



MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

newsletter to promote pharmacy and drug law compliance

Authorized Generic Dispensing

According to [Massachusetts law](#), pharmacists must dispense a less expensive, reasonably available interchangeable drug product as long as the drug product is listed in the [Massachusetts List of Interchangeable Drugs](#) and the prescriber has not indicated “no substitution” on the prescription.

An **authorized generic drug** is an approved brand-name drug that does not have the brand name on its label but is the exact same product. Authorized generics exist under the same New Drug Application (NDA) as the brand drug product.

Typical generic drugs are approved by the Food and Drug Administration (FDA) under an Abbreviated New Drug Application, which requires the generic to demonstrate bioequivalence to the corresponding brand product. Since an authorized generic is marketed under the brand-name drug’s NDA, it is not considered “bioequivalent” and is not listed in FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“[Orange Book](#)”).

Even though it is not listed in the “Orange Book,” a pharmacist may interchange a prescription written for a brand-name drug with its authorized generic version provided that the prescriber did not indicate “no substitution” on the prescription. To determine if a drug product is interchangeable, the [FDA listing of authorized generics](#) may be utilized or the manufacturers, distributors, or repackagers may be contacted directly.

Scam Calls

The Bureau of Health Professions Licensure (BHPL) has issued a [warning](#) about individuals impersonating Massachusetts BHPL investigators, Drug Enforcement Administration (DEA) agents, DEA investigators,

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Massachusetts Drug Control Unit investigators, Federal Bureau of Investigation investigators, and other law enforcement personnel as part of an extortion scheme.

The impersonators are contacting licensees by telephone, stating that they are the subject of an investigation and demanding money or threatening to revoke the individual's license. Please be advised that the BHPL will not contact licensees by telephone to demand money. Investigators may call to interview licensees or request documentation only. Licensing boards at BHPL will only send written notices to an individual's address of record regarding formal actions against their license such as suspension or revocation.

Licensees receiving such a telephone call are encouraged to report the call to the [Federal Trade Commission](#).

Temperature Excursions

Many medications require special storage conditions to ensure their safety and effectiveness. Two common examples are refrigerated and frozen medications. In the pharmacy, this is accomplished through the use of dedicated refrigerators and freezers – both of which require constant monitoring and temperature documentation.

According to United States Pharmacopeia General Chapter <1079>, refrigerators and freezers should be maintained between 36° to 46°F (2° to 8°C) and -13° to 14°F (-25° to -10°C), respectively. Any temperature that falls outside of those ranges is considered an excursion. However, be sure to check manufacturer instructions for any specific product storage requirements (eg, an ultra-cold freezer).

Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications outlines the steps to take in the event of a temperature excursion. It requires pharmacies to develop their own procedures, including an action plan, which should contain an easy-to-follow, stepwise approach detailing the excursion and required actions. This should include documentation requirements for the out-of-range temperature, duration, time of day, action, etc.

First, it is important to assess the excursion and quarantine all affected products. Upon inspection, any visibly altered or damaged products (eg, obvious particulate, refrigerated product that has been frozen) must be removed from the active inventory. For other products, contact the manufacturers to confirm safety and efficacy after exposure to temperatures outside of the recommended range. Any products deemed unsafe or ineffective, or any products that cannot be confirmed to be safe and effective, must also be removed. Prior to returning any products to stock, confirmation/evidence of safety and effectiveness must be documented. If an unsafe or ineffective medication has been inadvertently administered or dispensed to a patient, the patient and their health care provider must be notified.

While some excursions are the result of unpredictable circumstances, the best way to handle most temperature excursions is by taking appropriate steps to prevent them from happening. One important action is to ensure that the cold chain process is maintained through the life cycle of the product, including shipping, delivery, waiting bin storage, etc.

Additionally, temperatures should be documented at least twice daily. On days when the pharmacy is closed, there must be a mechanism in place to identify any temperature excursions. Lastly, the unit must be well organized and not overstocked. Both the inside and outside of the unit should be free from clutter so as not to impede proper air flow.

Getting to Know Your Board Members: Katie Thornell

Since both her parents worked in health care, Katie knew from a young age that she wanted to follow a similar path. After exploring several different avenues, she realized that pharmacy was the right choice for her.

Katie graduated from a joint program with Simmons University and Massachusetts College of Pharmacy and Health Sciences in Boston with degrees in both chemistry and pharmacy. Her college work experience included clinical trial lab work and interning at an independent pharmacy. After graduation in 1999, Katie accepted a Stop & Shop Pharmacy position and has been there ever since.

After becoming a district manager, Katie began to attend the open sessions of the Massachusetts Board of Registration in Pharmacy meetings and enjoyed hearing the reports and discussions. Since she found it so fascinating, Katie applied to become a member of the Board and was appointed into a chain pharmacy seat in February 2020.

Katie feels that the differing opinions and open discussions are valuable at the Board meetings. It is helpful to have subject matter experts for specific issues to facilitate dialogue and fully explore all views and concerns. Katie has expressed that it is her honor to be able to work with such a diverse group of individuals in service to the citizens of the commonwealth.

In Katie's eyes, the coronavirus disease 2019 (COVID-19) pandemic is the Board's biggest current challenge. To increase health care access, the Public Readiness and Emergency Preparedness Act has allowed a temporary expansion of pharmacy duties including COVID-19 testing and technician administration of vaccines. The Board will do what it can to ensure that pharmacy licensees can continue to practice at the top of their licenses post pandemic.

Katie's advice is to "encourage all students to take the time to speak with their patients. They play a critical role in patient care. Whether you are practicing as an intern or when you become a pharmacist, make sure you are practicing to the top of your license. Jump in and make a difference."

Katie lives in Beverly, MA, with her husband, Todd, and son, Tynan, and spends her weekends at the hockey rink.

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 if issued from any state.
- Schedule II **narcotic** prescriptions may only be filled if issued from Maine or states contiguous to Massachusetts (Connecticut, New Hampshire, New York, Rhode Island, and Vermont).
- 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.
- 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 list!

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David Sencabaugh, RPh - Executive Director

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Amy Sanchez - Publications and Editorial Manager

250 Washington Street | Boston, MA 02108 | www.mass.gov/dph/boards/pharmacy
