March 2017

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

About the District of Columbia Board of Pharmacy

Members of the District of Columbia Board of Pharmacy are:

Daphne B. Bernard, PharmD, RPh.....Chairperson
James C. Appleby, RPh, MPH.....Vice Chairperson
Emmanuel Bellegarde, BS.....Consumer Member
Eddie Curry, MPA, MIS.....Consumer Member
Alan Friedman, RPh.....Member
Tamara McCants, PharmD, RPh.....Member
Benjamin E. Miles, PharmD, RPh, BCPS.....Member
Shauna White, PharmD, RPh, MS.....Executive Director

The District of Columbia mayor appoints each Board member, including the chairperson. The Board consists of seven District of Columbia residents: five licensed pharmacists and two consumer members. Each appointed pharmacist must have been engaged in practice for at least three years preceding appointment. The consumer members must be at least 18 years old, must not be health professionals or in training to become one, and may have no household member who is involved directly or indirectly in providing health care. Board members are appointed for a term of three years. Members may be appointed for two consecutive terms. Interested in serving as a member of the Board? Contact the Mayor's Office of Talent and Appointments.

For additional information, visit the Board's website at *http://doh.dc.gov/bop* or *www.dcboard.pharmacy.*

Notice of Board Meeting Schedule

The Board holds open (public) session meetings on the first Thursday of 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, 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, April 6, 2017 - 9:30 AM
- Thursday, June 1, 2017 - 9:30 AM
- Thursday, August 3, 2017 - 9:30 AM
- Thursday, October 5, 2017 - 9:30 AM
- Thursday, December 7, 2017 - 9:30 AM

Meet Our Newest Board Member: Dr Benjamin E. Miles

The Board welcomes its newest member, Dr Benjamin E. Miles! Dr Miles, an Atlanta, GA native, joined Sibley Memorial Hospital's clinical pharmacy staff after he relocated to Washington, DC in 2009. At Sibley Memorial Hospital, Dr Miles is an emergency department clinical specialist. He received a bachelor of science in microbiology and biology in 2003, followed by a doctor of pharmacy degree in 2007, both from the University of Georgia in Athens, GA. He completed a postgraduate year 1 residency at Eastern Maine Medical Center in Bangor, ME, in 2008, where he also worked as a decentralized staff pharmacist for the year following his residency. Dr Miles has served as a resident advisor and a residency research advisor for Sibley's pharmacy residency program.

Dr Miles is a clinical associate professor at Virginia Commonwealth University School of Pharmacy and

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

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preceptor for Howard University College of Pharmacy. He serves as a preceptor for both schools for the advanced pharmacy practice experiential hospital rotation. Additionally, he is board certified in pharmacotherapy.

His interests are in emergency medicine, critical care, and internal medicine. Outside of work, Dr Miles is an avid runner, having completed four full marathons and 17 half-marathons.

Safe Medication Disposal Initiative

The District of Columbia Department of Behavioral Health (DBH) Substance Use Disorder Services, Office of Prevention Services is launching a new initiative in which it will disseminate 100,000 medication deactivation pouches through a generous donation from a pharmaceutical company. The purpose of this initiative, which will run from January through June 2017, is to provide residents of the District of Columbia with a safe means for disposing of unused medication.

Heretofore, the only options for getting rid of remaining medicine have been flushing it down the toilet, throwing it directly in the trash can, or traveling to a facility specializing in the safe disposal of medicine. Each deactivation pouch efficiently neutralizes up to 45 pills when it is filled with warm water, closed up, shaken for a few seconds, then tossed into the trash can.

In an effort to reach as many residents as possible, DBH has sought to establish partnerships within a number of arenas throughout the District of Columbia. One of the key vehicles for distribution has been engaging pharmacies that regularly fill prescriptions for opioid-based prescriptions. The desire is that customers would receive medication deactivation pouches along with their medication. After using the needed amount of medicine, the pouches can be used for the safe disposal of any remaining pills or liquid.

If your pharmacy is interested in partnering with DBH/Office of Prevention Services on this initiative or for additional information, please contact DBH by email at valerie.jordan@dc.gov or via phone at 202/442-4241. There is no cost or obligation to participate.

