October 2019

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
James C. Appleby, BS, RPh, MPH ..... Vice Chairperson
Ashlee Bow, PharmD, RPh, AAHIVP.....Member
Alan Friedman, BS, RPh.....Member
Benjamin E. Miles, BS, PharmD, RPh, BCPS....Member
Chikita Sanders ..... Consumer Member
Vacant..... 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 *https://dchealth.dc.gov/node/185772.* Should you need to contact the Pharmaceutical Control Division, its website is *https://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, December 5, 2019 – 9:30 AM
- 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

Board Licensees by the Numbers

Licensees as of August 23, 2019	
Pharmacists	2,077
Pharmacist Vaccination & Immunization Agents	645
Pharmacy Interns	523
Pharmacy Technicians	892
Pharmacy Technician Trainees	112
Pharmacy Technician Programs	11
Pharmaceutical Detailers	847

New Board Chair Dr Tamara McCants

Originally from Brooklyn, NY, Tamara McCants, PharmD, RPh, received her doctor of pharmacy degree from Florida A&M University (FAMU) in 2001. Upon graduation, she came to Washington, DC, to complete a community pharmacy residency program with Grubb's Care Pharmacy and Howard University. She has since dedicated her career to increasing the capacity of pharmacists to be a major contributor in the achievement of favorable health outcomes, especially for the underserved population. Dr McCants has always been very passionate about the community, coordinating outreach and training programs for all major disease states. She has worked in both the managed care and community pharmacy setting throughout her career.

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

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In 2002, she co-founded CMS Health Initiatives, a nonprofit organization that utilizes pharmacists to address health disparities. Dr McCants is currently the director of residency programs and practice transformation at Howard University College of Pharmacy. A staunch advocate for the profession, she is an active member of several pharmacy organizations on both the local and international levels. She has served on numerous task forces and working groups to help advance the profession. Most notable is her role as the convention planning chair for the National Pharmaceutical Association. She is an active member of the FAMU Alumni Association and a proud member of Alpha Kappa Alpha Sorority, Inc, Rho Mu Omega Chapter. She is married with two beautiful sons.

Dr McCants has been on the Board since 2006. The Board is excited to work with her in her new role.

New Board Member Dr Ashlee Bow

Ashlee P. Bow, PharmD, RPh, a Tupelo, MS native, is a pharmacy manager at Walgreens Community Pharmacy, a specialty pharmacy in the Logan Circle neighborhood. She received a bachelor of science in pharmaceutical sciences in 2010 and a doctor of pharmacy degree in 2013, both from the University of Mississippi. Dr Bow began working for Walgreens in 2010 as an intern, becoming a pharmacy manager in 2014, and relocating to Washington, DC, in 2016. She serves as a preceptor for the introductory pharmacy practice experience and advanced pharmacy practice experience community rotations at Shenandoah University and Campbell University. Dr Bow is also an American Academy of HIV Medicine-certified pharmacist. Outside of work, Dr Bow enjoys hiking, movies, and cross-stitching.

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 is taking 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.*

Narcan Training

DC Health offers Narcan training sessions for the community, where attendees are provided with free Narcan kits. During the hour-long sessions, educators teach about the signs and symptoms of an opioid overdose, how to administer the drug, and about opioid addiction.

Sign up for a free training in your local area. Space is limited and participants must be registered before attending the Narcan training. The next training session with availability is on January 28, 2020. For more information about Narcan training and access to free kits, visit *https://dchealth.dc.gov/page/cme-ceu-webinars-workshops-and-narcan-training.*

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.