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Minnesota Board of Pharmacy News

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Disciplinary Actions

Because of space limitations, information on disciplinary actions is no longer included in the *Minnesota Board of Pharmacy Newsletter.* A document that provides information about recent Board disciplinary actions can be found on the Minnesota Board of Pharmacy's website under the "Resources/FAQs" menu item.

Board Officers for 2020

During its November 13, 2019 meeting, the Board elected **Stuart Williams, JD,** a public Board member, to be its president for 2020. He is an attorney with the Minnesota law firm of Henson & Efron, P.A., where his practice includes business litigation and environmental law. He was first appointed to the Board in 2011 and was reappointed in 2015 and 2019. Mr Williams also serves as a public member on the Minnesota Board of Medical Practice, the Minnesota Department of Human Services (DHS) Drug Formulary Committee, and the Minnesota Supreme Court's Client Security Board. He formerly served on the Minnesota Boards of Nursing and Psychology and the Minnesota Lawyers Professional Responsibility Board. Mr Williams graduated from the University of North Carolina at Chapel Hill with a bachelor of arts degree and a juris doctor degree with honors.

The Board elected **Stacey Jassey, PharmD, RPh,** to be its vice president for 2020. Former Governor Mark Dayton appointed Dr Jassey to her current term in January 2018, but she has served on the Board before. On March 17, 2008, then-Governor Tim Pawlenty appointed her to a four-year term to fill the position that was vacated by Betty Johnson. Dr Jassey served most of one term but had to resign from the Board in 2011 when a new employer asked her to do so, upon acceptance of employment. Dr Jassey has over 25 years of experience in the pharmacy profession. She currently works as a medical science liaison (migraines) for Allergen. She has also worked for Genoa, a company with pharmacies that specialize in meeting the prescription needs of mentally ill patients. Her experience includes a position as a community clinical pharmacist for Walgreens, where she served as one of the nationwide interpreters for Spanish-speaking patients. She also worked as a pharmacist for Target (before the CVS buyout). Dr Jassey has held positions with other pharmaceutical manufacturers. She is an assistant professor at the University of Minnesota College of Pharmacy, from which she received bachelor of science and doctor of pharmacy degrees.

The Board also re-elected **Cody Wiberg, PharmD, MS, RPh,** to be secretary for 2020. The secretary is a non-voting officer of the Board who is also designated executive director and chief administrative officer. Dr Wiberg received a doctor of pharmacy degree from the University of Minnesota in 1985. He has worked as a clinical pharmacist, hospital pharmacist, community pharmacist, and nursing home consultant. From 1999 until he joined the Board in September 2005, he was the pharmacy program manager for the Minnesota DHS. Dr Wiberg is a clinical assistant professor and pharmacy law course director for the University of Minnesota College of Pharmacy. He is also an instructor and course director for the University of Florida Graduate School, from which he received a master of science degree in pharmacy policy and outcomes in 2009, and a course director for the University of Wyoming Graduate School. Dr Wiberg was named to *Minnesota Physician's* quadrennial list of the state's 100 influential health care leaders in 2008, 2012, and 2016. He received the 2017 Century Mortar Club Friend of the College Award from the University of Minnesota College of Pharmacy.

Pharmacist License Renewals

There are approximately 9,000 individuals who currently hold an active pharmacist license issued by the Board. Pharmacists who want to renew their license for the license period that starts on March 1, 2020, may do so at this time.

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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.

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.

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The Board encourages licensees to take advantage of the online renewal option for faster processing.

To renew your license, visit the Board's website and select the "Login to My Account" item from the "How do I" tab in the upper right-hand corner of the page. Then click the "Login" link, which will take you to the sign-in page. Click on the appropriate links and follow the prompts. The renewal screen will allow you to change your address, update your employment, or change your license status. If you have any questions, you may call the Board during normal business hours at 651/201-2825, and one of its staff members will assist you.

If you would rather submit a paper renewal, follow the directions in the paragraph above. Use the appropriate links on your account page to make any address and employment changes. Once you have made any necessary changes to your addresses and employment, instead of clicking on "Renewal-In-Progress," click on "Print Pharmacist Renewal Invoice" at the bottom of the page. Print the invoice, sign and date it, and send it to the Board office with your payment. If you do not have an internet connection, contact the Board office and the Board will print a renewal and mail it to you.

