November 2020

News

Massachusetts Board of Registration in Pharmacy

Published to promote compliance of pharmacy and drug law

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COVID-19 Updates

As with everyone in the state, country, and world, life has changed dramatically as a result of the coronavirus disease 2019 (COVID-19) pandemic. Life at the Massachusetts Board of Registration in Pharmacy was no exception. Because pharmacy plays such an integral role in health care, the Board was extremely busy during the early stages of the declared emergency. However, the Board quickly adapted to working remotely and handling the questions and needs of licensees while learning how to Zoom, conduct virtual inspections, and socially distance.

To date, the Board has fielded more than 200 inquiries related to the practice of pharmacy during COVID-19. Questions ranged from compounding hand sanitizer, to personal protective equipment, to curbside pickup, and what to do when an employee tests positive. In total, 30 COVID-19-related frequently asked questions (FAQs) and 10 commissioner's orders were posted on the website with the goal to assist licensees in their practice of pharmacy. In conjunction with the National Association of Boards of Pharmacy® (NABP®) Passport program, the Board has authorized more than **64 pharmacists and 26 technicians** to practice in Massachusetts during the emergency period using their current out-of-state licenses.

In addition to posting and distributing emails regarding the FAQs and orders that ultimately answered many of the inquiries, Board staff and investigators answered several questions with one-on-one responses. Board staff also reached out to many pharmacies randomly to check in and provide support.

Pharmacy has been supported in a big way by NABP, Drug Enforcement Administration, and Food and Drug Administration. All of these organizations have clearly spent many long hours making sure patient prescription needs were met during this emergency. FAQs and Orders will remain on the Board website as long as they are needed and in effect. For now, Board meetings will be virtual and held in shorter, more frequent segments. Please visit the Board website for information about upcoming meetings and agenda items.

While the Board still has a long way to go, it remains dedicated to patient safety and helping licensees toward that end. Please continue to send your questions to the Board at pharmacy.admin@massmail.state.ma.us as we all work to overcome this together.

Technician Trainees and Extensions

Recently revised regulation 247 Code of Massachusetts Regulations (CMR) 8.03 requires all pharmacy technician trainees (PTTs) to be licensed by the Board before working in a pharmacy. The licensing process provides prospective employers with the ability to see if an applicant has ever been involved in diversion or other misconduct. A PTT license is valid for up to 1,500 hours of employment or for one year, whichever period is shorter. **Board staff is only authorized to grant a maximum one-year extension.**

Extensions may be granted in the following scenarios:

- if the individual has not yet completed at least 500 hours of employment as a PTT;
- for up to 90 days after the license expiration date;
- if the individual has not yet reached 18 years of age, then it may be extended until the individual turns 18 years old or up to one year, whichever is sooner.

Getting to Know Your Board Members – Kim Tanzer

Although she works in academia, Kim Tanzer's answer to the question "What do you do?" is first and foremost, "I am a pharmacist." Her passion for the profession has led her to the academic seat on the Board. This has allowed her to give back to the profession of pharmacy in a unique way as well as support her fellow pharmacists while doing so.

After high school, Kim entered college at the University of Maryland, College Park as a pre-med major but was not sure about which direction to take. A roommate introduced her to pharmacy, and it turned out to be the perfect fit. She eventually transferred to the University of Maryland, Baltimore, where she completed her bachelor of science degree in pharmacy. Later in her career, she went on to complete the nontraditional doctor of pharmacy program at MCPHS University in Boston, MA.

Throughout her career, Kim had worked in several practice settings including community, hospital, and home infusion in the roles of pharmacist, manager of record, and director. In 2009, she moved into academia with a role in experiential education at MCPHS University. She currently serves as the assistant dean for experiential affairs and director of continuing education at Western New England University (WNE) College of Pharmacy and Health Sciences.

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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Kim's role at WNE included becoming the liaison to the Board and attending the monthly Board meetings. This was a new experience for her, and she was impressed with how collaborative the Board was in its discussions. She was even more intrigued with the work being done by the Board. The development of new regulations was a priority at the time, and Kim decided that she wanted to be a part of that process.

Once the academic seat on the Board became vacant, Kim applied and was appointed in November 2017. As a new Board member, she found the existing Board members and Board staff to be supportive and generous with their knowledge, helping her develop a greater understanding of Board processes. "As I have become a more experienced Board member, I have appreciated the mutual respect of the members towards each other, as we sometimes have to agree to disagree. While the Board does not always vote unanimously on all points, consensus is always met through a collaborative, respectful process."

Last year, the Board voted for Kim to be president, and she assumed that role in January 2020. "My role as president has been an incredible experience. It has given me the opportunity to work more directly with Board staff and interact on a more personal level with the pharmacists in Massachusetts. My experience on the Board has been the highlight of my career."

"Pharmacists have a lot of responsibility, and current practice models have placed a lot of pressure on pharmacists with regards to workload and multitasking. For pharmacists in all practice settings, my advice is the same; focus on patient safety. When things get busy and you are spread thin with your workload, pull back and refocus your efforts on patient safety. With this mindset, and the Board to guide you, you will be successful."

Retail Compliance Inspectional Deficiencies in 2019

Every year, the Board investigators report the number of inspections, plans of correction, and most common inspectional issues for the previous year. A plan of correction is a written statement outlining the specific steps that a pharmacy will take to remediate inspectional violations.

In 2019, investigators completed 1,939 retail compliance inspections and issued 267 plans of correction. Although the number of plans of correction have been declining over the past three years, many of the same deficiencies continue to be observed year after year.

1. **Equipment, Facility, and Drug Storage:** Of the 1,939 inspections, 108 had deficiencies cited with equipment, facility, and drug storage. Most commonly this included expired medications in active inventory and/or dispensed to a patient, substandard medications due to temperature excursions, and pharmacy balance or scale seals that were expired.
2. **Controlled Substance Records:** Deficiencies with controlled substance records were cited during 83 inspections. Although the number of these deficiencies has decreased by almost 40% from 2018, expired and damaged Schedule II medications that had not been maintained in perpetual inventory continues to be a common problem. Schedule II reconciliation not being performed every 10 days was the next most often observed deficiency.
3. **Refrigeration:** Temperature excursions in pharmacy refrigerator(s) and/or freezer(s), lack of documentation of actions taken by the staff to validate that medications were still safe and effective after excursions, and overstocked refrigerators were common deficiencies in this portion of the inspection. Deficiencies of these types were cited in 65 inspections. (**Note:** Please review the Board's recently updated Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications.)
4. **Manager of Record:** Almost half of the 57 deficiencies regarding managers of record were due to supervisory ratios being out of compliance with 247 CMR 8.06 (3). Other issues included improper maintenance of records and untimely submittal of change in manager of record applications to the Board.
5. **Immunization:** Unavailable proof of current CPR certification was cited in over half of the 49 inspections with a deficiency in this section. Additional deficiencies included lack of immunization certificates and expired and/or substandard vaccines located in a pharmacy's refrigerators and freezers.

Managers of record should conduct periodic self-inspections using the inspection templates to help identify and correct deficiencies.

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