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News

Massachusetts Board of Registration in Pharmacy

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Getting to Know Your Board Members – Patrick Gannon

This quarter, the Massachusetts Board of Registration in Pharmacy is shining a spotlight on one of its longest tenured Board members, Patrick Gannon, RPh, who was appointed to the Board in December 2012.

Patrick's first connection with pharmacy started in high school when he worked as a front shop clerk in a privately-owned retail pharmacy. This experience sparked his interest in a pharmacy career. A year prior to graduation from pharmacy school, he began to work at a local hospital pharmacy, and from there his career path advanced rather quickly to staff pharmacist, supervisor, and director. Simultaneously, his role at the hospital expanded into quality improvement work; an administrative position over several departments; and most recently, as chief quality officer. Patrick's current role allows him to interact with pharmacy service leaders within a health system.

Throughout his career, Patrick has had an affinity for statutory and regulatory topics, with a personal goal to add greater clarity to regulatory language. Becoming a Board member was the opportunity he needed to help revise regulations, so they may be clear and useful tools for licensees.

Prior to his appointment, Patrick had little knowledge of the extent of the Board's operations and the role of Board members, but he adjusted quickly. "In my experience, the Board staff addresses a very wide array of responsibilities in a very efficient, collegial, and supportive manner," says Patrick. "Appointed Board members hold a significant responsibility and opportunity to work very collaboratively with Board staff and licensees alike. I am grateful for the opportunity to serve, as the position affords an additional venue to affect pharmacy practice in ways that can raise the bar for public safety at a regional level, combined with an ability to protect, preserve, and advance professional practice through Board activities."

Patrick finished by saying, "Be thankful and supportive of your local Board; they work hard and act as advocates for doing the right thing in the name of public safety."

Update on Draft Regulations of 247 CMR 6.00: Licensure of Pharmacies

The Board's draft regulations of 247 Code of Massachusetts Regulations (CMR) 6.00: Licensure of Pharmacies are currently under administrative review for finalization. The current 247 CMR 6.00 has been revised to incorporate several new licensing categories as mandated by the pharmacy reform legislation (An Act Relative to Pharmacy Practice in the Commonwealth). Some standards in the existing version of 247 CMR 6.00, such as requirements for a pharmacy and operation of a pharmacy will be relocated to the Board's proposed regulations of 247 CMR 9.00: Professional Practice Standards.

In addition to new licensing categories for sterile compounding pharmacies (including institutional sterile compounding pharmacies), the draft regulations include new licensing categories for complex nonsterile compounding pharmacies as well as nonresident pharmacies.

At the December 2018 Board meeting, Board members voted to approve a final draft of the sterile compounding regulations (247 CMR 17.00: Sterile Compounding) and to move it on to the administrative review process. Based on the timeline of proposed regulations, it is likely that the Board's draft licensing regulations (247 CMR 6.00) will be promulgated prior to the new sterile compounding regulations (247 CMR 17.00).

This means that sterile compounding pharmacies licensed by the Board will be inspected on the current version of United States Pharmacopeia (USP) <797> until the new sterile compounding regulations are promulgated. In addition to those USP <797> requirements, the Board's inspection tool includes best practices based on the draft regulations and may go beyond USP <797> requirements. All of the Board's draft regulations and current inspection tools can be found on the Board's website.

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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWAR$_X$E® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWAR$_X$E program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

Technicians in Training

Recently revised regulations of 247 CMR 8.03 now require all pharmacy technician trainees (PTTs) to be licensed by the Board. No individual may work as a technician trainee without holding a valid PTT license. The Board's existing regulations impose certain qualifications for PTTs and limit the number of hours that an individual may be employed as a PTT. The license also provides prospective employers the ability to see if a trainee applicant has ever been involved in diversion or other misconduct.

An individual may not work as a PTT for more than 1,500 hours or for more than one year, whichever period is shorter, unless the Board grants an extension.

Board staff is authorized to grant an extension:

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

CDTM Experience Equivalency

According to 247 CMR 16.02 and Massachusetts General Law Chapter 112 §24B1/2, a pharmacist must have five years of experience as a licensed pharmacist before participating in a collaborative drug therapy management (CDTM) agreement. However, the Board has recently released an advisory regarding education that would be considered equivalent to five years of experience.

Pharmacists without five years of experience who wish to participate in a CDTM agreement must meet one of the following conditions:

1. certification from the Board of Pharmacy Specialties
2. completion of a postgraduate year one residency that is American Society of Health-System Pharmacists (ASHP)-accredited **and** one of the following:
   a. two additional years of experience as a pharmacist or
   b. twelve months of CDTM practice under a CDTM-practicing pharmacist
3. completion of a postgraduate year two residency that is ASHP-accredited **and** one of the following:
   a. one additional year of experience as a pharmacist or
   b. six months of CDTM practice under a CDTM-practicing pharmacist

If a pharmacist does not meet these requirements, but would still like to be considered for a CDTM agreement, he or she can petition the Board for consideration of other education, residency, or experience.

Substance Use Disorder and Mental Health Medication Administration

Under 105 CMR 700.004(B)(9) and Circular: Drug Control Program 19-2-105, pharmacists and pharmacy interns are permitted to administer certain medications for mental illness and substance use disorder. Guidance on how to proceed has been given for both prescribers and pharmacists/pharmacy interns who wish to provide this optional service.

The circular letter furnishes requirements such as training, CPR, and counseling. The circular letter also includes a list of approved medications that may be administered to patients 18 years of age or older.

For clarity, the best practice is for the prescriber to write "for pharmacist administration" on the prescription. If there is any question regarding the intent for pharmacist or other provider administration, you are encouraged to contact the provider.

Did You Know?

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

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