February 2020

News

Massachusetts Board of Registration in Pharmacy

Published to promote compliance of pharmacy and drug law

239 Causeway Street, 5th Floor • Boston, MA 02114 • *www.mass.gov/dph/boards/pharmacy*

e-Prescribing Mandate

In 2018, the Massachusetts Legislature issued a mandate that all controlled substance (CS) and device prescriptions be issued electronically as of January 1, 2020. Changes to the regulations were made to implement this mandate based on public comments and other states' experiences when implementing their own e-prescribing requirements. Although the changes took effect on January 1, 2020, the regulation includes a one-year grace period before e-prescribing will be required. This will give prescribers, facilities, and pharmacists more time to fully transition to e-prescribing.

Starting January 1, 2021, all prescriptions for federally scheduled CS and medical devices must be issued on federally compliant e-prescribing systems. However, there are several exceptions to the e-prescribing requirement, including prescriptions issued in emergency situations, prescriptions for Schedule VI medications (non-federally scheduled CS), prescriptions for residents of nursing homes (mandate delayed through January 1, 2023), and other exceptions as stated in the revised 105 Code of Massachusetts Regulations (CMR) 721.070. Time-limited waivers are also available.

Waiver requests may be submitted to the Drug Control Program at any time after January 1, 2020, but should be submitted by October 1, 2020, to ensure processing and approval of the request by January 1, 2021.

If a prescriber chooses to e-prescribe a Schedule VI medication and the prescription fails to transmit properly, resulting in a computer-generated fax, a pharmacist may dispense the medication as if it were a valid oral prescription.

At any time, a pharmacist receiving an otherwise valid written or oral prescription may dispense the prescription without having to verify that a waiver has been granted to the prescriber or that an exception applies.

For more information on e-prescribing, prescription format and security, and these regulatory changes, please contact the Drug Control Program and view 105 CMR 721 (choose "Post-Comment Regulation" to show changes effective in 2020).

USP Chapter <800> in Community Pharmacies

Massachusetts regulations require pharmacists to follow all current chapters of United States Pharmacopeia (USP), including USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. Even though most community pharmacies typically only dispense hazardous drugs (HDs) in their final dosage form, they are also required to follow those standards. The Massachusetts Board of Registration in Pharmacy has recently approved an advisory to aid retail pharmacies with compliance of USP Chapter <800>.

All the containment strategies of USP Chapter <800> **must** be followed in these three situations:

1. when manipulating antineoplastic drugs;
2. when compounding with any National Institute for Occupational Safety and Health HD active pharmaceutical ingredient (API), including crushing tablets or opening capsules of an HD; or
3. if an assessment of risk has not been performed.

As an example, if clonazepam tablets are crushed to compound a suspension, this would be considered nonsterile HD compounding with a hazardous API and subject to the containment requirements of USP Chapter <800>. Containment would include using a powder hood that is located in a negative pressure room.

Each entity must have a designated person to develop and implement procedures, monitor for compliance, and meet other requirements of USP Chapter <800>. This person does not have to be a pharmacist or pharmacy technician, and does not have to be in the pharmacy.

An HD program must be developed to address all applicable requirements of USP Chapter <800> including at least the following:

- identify all HDs and the risk category of each one, make an assessment of risk, and address scenarios where personal protective equipment may be needed;
- develop standardized storage and handling procedures;

Continued on page 4

National Pharmacy Compliance News

February 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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

Continued from page 1

- make sure all personnel are appropriately trained for their specific job function; and
- develop comprehensive policies and procedures to include situations such as spills, deactivation, decontamination, cleaning, and waste.

Veterinary Prescription Pearls

Most veterinary medications are dosed by weight, similar to pediatric medicine, and may seem significantly higher or lower than a typical human dose. For instance, since dogs metabolize levothyroxine very quickly, doses are usually quite high and are therefore dosed in mg not mcg.

Human over-the-counter (OTC) drugs are not labeled for use in any species other than humans. Consequently, pharmacists are prohibited by federal law to recommend a human OTC drug for an animal unless such use is pursuant to a prescription or documentation from a veterinarian.

Veterinarians do not have National Provider Identifier numbers because they do not provide care to humans. Their prescriptions require their Massachusetts Controlled Substances Registration number for Schedule VI and Drug Enforcement Administration (DEA) number for Schedules II through V.

Food and Drug Administration's (FDA's) "Green Book" contains a listing of FDA-approved drugs for animals, most of which are sold by veterinary distributors who limit distribution only to veterinarians.

Pharmacists who fill veterinary prescriptions should have access to at least one veterinary drug reference (eg, Plumb's Veterinary Drugs). References will contain valuable information such as:

- xylitol, which is found in commercial gabapentin 50 mg/ml, is toxic to dogs
- since cats do not absorb or convert prednisone to prednisolone very well, prednisolone is preferred over prednisone
- any amount of acetaminophen is toxic to cats

As a reminder, there are no requirements for veterinarians in Massachusetts to review the Massachusetts Prescription Awareness Tool prior to issuing prescriptions. Monitor veterinary prescriptions for federally controlled drugs for any potential substance misuse issues.

Getting to Know Your Board Members – Susan Cornacchio

This quarter, the Board is highlighting member **Susan Cornacchio.**

As a public member of the Board, Susan Cornacchio began her career as a critical care nurse and later became an attorney to practice as court-appointed counsel for indigent criminal defendants.

Susan eventually transitioned to a role at the Board of Registration in Medicine, to direct the monitoring program for physician compliance with substance abuse and mental health monitoring contracts. She conferred with physicians and counsel with the goal of helping physicians in their recovery, while keeping patients in the commonwealth safe.

From there, she began the patient safety and risk management part of her career and was responsible for reducing errors, improving the quality of patient care, and reducing malpractice risk in a wide variety of clinical and corporate settings across the greater Boston, MA, area.

With her current organization, she continues to promote patient safety in a transformative health care setting on a national scale.

Susan feels that as the health care landscape changes and the role of the pharmacist expands over the next several years, health care regulators will need to keep pace. They will need to protect the public by quickly identifying emerging pharmacy practice risks, while also supporting the profession as it evolves.

Susan advises pharmacists to "fully participate in the pharmacy community as possible, by attending conferences, educational programs, and attending board meetings. Exposure to pharmacists from a wide variety of practice settings will broaden their perspective and ability to adapt to the ever-changing world of pharmacy."

Did You Know?

The Board's policy on the use of automated dispensing devices (ADD) requires retail pharmacies that have placed an ADD in an authorized facility for dispensing routine medications to obtain a machine-specific DEA number and CS registration.

Board Staff

David Sencabaugh, RPh..... Executive Director
Monica Botto, CPhT.....Associate Executive Director
William Frisch, Jr, RPh..... Director of Pharmacy Compliance
Michelle Chan, RPh ..... Quality Assurance Pharmacist
Heather Engman, JD, MPH.....Counsel to the Board
Joanne Trifone, RPh.....Director of Pharmacy Investigations
Ed Taglieri, RPh.....Pharmacy Substance Use Disorder Program Supervisor

The *Massachusetts Board of Registration in Pharmacy News* is published by the Massachusetts Board of Registration in Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

David Sencabaugh, RPh - Executive Director
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Sanchez - Communications Manager