January 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:

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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 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, February 7, 2019 – 9:30 AM
- Thursday, April 4, 2019 – 9:30 AM
- Thursday, June 6, 2019 – 9:30 AM
- Thursday, August 1, 2019 – 9:30 AM
- Thursday, October 3, 2019 – 9:30 AM
- Thursday, December 5, 2019 – 9:30 AM

2018 NABP/AACP Districts 1 and 2 Annual Meeting Highlights

On September 20-22, 2018, the Board and the Howard University College of Pharmacy hosted National Association of Boards of Pharmacy® (NABP®) and American Association of Colleges of Pharmacy (AACP) members at the Hyatt Regency Washington on Capitol Hill. The joint meeting was attended by approximately 121 representatives from all of the 14 state boards of phamacy and a remarkable 60% of the 37 schools of pharmacy from Districts 1 and 2.

There were many conversations around key factors for both regulators and educators to discuss, as we consider the currrent landscape and future direction of the profession. Interesting findings from a national survey of patient perspectives on expanded pharmacy practice were presented by the keynote speaker and former American Pharmacists Association president, Dr Lawrence "LB" Brown, which highlighted the evolving role of pharmacists and addressed the challenges often faced with getting patients to utilize pharmacy services.

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National Pharmacy Compliance News

January 2019

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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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A range of other pertinent topics were presented, including:

- Student Mental Health Challenges and Accommodating Testing Needs in Professional Schools & Colleges and State Boards
- New ASHP/ACPE Accreditation Standards for Education Preparation of Pharmacy Technicians
- Updates: Recent Advances in Telepharmacy
- Challenges in Tackling the Opioid Crisis: Industry Influences
- Challenges in Tackling the Opioid Crisis: Practice Limitations

Thank you to all attendees who helped make the meeting such a huge success!

License Renewal Notice

In accordance with the District of Columbia Municipal Regulations (DCMR), there are continuing education (CE) requirements for licensed pharmacists and pharmacy technicians for the upcoming renewal period. Pharmacists are to complete a minimum of 40 contact hours of CE, including a minimum of two contact hours of cultural competency/lesbian, gay, bisexual, transgender, gender nonconforming, queer, or questioning their sexual orientation or gender identity and expression (LGBTQ) training; two contact hours of human immunodeficiency virus training; and two contact hours of medication/dispensing errors training. Pharmacists who immunize are also required to complete a minimum of two contact hours relevant to the administration of immunizations and vaccinations. A contact hour for pharmacist CE requirements is defined as 50 minutes of instruction in an approved CE program and equals 0.1 CEU. A minimum of 10 hours is to be completed in live training courses. Further information on CE requirements for pharmacists can be found in DCMR Chapter 65.

Pharmacy technicians are to complete a minimum of 20 contact hours of CE with at least two contact hours in pharmacy law; two in medication safety; and two in cultural competency/LGBTQ training. A contact hour for technicians is defined as a minimum of 60 minutes of instruction in an approved CE program and shall equal 0.1 CEU. A maximum of 10 contact hours of the required 20 may be earned by completing relevant college courses with a grade of C or better. Further information on CE requirements for pharmacy technicians may be found in DCMR Chapter 99.

For this upcoming renewal, pharmacist licenses and pharmacy technician registrations will be emailed to the licensee. Please ensure that you register your correct email address with the new DC Health online licensing portal. The link to the new portal is scheduled to be sent out around January 1, 2019. The portal will have an option for you to upload your CPE Monitor® transcript or CE certificates during the renewal period. The renewal fee is $310 for pharmacists, $50 for vaccination and immunization for pharmacists, and $50 for pharmacy technicians. There will be an additional $50 charge for the criminal background check. Additional information will be provided in the renewal instructions and on the Board's website at *https://dchealth.dc.gov/bop.*

Please visit the DC Center for Rational Prescribing (DCRx) website at *https://dchealth.dc.gov/dcrx* and the Pharmacists' Learning Assistance Network at *https://plan.acpe-accredit.org* to access CE courses required for renewal. CE courses are not required for a licensee's first renewal. Renewal information will be posted on the website and emailed to licensees.

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 DC residents. The NPO standing order must be signed by a DC-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 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.*

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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