August 2019

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*

Getting to Know Your Board Members – Andrew Stein

This quarter, the Massachusetts Board of Registration in Pharmacy is highlighting President **Andrew "Andy" Stein, PharmD, RPh.** Andy was one of the first members appointed by Governor Charlie Baker in 2015, and is one of the two independent pharmacy members on the Board.

Andy graduated from Massachusetts College of Pharmacy and Health Sciences in Boston, MA, in 2005, after experiencing the profession through an externship during his senior year of high school. A year after graduating from pharmacy school, an opportunity arose to move from his position at a chain pharmacy to an independent pharmacy. This paved his way to pharmacy ownership. Andy now serves as the manager and co-owner of Bird's Hill Pharmacy in Needham, MA, a neighborhood pharmacy that also provides complex nonsterile compounding services.

Andy has commented that even though the Board members' opinions are occasionally at odds with each other, the dialogue is always respectful and appreciated.

"This is probably the best reason for why there is a board of pharmacy," said Andy. "We have representatives from different practice settings all bringing together their different experiences and even different cultural backgrounds. When disagreements occur, we discuss the issue, educate each other on our opinions and experiences in the matter, and we vote."

Andy's message to pharmacists is that Board members and staff are happy to provide education and guidance. "Feel comfortable to reach out . . . with questions, clarifications, and/or ideas of what we can do to best guide the practice of pharmacy. The Board's mission is to ensure public safety, not be punitive. Attend a meeting to see the process in action!" said Andy.

Support of Patients in Recovery

The Board has had recent reports of Suboxone®/buprenorphine stock issues at some pharmacies. Of course, no pharmacy wants to be out of stock of **any** product needed by a customer, but buprenorphine products are especially worrisome, considering their importance for whom they are prescribed. A lack of access to medications for opioid use disorder, including buprenorphine, may result in patient relapse or harm.

Orders for federally designated controlled substances (CS) are monitored closely by wholesalers as part of their suspicious orders programs. When a store orders a larger supply of a drug than usual, it can trigger a hold on shipping while the wholesaler reviews the order to determine its validity. Once verified, the order can be sent, but that delay can cause a continuity of care issue.

Certainly, changes in your market area may change the demand of buprenorphine products, such as the opening of a new treatment clinic or increased beds in a facility. It may be a good idea to proactively notify your wholesaler in **advance** of ordering a higher-than-usual amount.

Limited or Out-of-Stock Situations

In the interest of continuity of care, dispense a partial supply of Suboxone®/buprenorphine if you do not have enough product to fill the entire prescription.

If you do not have **any** product, check nearby stores to locate it and either transfer the prescription or contact the prescriber to send a new prescription to that store.

Naloxone Purchases

Under a statewide standing order, naloxone must be dispensed to anyone asking to purchase it. **State law allows purchasers to use their own insurance to buy naloxone regardless of who the end user may be.** The pharmacy must make a reasonable effort to determine if the purchaser's insurance will cover the drug. Instructions for dispensing and a copy of the standing order can be found here.

Identification at Pick Up

Massachusetts law requires identification when picking up prescriptions for gabapentin or federally designated CS in Schedules II through V. As a reminder, there are exceptions allowing you to dispense them to customers without identification.

If the pharmacist has a reason to believe that the failure to dispense the medication would result in a serious hardship

Continued on page 4

National Pharmacy Compliance News

August 2019

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 Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

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

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. 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 legitimate investigation or legal action is 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.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

Continued from page 1

for the patient, it may be dispensed without identification if the reason is documented and either of the following conditions are met.

1. The patient or agent of the patient prints his or her name and address on the back of the prescription and signs his or her name; or
2. The patient or agent of the patient provides an electronic signature in the case of an electronic prescription.

Further instructions can be found in the PMP Data Submission Dispenser Guide.

'Locked-In' Patients

You are probably aware that some patients may be restricted to receiving medications from only one specific pharmacy. Once that specific pharmacy is designated as the primary location, no other pharmacy may dispense medications, especially federally designated CS in Schedules II through V. If a claim is adjudicated to the health plan by a pharmacy that is not the designated location for a locked-in patient, a rejection message is returned.

If a medication is urgently needed for the treatment of an acute injury or serious condition, and the primary pharmacy is either closed or out of stock, the locked-in patient may receive medications at an alternate location with an override. If an override cannot be obtained from the health plan (eg, the agency is closed), and it is the professional opinion of the pharmacist that the patient's health or safety would be jeopardized without treatment, a limited supply may be dispensed. Detailed documentation and notification to the health plan must be completed as soon as possible.

Please make a professional, good faith effort to try to help these patients who may be vulnerable as they work toward recovery.

Electronic Prescriptions for CS

Currently, prescriptions may be accepted at Massachusetts pharmacies through various methods, such as paper, fax, and electronic prescribing. In order to help combat the current epidemic of opioid abuse via paper-based prescriptions, only electronic prescriptions will be accepted at pharmacies for all CS in Schedules II through VI, effective January 1, 2020.

Exceptions to the new law include veterinary prescriptions, out-of-state prescriptions, instances where electronic prescribing is not available due to temporary technological or electrical failure, emergency prescriptions as defined by the commissioner of the Massachusetts Department of Public Health, and in cases where the prescriber has been issued a temporary waiver.

Other exceptions have been proposed by the Massachusetts Drug Control Program in the draft regulations of 105 Code of Massachusetts Regulations (CMR) 721.000. Public comments were accepted for these amendments through July 2, 2019.

Institutional Sterile Compounders – Voluntary Inspections

In anticipation of the finalization of 247 CMR 6.00: Licensure of Pharmacies, the Board is seeking institutional sterile compounding facilities to voluntarily participate in Board inspections before the regulations actually go into effect. This is an opportunity for potential licensees to get an early start in determining the compliance of their sterile compounding areas and to have an opportunity to discuss issues and ask the inspectors questions.

The tool that will be used for the inspections is available on the Board's website, and investigators would schedule the inspection for a mutually agreeable time. If the sterile compounding area is deemed compliant based on this inspection, a license may be issued as a result of it when the licensing regulations are promulgated. The voluntary inspections will be scheduled on a first-come, first-served basis. If interested, please contact Pharmacy Investigator Nathan Van Allen via email at nathan.vanallen@massmail.state.ma.us.

Did You Know?

- As a reminder, all pharmacies licensed by the Board must be compliant with all chapters of United States Pharmacopeia (USP). Newly revised USP General Chapters <795>, <797>, and <800> will go into effect on December 1, 2019.
- Dr Anita Young, EdD, RPh, director of continuing pharmacy education at Northeastern University, has been named the 2019 honorary president of the National Association of Boards of Pharmacy® (NABP®) for her commitment to the protection of public health and her involvement with NABP and the state boards of pharmacy.
- Timothy D. Fensky, RPh, DPh, FACA, a member and past president of the Massachusetts Board of Registration in Pharmacy, has been elected as president-elect of the 2019-2020 NABP Executive Committee. He is the chief operating officer of Sullivan's Health Care.

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