May 2020

News

Massachusetts Board of Registration in Pharmacy

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Prescription Changes

As a reminder, changes to the Permitted Prescription Changes and Additions policy allow pharmacists to change days supply dispensed (eg, 30-day supply with 11 refills versus 90-day supply with three refills or vice versa) without consulting the prescriber. However, this is not permissible for drugs that must be reported to the prescription monitoring program, including gabapentin. Pharmacists are advised to exercise extreme caution with drug classes where a change in days supply may put a patient at risk. Narrow therapeutic index drugs (eg, lithium, warfarin) and behavioral health drugs (eg, antipsychotics, antidepressants) are two classes of drugs where changing the days supply may not be appropriate. Before changing the days supply, it is strongly recommended to consult prescribers upon initiation of new therapy and changes for any drugs that may be of concern.

Voluntary Assessments for Institutional Sterile Compounders

The proposed regulation Draft 247 Code of Massachusetts Regulations 6.00: Licensure of Pharmacies will require the Massachusetts Board of Registration in Pharmacy to license and inspect institutional sterile compounding pharmacies. In preparation, "voluntary assessments" are available for those future licensees (eg, clinic and hospital pharmacies) to have the opportunity for a Board inspector to assess sterile compounding areas for compliance with current United States Pharmacopeia (USP) standards, as well as make recommendations in view of future Massachusetts regulations and USP revisions. This is an opportunity for education, informal feedback, development of cross collaboration, and help with resource planning.

The assessments would evaluate the following areas: facility, standard operating procedures, certifications, environmental monitoring, employee training, cleaning, personnel garbing, compliance, and verification practices. To date, 15 assessments have been performed with many observational findings supporting the need for some upgrades or renovations in order to become compliant with USP General Chapters <797> and <800>.

The voluntary assessment would take place at a mutually agreeable date and time, and at the conclusion of the assessment, Board investigators will provide the completed assessment document and discuss observations in detail.

If interested in participating in a voluntary assessment, directors of pharmacy or other authorized representatives may contact Nathan Van Allen via email at nathan.vanallen@massmail.state.ma.us. The current coronavirus disease 2019 (COVID-19) situation may affect availability.

Getting to Know the Board Staff – Rick Harris

As a member of the Board staff, Rick serves as the program analyst. He came to the Board after 25 years of working with children and families in a variety of settings in both Massachusetts and Connecticut. Along the way, Rick has kept busy as a published author, composer, singer, and had a brief stint in the Actors' Equity Association. He has also served as an emergency medical technician and an instructor/trainer in water safety, first aid, and CPR.

When Rick first joined the Bureau of Health Professions Licensure, he worked in the office of public protection and then joined the Board in 2014. He wears a variety of hats, but his primary focus is licensing. Rick helps pave the way for individuals and facilities navigating the licensing process. This means providing organizational systems, assisting applicants, troubleshooting problems, and answering various questions about the licensing process.

Rick works closely with applicants who have had previous legal difficulties or who have received discipline on a professional license here in Massachusetts or in other jurisdictions. These "Good Moral Character" applicants often need support and guidance as they prepare to appear before the Board. Rick says, "It is one of my favorite parts of my job. I get to work with people who have made some mistakes in the past but are trying hard to move forward with their careers. I find that very rewarding."

National Pharmacy Compliance News

May 2020

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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations*® (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy®'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain:*

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

Security Cameras

There are many measures that pharmacies and pharmacists can employ to guard against controlled substance (CS) loss and diversion. These range from policies and physical security methods, to more sophisticated video surveillance. In addition to investigations of drug losses, security cameras can also minimize opportunities for theft or diversion and should be an integral part of a comprehensive security plan. The main goals of any pharmacy security camera system are to protect employees and customers as well as safeguard the security of the drugs.

One consideration is for pharmacies to perform a risk assessment of the vulnerabilities of the pharmacy to determine how to implement and maximize the use of video surveillance. Strategically placed high-resolution security cameras can cover all areas where employees interact with CS and deter opportunities for undetected employee theft. Cameras should capture entrances and exits, as well as any areas CS are received, stored, dispensed, counted, held, or returned to stock, and should also have a clear view of the point of sale locations.

A quality security camera system can be a valuable tool to help investigate a loss or otherwise determine what happened to a particular prescription during the filling and pickup processes. A review of security footage may conclusively determine that a full bottle of medication was inadvertently discarded in the trash or identify the culprit of a theft. Without security footage, these issues could not be resolved.

Another consideration is video retention. During the risk assessment, the pharmacy should determine a realistic time frame between audits and manual inventory counts to decide how long to keep footage. Having security cameras and a minimum retention period for the videos will help with investigations as well as deter theft.

Identification Requirements

Patients or their agents **do not need an ID** to pick up prescriptions for federally scheduled CS in certain circumstances. However, an individual must print his or her name and address on the reverse side of the prescription and sign it. In the case of an electronic prescription, he or she must provide an electronic signature. Review the Data Submission Dispenser Guide for details.

Did You Know?

- Veterinarians do not have National Provider Identifier numbers and are not required to provide their Drug Enforcement Administration (DEA) numbers for Schedule VI prescriptions. Contact your help desk/IT department if you need assistance adding veterinarians to your computer system.
- COVID-19 updates and resources can be found on the Board's website.
- Be aware of unusual calls or emails from the Federal Bureau of Investigation, DEA, or the Board asking for identifying information or money. There have been reports of calls and emails that appear to have originated from official agencies but are really from spoofed phone numbers or emails. The Board will never call to ask you for money. If you have concerns, verify the requestor's identity through other means before acting on suspicious communications.
- Review your own knowledge and help your interns study for the Multistate Pharmacy Jurisprudence Examination® with these references.
- You can always ask pharmacy practice questions at Pharmacy.admin@massmail.state.ma.us.

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