The renewal period for pharmacists opened in mid-December, and the deadline for completing the renewal process is **February 1,** not February 28 or 29, as many people mistakenly believe. The month of February is a grace period during which no late fees are assessed for pharmacists who have missed the February 1 deadline. If your completed application and required fee are not received by the Board office prior to March 1, your license will expire and the late fee will be imposed. You will not be allowed to practice pharmacy in the state of Minnesota until the Board receives the completed application and fees.

Pharmacy Technician Registration

Pharmacy technician registration renewals were due on December 1, 2019. Technicians were then given the month of December as a "grace period." The registrations of technicians who failed to renew by December 31, 2019, have expired. Individuals cannot continue working as technicians if their registrations have expired. Pharmacists-in-charge (PICs) are encouraged to verify that technicians working under their supervision have current registrations. That can be done by using the license verification feature on the Board's website. If an unregistered individual performs duties that require a technician registration, the Board can take disciplinary action against that individual, the PIC, and the pharmacy.

New Resource for Saving on Prescription Drugs

In 2019, the Minnesota Legislature enacted legislation directing the Board to provide information useful to individuals who are attempting to purchase prescription drugs at lower costs. Governor Tim Walz signed the legislation into law. In response, the Board has created a web page of resources to help residents purchase prescription drugs at a lower cost. This is the first step the Board is taking to provide helpful information to pharmacists, prescribers, and the public.

The new law also states that, "the board shall require pharmacists and pharmacies to make available to patients information on sources of lower cost prescription drugs, including information on the availability of the website." It further requires boards that license prescribers to require them to also provide such information to patients. To help pharmacists and prescribers meet this new obligation, the Board will publish documents on its website that can be downloaded, printed, and provided to patients.

To view the Board's new Saving on Prescription Drugs web page, click here.

Emergency Preparedness Efforts and the Minnesota Department of Health

In emergencies such as terrorist attacks or pandemics, large numbers of people may be exposed to disease-causing germs. Medical countermeasures (MCMs) are medicines (eg, antibiotics, antivirals, or antitoxins) that may be given in support of treatment or as prophylaxis (oral or vaccination) to the identified population in accordance with public health guidelines or recommendations. Lives may depend on dispensing MCMs to a large number of people in a short amount of time.

In such an emergency, the Minnesota Department of Health (MDH) can request large quantities of MCMs from the United States Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response (ASPR). ASPR maintains a large cache of MCMs called the Strategic National Stockpile, which can be quickly mobilized for emergency distribution. MDH then works with partners to dispense the MCMs to the health care system and the public directly.

Coordination between public health programs and private sector pharmacies in planning and response is essential to expanding access to MCMs during a public health emergency. Improved coordination reduces severity and ultimately saves lives by leveraging the strengths of all partners, including existing pharmaceutical and vaccine management, distribution,

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and administration infrastructures. Improved coordination prior to and during a public health emergency also improves relationships, not only for public health emergencies, but also for routine public health delivery.

Pharmacies can support this planning by participating in a memorandum of understanding (MOU) with MDH. The MOU sets forth the terms between MDH and pharmacies for the coordination of MCM dispensing and administration during a public health emergency. The agreement is not legally binding but makes it possible to plan for action ahead of time, rather than during an emergency.

All pharmacies in Minnesota are encouraged to participate. To learn more about the project, read the language of the MOU, and see which pharmacies have already signed, visit the project web page at *www.health.state.mn.us/mou.*

Pharmacists Are Essential for Helping People Quit Tobacco Use

Did you know that pharmacists can easily connect people who use tobacco with the help that they need to quit by using their existing authority to write prescriptions for over-the-counter (OTC) tobacco cessation medications for patients who are covered by Medicaid? Your active participation in this initiative is central to its success and will help save lives and reduce tobacco-related disease and fatalities. Information about this authority can be found on the Minnesota DHS website.

Tobacco use remains the number one preventable cause of death and disease in Minnesota, with a price tag of over $3 billion in excess health care costs annually. To better address the health inequities of Medicaid beneficiaries, who smoke at twice the rate of the general population, MDH recently launched a Medicaid pharmacy initiative to encourage medical assistance beneficiaries to go to their pharmacists for a prescription for OTC tobacco cessation nicotine replacement therapy medications including patches, gum, and lozenges. Pharmacists can write prescriptions for OTC drugs for the purpose of billing Medicaid.

More information on access to Medicaid tobacco cessation medication can be found at *www.health.state.mn.us/divs/hpcd/tpc/quit.html.*

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