagues and friends along the way, although her favorite times are spent with family, especially relaxing on the beach with them in Maine.

Did You Know?

- **MassHealth** has recently published information regarding [co-pay changes](#) and the [end of the PHE](#). You can see all their documents, as well as sign up for MassHealth Pharmacy Facts, [here](#).
- 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](#).
- 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.
- Please visit this [web page](#) for the 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](#).
- Please review the updated [Data Submission Guide for Dispensers](#) for **acceptable identification**, as well as the dispensing procedures for when identification is not available. Although not specifically listed, firearms licenses are acceptable for identification since they are a state-issued form of ID.

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