January 2020

News
District of Columbia Board of Pharmacy

Published to promote compliance of pharmacy and drug law

899 N Capitol St NE, 2nd Floor • Washington, DC 20002

News From the District of Columbia Board of Pharmacy

The District of Columbia Board of Pharmacy members are:

Tamara McCants, PharmD, RPh ..... Chairperson
Vacant ..... Member
Ashlee Bow, PharmD, RPh, AAHIVP ..... Member
Alan Friedman, BS, RPh ..... Member
Benjamin E. Miles, BS, PharmD, RPh, BCPS .... Member
Gregory Cendana ..... Consumer Member
Chikita Sanders ..... Consumer Member
Shauna K. White, MS, PharmD, RPh .. Executive Director

Contact the Board! All inquiries regarding licensure and general information should be directed to Ms Karin Barron, health licensing specialist, at karin.barron@dc.gov, or Ms Luanne Greenaway, health licensing specialist, at luanne.greenaway2@dc.gov.

To contact the Board directly, visit its website at *www.dchealth.dc.gov/bop.* Should you need to contact the Pharmaceutical Control Division, its website is *www.dchealth.dc.gov/pcd.*

Notice of Board Meeting Schedule

The Board holds open (public) session meetings in the even-numbered months of the year, ie, February, April, June, August, October, and December. In these months, the meetings will begin at 9:30 AM. These meetings are open to the public, including licensed pharmacists, where parties may share their comments pertaining to Board activities. All are invited to attend.

In the odd-numbered months of the year, ie, January, March, May, July, September, and November, the Board may meet in subcommittees and/or hold executive (closed) session meetings as needed. Pursuant to D.C. Official Code §2-575(b), and for the purposes set forth therein, these meetings are not open to the public.

The Board meets at 899 N Capitol Street NE, Second Floor, Washington, DC 20002.

Future open session meeting dates are:

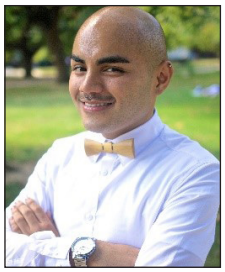
- Thursday, February 6, 2020 – 9:30 AM
- Thursday, April 9, 2020 – 9:30 AM
- Thursday, June 4, 2020 – 9:30 AM
- Thursday, August 6, 2020 – 9:30 AM
- Thursday, October 1, 2020 – 9:30 AM
- Thursday, December 3, 2020 – 9:30 AM

Board Licensees by the Numbers

Licensees as of December 5, 2019	
Pharmacists	2,132
Pharmacist Vaccination & Immunization Agents	695
Pharmacy Interns	747
Pharmacy Technicians	937
Pharmacy Technician Trainees	157
Pharmacy Technician Programs	11
Pharmaceutical Detailers	912

New Board Member Gregory Cendana – Consumer Member

Strategist, politico, and dot connector, Gregory Cendana is president and co-founder of Can't Stop! Won't Stop! Consulting. He was the first openly gay and youngest-ever executive director of the Asian Pacific American Labor Alliance and Institute for Asian Pacific American Leadership & Advancement. Gregory was chair of the National Council of Asian Pacific Americans and co-founder of the diversity initiative Inclusv. He serves as treasurer on the board of directors for United We Dream and as chair for 18 Million Rising.



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National Pharmacy Compliance News

January 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.

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Gregory was president of the United States Student Association, where he played an integral role in the passage of the Student Aid & Fiscal Responsibility Act and Healthcare & Education Reconciliation Act.

Gregory is a graduate of the Rockwood Leadership Institute, the Management Center's Managing to Change the World, the Midwest Academy's Organizing for Social Change, Training for Change's Training of Trainers, Spitfire's Executive Training Program, and re:power's Political Training Program. Prior to his role on the Board, Washington, DC Mayor Muriel Bowser also appointed Gregory to serve on the Commission on Asian and Pacific Islander Affairs after he served a two-year term on the Gay, Lesbian, Bisexual & Transgender Advisory Committee under the leadership of Mayor Vince Gray. Gregory has been named one of Washington, DC's most influential 40-and-under young leaders, one of the 30 Most Influential Asian Americans Under 30, and one of 40 Influential Asian Americans in Washington. He has received DC's Inaugural Power 30 Under 30 Award Recipients and has been called the "Future of DC Politics." In his spare time, Gregory enjoys singing karaoke, choreographing dances, and trying new recipes with his partner, Terrence. Follow Gregory on Twitter and Instagram: @GregoryCendana @CSWSconsulting.

Now Available: Pre-MPJE

The National Association of Boards of Pharmacy® (NABP®) is offering a practice examination for the Multistate Pharmacy Jurisprudence Examination (MPJE®), known as the Pre-MPJE™. You can register online by logging in to your e-Profile at *https://dashboard.nabp.pharmacy/Login/Splash.* This is an official practice exam that features valid questions from previous versions of the MPJE to give a realistic testing experience. The Pre-MPJE costs $65 per session and is nonrefundable. Once you register and pay, you will have seven days to take the test. The Pre-MPJE will last for 50 minutes and includes 40 questions. More information can be found at *https://nabp.pharmacy/programs/mpje/pre-mpje.*

Free Narcan Kits

DC Health recognizes that people struggling with opioid use disorder, others on prescription pain medications, and their loved ones can benefit from having access to naloxone (Narcan®) in the event of an accidental overdose. People are often not aware of the many avenues in which to receive this lifesaving medication.

As of August 31, 2019, DC Health has taken a new approach in dealing with the opioid epidemic and is partnering with different retail pharmacies throughout DC to distribute **free** naloxone kits to anyone who wants them – no questions asked and no prescription needed. The Narcan kits will be available until supplies deplete at select locations of chain pharmacies, such as Walgreens, Safeway, and CVS, as well as at community pharmacies across DC.

For more information, visit *https://dchealth.dc.gov/opioids.*

Pharmaceutical Detailer License Renewal

In accordance with the District of Columbia SafeRx Amendment Act of 2008, all pharmaceutical detailer licenses will need to be renewed by February 28, 2020. Pharmaceutical detailers will need to complete 15 hours of approved continuing education (CE) credit during the two years preceding the date of license expiration. This includes two hours of CE credit on cultural competency or specialized clinical training focusing on patients or clients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, queer, or questioning their sexual orientation or gender identity and expression to be in compliance with D.C. Official Code §3-1205.10(b)(5). CE credits are subject to audit.

Licenses can be renewed online with the new DC Health online licensing portal. A link to the portal will be emailed to the licensee. The portal will have an option for you to upload your CE certificates or CPE Monitor® transcript. The renewal fee for pharmaceutical detailers is $175. Additional information can be found on the Board's website at *https://dchealth.dc.gov/bop.*

The *District of Columbia Board of Pharmacy News* is published by the District of Columbia Board of 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.