District of Columbia PDMP Is Officially Active

Since October 19, 2016, patient care providers have been able to access prescription drug monitoring information that can serve as a tool to determine the legitimate use of controlled substances (CS) for their patients. The District of Columbia Prescription Drug Monitoring Program (PDMP) is an electronic database used to monitor and collect data on the dispensation of prescriptions for Schedule II, III, IV, and V CS, as well as products containing butalbital and cyclobenzaprine.

Prescribers and dispensers who plan to obtain District of Columbia PDMP information shall provide notice to the patient that a request may be made to obtain information on all covered substances dispensed to that patient. The notice may be provided by use of a conspicuous sign in an area that will be easily viewed and read by the patient. Examples of signs include the following:

- "This Practice May Access Your Prescription Drug Monitoring Information"
- "This Pharmacy May Access Your Prescription Drug Monitoring Information"

In lieu of posting a sign, the prescriber or dispenser may provide notice in written material given to the patient or may obtain written consent from the patient.

Please visit *https://districtofcolumbia.pmpaware.net/login* to log in to the District of Columbia PDMP. To request a new account to the PDMP, the user must navigate to the login screen for the PMP AWAR$_X$E database and create an account using a unique email address. For more information on registration, refer to the user support manual available on the District of Columbia PDMP website. The review process may take up to two weeks.

If you have any questions or concerns about navigating the system, please contact Appriss, Inc technical support directly at 855/932-4767. Technical assistance is available 24/7. Please submit any program questions by email to doh.pdmp@dc.gov.

The Importance of Serving on the Board: A Consumer Board Member's Perspective

Mr Emmanuel Bellegarde serves as the newest consumer member of the Board. When asked what value he adds as a member of the Board, he provided the following response:

"As a consumer member with the Board of Pharmacy, I advocate on behalf of District residents and visitors who rely on the District's pharmacies for life-saving medications and care. I've worked in the public sector for nearly two decades to empower disenfranchised communities. My passion and professional experience are aligned with the mission and vision of the Board of Pharmacy. Members of the Board play an important role in ensuring the safety and strict adherence to the rules and regulations associated with dispensing and managing prescriptions in the District of Columbia. In addition, Board members are keenly aware of the immense responsibility that comes with the position."

The views expressed by Mr Bellegarde are a reminder of Board members' primary duty in their regulatory oversight role as state representatives – to protect the public's well-being. It is an honor to serve as a Board member, which is a position of immense responsibility. Residents

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of the District of Columbia should feel confident that their concerns are adequately taken into account in the Board's decision making and that their interests are strongly advocated for by Consumer Board Members Emmanuel Bellegarde and Eddie Curry!

DCRx: Better Prescribing for Better Patient Care

The DC Center for Rational Prescribing (DCRx) provides information about medications and other therapeutic options to physicians and health care professionals. Rational prescribing is defined as choosing treatments based on the best available evidence and benefits that outweigh harms. High cost can be considered a possible harm. In order to help health care professionals in the District of Columbia prescribe rationally, the District of Columbia Department of Health is providing noncommercial, independent continuing education (CE) along with access to other educational resources. DCRx offers CE courses at no cost to District of Columbia-licensed health care professionals and at a minimal cost to health care professionals not licensed in the District of Columbia. All CE videos are free to view for those not seeking CE credit. Currently, there are courses totaling 10.5 CE credit hours offered through DCRx. For links to CE and more information about DCRx, please visit *https://doh.dc.gov/dcrx*.

Pharmacy Technician Licensing Update

As of December 31, 2016, all pharmacy technicians and pharmacy technician trainees working in the District of Columbia are required to be registered with the Board. The grandfathering provision for registration ended on December 31, 2016. It is the duty of the pharmacist-in-charge to ensure that technicians are licensed with the Board. If a pharmacy technician wants to work in the District of Columbia, he or she would need to submit an application to the Board for registration. Applicants have three choices for registration: pharmacy technician, pharmacy technician by reciprocity, or pharmacy technician trainee. Pharmacy technician applicants must have documentation of having completed a Board-approved training program. Pharmacy technicians licensed in another state would be eligible to apply as a pharmacy technician by reciprocity. For applicants applying via reciprocity, please ensure that your license in another state is active and in good standing. Applicants who are enrolled in a Board-approved training program would need to apply as a pharmacy technician trainee. For additional details, requirements, and application for registration, please visit the Board's website at *http://doh.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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