

June 2019



District of Columbia Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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News From the District of Columbia Board of Pharmacy

The District of Columbia Board of Pharmacy members are:

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Vacant.....Consumer Member
Shauna White, PharmD, RPh, MS.....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 <https://dchealth.dc.gov/bop>. Should you need to contact the Pharmaceutical Control Division, the website is <https://doh.dc.gov/pcd>.

Notice of Board Meeting Schedule

The Board holds open (public) session meetings on 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 North Capitol Street NE, Second Floor, Washington, DC 20002.

Future open session meeting dates are:

- ◆ Thursday, August 1, 2019 – 9:30 AM
- ◆ Thursday, October 3, 2019 – 9:30 AM
- ◆ Thursday, December 5, 2019 – 9:30 AM
- ◆ Thursday, February 6, 2020 – 9:30 AM
- ◆ Thursday, April 9, 2020 – 9:30 AM

Board Licensees by the Numbers

Licensees as of June 6, 2019

Pharmacists	2,026
Pharmacist Vaccination & Immunization Agents	617
Pharmacy Interns	682
Pharmacy Technicians	851
Pharmacy Technician Trainees	125
Pharmacy Technician Programs	11
Pharmaceutical Detailers	799

PDMP – Mandatory Registration

On April 11, 2019, D.C. Law 22-288 went into effect, mandating all practitioners who are registered to prescribe and/or dispense controlled substances (CS) or other covered substances in the District of Columbia to register with the District of Columbia Prescription Drug Monitoring Program (PDMP).

Specifically, D.C. Law 22-288 states:

Any prescriber who is currently licensed, or becomes licensed before March 31, 2019, in the District to prescribe a controlled substance or other covered substance in the course of his or her professional practice, and any dispenser who is currently licensed, or becomes licensed before March 31, 2019, in the District to dispense a controlled substance or other covered substance to

continued on page 4

National Pharmacy Compliance News

June 2019



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.

NABPF

National Association of Boards
of Pharmacy Foundation

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 AWARxE® 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 AWARxE program, visit the Initiatives section of the NABP website at www.nabppharmacy.org.

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>.

continued from page 1

an ultimate user or his or her agent shall register with the Program by March 31, 2019.

If you are already registered with the PDMP, **no further action is required.**

For those not registered with the PDMP, the deadline to register is July 31, 2019. Failure to register with the PDMP by July 31, 2019, may impact the status of your professional license and CS registration.

To register for the PDMP, visit <https://districtofcolumbia.pmpaware.net/login>.

Once there, click the “Create an Account” button to begin the registration process.

In order to register, you will need your:

1. DC Health professional license number
2. Employer’s DC Health CS registration number
3. Employer’s federal Drug Enforcement Administration (DEA) registration number

Pharmacists without an employer DEA or National Provider Identifier number need to register as a non-dispensing pharmacist.

For more information on how to register, refer to the [PMP AWARxE User Support Manual](#). If you have any questions or concerns about navigating the system, please contact Appriiss technical support directly at 855/932-4767. Technical assistance is available 24 hours a day, seven days a week.

For further information on PDMP laws and regulations, user guides, and frequently asked questions, visit the PDMP website, <https://dchealth.dc.gov/pdmp>.

Please submit any program questions via email to doh.pdmp@dc.gov.

Naloxone Policy Statement

DC Health has established a policy statement to allow pharmacists to dispense naloxone without a prescription pursuant to a standing order. The policy will allow national

pharmacy organizations (NPOs) to use their own training programs and standing orders to dispense naloxone to District of Columbia residents. The NPO standing order must be signed by a District of Columbia-licensed physician. The training program must meet the requirements outlined in the policy statement.

Pharmacies that are not members of an NPO can dispense naloxone if the pharmacists have completed DC Health’s naloxone training program and have signed the DC Health standing order. The DC Health training program can be found on the DC Center for Rational Prescribing (DCRx) website, <https://dchealth.dc.gov/dcrx>. Additionally, the pharmacist-in-charge (PIC) will need to complete the written standing order from DC Health and provide a certificate of completion from the DCRx course. If your pharmacy would like to complete the DC Health standing order, email Dr Justin Ortique, supervisory pharmacist, at justin.ortique@dc.gov for additional information.)

If there is a change in the PIC, a new DC Health standing order will need to be completed. A copy of the standing order must be maintained at the pharmacy and be readily available upon request by the Board.

For more information, please visit www.dchealth.dc.gov/bop.

Page 4 – June 2019

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.

Muriel Bowser - Mayor

Shauna K. White, PharmD, RPh, MS - Executive Director

Daphne B. Bernard, PharmD, RPh - District News Editor

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

Amy Suhajda - Communications Manager