September 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
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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.

To contact the Board directly, visit its website at *www.dchealth.dc.gov/node/185772.* Should you need to contact the Pharmaceutical Control Division, its website is *www.doh.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 meetings will be held via Webex during the coronavirus disease 2019 public health emergency. The link will be posted on the Board website.

Future open session meeting dates are:

- Thursday, October 1, 2020 – 9:30 AM
- Thursday, December 3, 2020 – 9:30 AM
- Thursday, February 4, 2021 – 9:30 AM
- Thursday, April 1, 2021 – 9:30 AM
- Thursday, June 3, 2021 – 9:30 AM
- Thursday, August 5, 2021 – 9:30 AM

Board Licensees by the Numbers

Licensees as of August 6, 2020

Pharmacists:	2,197
Pharmacist Vaccination & Immunization Authority:	742
Pharmacy Interns:	685
Pharmacy Technicians:	1,015
Pharmacy Technician Trainees:	108
Pharmacy Technician Programs:	13
Pharmaceutical Detailers:	569

Meet and Greet With Board Members

You are invited! Please join us for a meet and greet with members of the Board from 8:30 - 9:30 AM on Thursday, October 1, 2020, before the next scheduled public meeting. Even in the midst of a pandemic, the Board's goal is to be accessible to the broader community in safe and healthy ways. The Board members would love to meet you, learn more about your experiences, and how to better serve you. Questions for the Board are welcomed; please submit topics to ashlee.bow@dcbc.dc.gov. The link for the meet and greet will be posted on the Board website.

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National Pharmacy Compliance News

September 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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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New CE Requirements on Public Health

Did you hear? There are new continuing education (CE) requirements on public health priorities. As of November 1, 2019, the director of the Department of Health announced rules requiring licensed health professionals to complete at least 10% of their required total CE in public health priorities. Some topics include: responsible opioid prescribing and effective pain management; sexual health, including sexually transmitted diseases; and vaccinations, including legal requirements and appropriate exemptions. Please review the regulations for your respective profession on the implementation timeline. For the full list of topics and full public notice, visit *https://dchealth.dc.gov/node/1441501.*

DCRx and the Opioid Learning Institute

Health care professionals need unbiased, evidence-based information to guide their practices for the prescribing, dispensing, and management of medications to patients in our community.

Faced with a steady stream of new prescription products, fast-paced changes in health care delivery, and immense time pressures, professional CE programs need to be applicable to real-world situations and be practical and efficient to meet the needs of today's busy providers and pharmacists. The DC Center for Rational Prescribing (DCRx) and the Opioid Learning Institute are CE resources available to pharmacists in the District of Columbia.

DCRx provides free, state-of-the-art learning content that providers and pharmacists need to meet professional growth and recertification requirements. Each new module provides up to two hours of certified CE credits, and covers an emerging public health area of concern with a clinical practice emphasis on topics such as tobacco cessation and implicit bias. And more modules are on the way! DCRx provides practice-oriented topics, evidence-based content, and engaging, easy-to-use presentations from nationally recognized experts. DCRx is your one-stop, free CE resource. Visit *https://dchealth.dc.gov/dcrx* to learn more about DCRx and to access course listings.

The Opioid Learning Institute is available until September 27, 2020, for health care professionals who want to learn more about safe and effective prescribing practices and care of patients with opioid use disorder in multiple health care settings. Some topics include:

- nutrition for pain management,
- opioid overdose prevention,
- naloxone education, and many more.

To learn more, visit *https://opioidhealth.org/education-training/elearning-courses-for-providers.*

PIC Responsibilities

Being the pharmacist-in-charge (PIC) is a very important role in any pharmacy setting. The PIC is the pharmacist who manages the retail/community pharmacy, special or limited use pharmacy, or nonresident pharmacy. The pharmacist must be licensed to practice pharmacy in the District of Columbia, unless the pharmacy is a nonresident pharmacy. A pharmacist can only be the PIC at one pharmacy at a time. Before registering as a PIC with the Board, it is important for each person to read the required responsibilities of a PIC. These responsibilities can be found in Chapter 19 of the District of Columbia Municipal Regulations for Pharmacies, Section 1920. For exact language and specifics, view the link to be directed to Chapter 19: *https://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Chapter%2019_Pharmacies_0.pdf.*

Some of the responsibilities include:

- Developing a quality assurance program to prevent and detect drug diversion
- Verifying pharmacy personnel are properly trained and legally authorized to assist the practice of pharmacy
- Ensuring the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate record keeping and security safeguards
- Notifying the director of the following: permanent closing; change of proprietorship, management, location, or PIC; any theft or loss of prescription drugs or medical devices; conviction of any employee of federal, state, or District of Columbia drug laws; disasters, accidents, or any theft, destruction, or loss of records required to be maintained by federal or DC laws or regulations; occurrences of significant adverse drug reactions; illegal use or disclosure of protected health information
- Establishing/verifying policies to prevent the illegal use of protected health information
- Developing/verifying policies to maintain proper execution of drug recalls
- Developing and implementing policies to specify the duties of pharmacy interns and pharmacy technicians

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PDMP Hot Topics

Below are three tips the Board found helpful when utilizing the prescription drug monitoring program (PDMP):

1. Check PDMP announcements for pertinent information regarding prescribers and unauthorized prescriptions.
2. Users may assign two licensed delegates to perform searches under their account. Users may approve, remove, or reject delegates. They will receive email notifications for pending delegates. Access delegate information by menu > user profile > delegate management.
3. Users can easily customize their accounts to automatically query other state databases in three easy steps. To edit your defaults:
   a. Log in to your PMP AWARxE account and navigate to "User Profile" and select "Default PMPi States."
   b. Select all of the states you wish to automatically query during patient searches.
   c. Complete the process by saving your settings. Press the "Update Defaults" button at the bottom right of the screen.

Bonus: When requesting patient reports from other states, do not check off the partial spelling field to promote successful query results.

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.