January 2018

District of Columbia Board of Pharmacy News

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

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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 the Board's website at *http://doh.dc.gov/bop*. Should you need to contact the Pharmaceutical Control Division, the website is *http://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 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, February 1, 2018 - 9:30 AM
- Thursday, April 5, 2018 - 9:30 AM
- Thursday, June 7, 2018 - 9:30 AM
- Thursday, August 2, 2018 - 9:30 AM

National Prescription Drug Take-Back Efforts and The Role of Pharmacists

By Ryan J. Frazier, Howard University College of Pharmacy

October was American Pharmacists Month, which served as a great opportunity to celebrate the pharmacy profession and highlight the critical roles that pharmacists play in improving medication use and advancing patient care in all practice settings. This came at no greater time in 2017, as also in October, President Trump directed the United States Department of Health and Human Services (HHS) to declare the opioid crisis a public health emergency to address a rapidly escalating epidemic of drug use. According to HHS, 12.5 million people in the US misused prescription opioids in 2015. In addition, the Centers for Disease Control and Prevention reports that as many as 91 Americans die from opioid drug overdoses each day.

A critical role that pharmacists and student pharmacists are playing to combat this public health emergency is to participate in the federal Drug Enforcement Administration's National Prescription Drug Take Back Day. On October 28, 2017, Howard University College of Pharmacy partnered with Capitol City Pharmacy Medical Reserve Corps (CCPMRC) and Howard University Medical Reserve Corps (HU MRC) to safely dispose of unused and expired medications collected from District of Columbia residents, pharmacies, and clinics. This was done in an effort to prevent drug addiction, overdose deaths, and potential medication errors.

MRC are units of trained volunteers who work with local health agencies and partners to meet the public health needs of their community. Utilizing CCPMRC, which is the country's first pharmacy-based MRC unit, and HU MRC, which is the first MRC unit in the District of Columbia, Howard University College of Pharmacy was able to collect and dispose of over 85 pounds of prescription medications from local collection sites.

As pharmacists, we must educate and empower our patients on how to properly dispose of medications. Feel free to view the latest guidelines for safe drug disposal on Food and Drug Administration's (FDA's) website. If you are interested in coordinating your own drug disposal initiative or want more information on National Prescription Drug Take Back Day, visit the official website at *TakeBackDay.dea.gov*. I challenge each of you to get engaged and make an impact on your community. Let's show the

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National Pharmacy Compliance News

January 2018

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 Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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world that pharmacists are on the front line of patient care, drug safety, and combating this public health crisis!

Sources

- Opioids: the prescription drug and heroin overdose epidemic. HHS website. www.hhs.gov/opioids. Updated October 25, 2017. Accessed December 29, 2017.
- About the epidemic. HHS website. www.hhs.gov/opioids/about-the-epidemic. Updated October 31, 2017. Accessed December 29, 2017.
- Buying and using medicine safely. FDA website. www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines. Updated October 1, 2016. Accessed November 21, 2017.

Pictured above: Students from Howard University College of Pharmacy and representatives from CCPMRC and HU MRC safely dispose of unused and expired medications on October 28, 2017.

Pharmacists Addressing Health Disparities in the Nation's Capital: Focus on Diabetes

National Diabetes Month is observed every November so that individuals, health care professionals, organizations, and communities across the country can bring attention to diabetes and its impact on millions of Americans. In 2016, the National Diabetes Education Program's theme was Managing Diabetes – It's Not Easy, But It's Worth It. This theme highlighted the importance of managing diabetes to prevent diabetes-related health problems such as heart attack, stroke, kidney disease, vision loss, and amputation. The theme also served as a reminder to people who may be struggling with the demands of managing diabetes that they are not alone. This was a perfect opportunity for pharmacists to remind patients and their caregivers of the vital role that pharmacists play in helping to manage diabetes. Here are **five ways** that you can observe National Diabetes Month every day:

- Conduct risk assessment testing,
- Provide education to newly diagnosed patients,
- Serve as a referral source,
- Make sure patients have testing supplies, and
- Ensure medication regimen is accurate.

Keeping Our Future Pharmacist Colleagues Engaged: Board Meet and Greet at Howard University College of Pharmacy

The Howard University American Pharmacists Association Academy of Student Pharmacists Chapter kicked off American Pharmacists Month by hosting a District of Columbia Board of Pharmacy member meet and greet on Thursday, October 5, 2017. The event was sponsored by the Washington DC Pharmacy Association (WDCPhA). The Executive Committee of WDCPhA and several Board members were present to encourage students to advocate for the profession through active participation in policy development and pharmacy associations. Attendees also gained a clearer understanding of the specific roles of the Board and the WDCPhA and how regulators and professional associations often work collaboratively. As a special treat, Board Chairperson Daphne Bernard, PharmD, RPh, announced that she would cover the membership fee for all students in attendance to become active members of WDCPhA that day.

Pictured above: Students of the American Pharmacists Association Academy of Student Pharmacists Chapter host a meet and greet with Board members and WDCPhA Executive Committee members.

Board Licensees by the Numbers

Licensees as of December 22, 2017	
Pharmacists	2,011
Pharmacist Vaccinations & Immunization Agents	597
Pharmacy Interns	633
Pharmacy Technicians	884
Pharmacy Technician Trainees	199
Pharmacy Technician Programs	9
Pharmaceutical Detailers	1,242

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.

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