November 2018

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

Starting this quarter, the Massachusetts Board of Registration in Pharmacy will be highlighting a member (or two), so that its licensees can get to know more about those making decisions for the profession.

This quarter, the Board will highlight its **president, Michael J. Godek, RPh,** and **pharmacy technician member, Julie Lanza, CPhT.**

Michael Godek

Michael "Mike" Godek graduated from Massachusetts College of Pharmacy and Health Sciences in 1992, and his career with Walgreens began as a staff pharmacist in August 1993. As the years progressed, he became a pharmacy manager, managed two pharmacy departments, and was then promoted to district pharmacy supervisor for the Boston, MA, area. Walgreens eventually named him area health care supervisor, and he was promoted to his current role as regional director of operations in June 2015.

As a pharmacy supervisor, he would attend the monthly Board meetings and would report on the discussions to the Walgreens corporate office. The more meetings he attended, the more his desire to be actively involved with the Board grew.

Mike was appointed to the Board on November 28, 2014, and he has found that being involved with the Board exceeded his expectations. He finds actively updating regulations to advance the profession of pharmacy and protect patient safety very rewarding.

"I was both humbled and honored to be elected as the Board of Pharmacy president for 2018," he said. As president, preparation for the monthly meetings takes a little longer, but creativity with time management is essential. The Board president must facilitate the meeting and the conversations around the issues being discussed. If conversations get off-topic, it is the Board president's job to redirect the conversation.

Board members come from many different backgrounds and practice settings, and everyone's participation is important and valuable. It is okay to have differences of opinion as long as the goal of patient safety remains priority.

Mike feels that some of the biggest challenges facing Board members are keeping regulations and polices congruent with the evolution of the profession and with society. The current opioid crisis, not only in the state of Massachusetts but in the entire nation, is a prime example.

"If I look back on my career, I think I would give the advice to always have the best interest of the patient in mind; if you are not sure about a policy, do not hesitate to ask; be truthful and respectful because we are all human, and humans make mistakes," Mike said. "It all depends on how you handle yourself, and you will learn something along the way. In short, never compromise your integrity or work ethic."

Julie Lanza

As one of the 13 members of the Board, Julie Lanza occupies the pharmacy technician seat as designated and required by law. She has been a certified pharmacy technician at Beth Israel Hospital for 19 years and has been in her current regulatory role for the last 18 months. Julie is committed to pharmacy as indicated by her involvement in organizations such as the American Society of Health-System Pharmacists and Massachusetts Society of Health-System Pharmacists.

Having been appointed to the Board in December 2017, Julie said she is both "overwhelm[ed] and excit[ed]" to be a part of the team. Being the only pharmacy technician on the Board, Julie felt a little uncomfortable on her first day, but quickly felt at ease after meeting the other Board members and staff. "As soon as I sat down and met everyone, the pressure went away," she said.

Her role with the Board began with her desire to take on a new path. She explained that she "thought it would provide

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National Pharmacy Compliance News

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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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[an opportunity] to be an advocate for technicians." Julie hopes to add value to the Board by providing a different outlook, stating, "I feel that I can offer a perspective that the other members cannot. That's what I meant by advocating. I can look through the lens of a technician."

One of the biggest obstacles Julie faced in her duties as a Board member was to become more knowledgeable about other areas of the profession where she does not have as much experience. To enhance her participation in these areas, Julie said she desired to "overcom[e] the lack of experience with other practice settings . . . [and] learn about other practice settings to be able to make a good decision when voting on matters involving others."

When asked if she had any words of advice to give to other pharmacy technicians in Massachusetts, Julie stated, "That's easy. I would tell them that the role of pharmacy technicians is changing, and they should never pass up any opportunities that come with the change. Whether it is making presentations, attending meetings, or sitting on the Board, never pass up an opportunity to advance and show the world what the value of technicians can be. Advocacy really needs to come from within."

Delivery Best Practices Overview

The Board has developed a Best Practice Recommendations for Prescription Delivery document. In addition to general recommendations, this guidance document advises on obtaining patient consent for delivery and provides specific recommendations for federally designated controlled substances (CS), hazardous drugs, and temperature-sensitive products.

Among other things, appropriate shipping containers and tamper-resistant tape should be utilized. For federally designated CS, consider having two employees verify the contents before sealing the package. Consider removing the name of the pharmacy and any other pharmacy indicators from the package to deter tampering or theft during transport.

Track lost packages through the courier and notify the proper authorities, if necessary. If the lost package contains federally designated CS or drugs with abuse potential, report it to Drug Enforcement Administration (DEA) and the Board in accordance with DEA's policy on requirements and procedures for reporting theft or loss of CS.

When delivering temperature-sensitive medications, have policies and procedures requiring time-test studies at least twice yearly to ensure products maintain their temperature throughout the delivery process. Review the National Institute for Occupational Safety and Health list and package hazardous products separately whenever delivering or shipping. If a specialty pharmacy delivers to another pharmacy location for patient pickup, it must be in its final packaging, as the receiving pharmacy may not alter the package in any way.

Counseling for delivered medications may be in the form of written drug information containing a phone number to call the pharmacy for questions. Include a proper measuring device with all liquid medications. In the event the package is returned to the pharmacy as undeliverable, notify the patient and document the receipt of the returned package.

Conduct background checks for contracted drivers, provide and document annual training, and have a policy in place to ensure that deliveries to an assisted living facility are not left at the front desk or in the hands of a staff member. Deliveries should be documented and logs with recipient signatures retained.

This best practices document contains many more recommendations. Please review the full document here.

Vaccinations

Now that it is flu season, the Board suggests a refresher of its policy on vaccinations. Protect yourself and your patients by encouraging flu shots for all.

Did You Know?

- To view policies, regulations, and other helpful information online, visit the "What you need to know" web page on the Board's website.
- The easiest and fastest way to renew your pharmacist's license is online. Avoid any technical issues, penalties, or late fees by doing it as soon as possible!
- Effective December 31, 2018, any retail stores containing Board-licensed pharmacies may no longer sell tobacco products, per Chapter 157 of the Acts of 2018, which was passed in July 2018.

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David Sencabaugh, RPh - Executive Director

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager