November 2018

Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

Published to promote compliance of pharmacy and drug law

320 W Washington, 3rd Floor • Springfield, IL 62786 • Phone: 800/560-6420
Website: *www.idfpr.com/profs/pharm.asp*

A Message From Secretary Schneider

Greetings,

Welcome to the November issue of the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter.* I hope that everyone is enjoying the fall season.

I am pleased to say there have been several efforts in combating the Illinois opioid crisis since the time of the last *Newsletter.* One example involves the passing of Senate Bill 2777, now known as Public Act 100-1106. This amendment to the Illinois Controlled Substance Act mandates three hours of continuing education on safe opioid prescribing for all medical professionals holding a controlled substance (CS) license. This law ensures that medical professionals with the ability to prescribe CS will obtain valuable education while still preserving their ability to use judgment and treat patients appropriately. As a reminder, disciplinary action on CS licenses may be found on Illinois Department of Financial and Professional Regulation Pharmacy's (IDFPR's) License Look-Up page. This page is also where licensed professionals may check the status of license renewals and applications.

Very truly yours,

Bryan A. Schneider
Secretary, IDFPR
bryan.schneider@illinois.gov, 312/793-3676

Volunteers Wanted!

The following article was submitted by the Illinois State Board of Pharmacy.

The Illinois Department of Public Health (IDPH), the Illinois Pharmacists Association (IPhA), and other stakeholders have partnered together to form a pharmacist Medical Reserve Corps (MRC). An MRC is a community-based, civilian volunteer program that helps build the public health infrastructure of communities nationwide. Each MRC unit is organized and trained to address a wide range of challenges from public health emergencies and education to disaster response. Volunteers will be prepared to respond to natural disasters, such as wildfires, hurricanes, tornados, blizzards, and floods, as well as other emergencies affecting public health, such as disease outbreaks (eg, influenza pandemic).

In its development process, IDPH and IPhA recognized the impact and expertise that pharmacists can offer during a public health emergency or natural disaster. We also recognize the need to prepare volunteers for their responsibilities. The Illinois pharmacy work group is looking for Illinois-licensed pharmacists to assist in the event of a public health emergency or natural disaster and to be part of our MRC. If you are interested or have additional questions about the program, please contact Debra Paul Moorman, PharmD, RPh, with IDPH/IPhA, at 630/809-5654 or dpmoorman1@gmail.com; or contact Carla Little, PhD, with IDPH at 312/814-1091 or carla.little@illinois.gov.

Upcoming Pharmacy Board Meetings

The IDFPR, Division of Professional Regulation – State Board of Pharmacy is scheduled to meet:

- ♦ November 13, 2018 – Chicago, IL
- ♦ January 8, 2019 – Chicago
- ♦ March 12, 2019 – Springfield, IL
- ♦ May 14, 2019 – Chicago

The meetings are open to the public.

Chicago location: 160 N LaSalle St, Room 505N

Springfield location: 320 W Washington St

USP <795>, <797>, and <800>

A brief introduction to nonsterile, sterile, and hazardous drug handling and compounding

continued on page 4

National Pharmacy Compliance News

November 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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

continued from page 1

By: Jamal Pratt, pharmacy practice resident, Northwestern; Nikola Markoski, resident, Northwestern; and Katherine Gauen, pharmacist, Northwestern (Individuals not affiliated with IDFPR)

United States Pharmacopeial Convention (USP) develops standards for drugs to help ensure consistency, patient safety, employee safety, and reduce risks such as contamination, infection, or incorrect dosing. USP is a not-for-profit, science-driven organization that has an established process for convening independent experts in the development and maintenance of health care quality standards.

USP General Chapter <795> provides standards for nonsterile compounding to help minimize the risk of contamination and incorrect dosing. USP <795> includes guidance on the compounding practice, beyond use dating, equipment, and documentation. In the spring of 2018, an updated version of USP <795> was released for public comment. Those comments are currently under review, with an anticipated publication date of mid-2019.

USP General Chapter <797> describes a number of requirements, including the responsibilities of sterile compounding personnel, training, facilities, environmental monitoring, and storage and testing of finished preparations. USP <797> defines the standards of sterile compounding that must be adhered to and enforced by some state boards of pharmacy, the Joint Commission, and Centers for Medicare & Medicaid Services. The latest version of USP <797> is in the development process, and drafts have been released for public comment. The final version has an anticipated release of mid-2019.

USP General Chapter <800> provides standards for safe handling of hazardous drugs to minimize the risk of exposure to health care personnel, patients, and the environment. The National Institute of Occupational Safety and Health defines hazardous drugs (HDs) as carcinogenic, teratogenic, or toxic at low doses, and categorizes them into three groups. USP <800> applies to all health care personnel who handle HD preparations and all entities that store, prepare, transport, or administer HDs (eg, pharmacies, hospitals and other health care institutions, patient treatment clinics, physician practice facilities, and veterinarian offices).

USP <800> was first published on February 1, 2016, and health care institutions have slowly begun to implement these new standards. USP <795>, <797>, and <800> are anticipated to become enforceable on December 1, 2019, at which time affected users are expected to meet the requirements.

References:

1. USP. General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. *www.usp.org/compounding/general-chapter-797.*
2. Travis Clean Air. USP Chapter 800 delayed. *https://www.traviscleanair.com/blog/usp-chapter-800-delayed.*
3. USAGov. National Institute of Occupational Safety and Health. *https://www.usa.gov/federal-agencies/national-institute-of-occupational-safety-and-health.*
4. USP. FAQs: <800> Hazardous Drugs—Handling in Healthcare Settings. *www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.*

The *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter* is published by the Illinois Department of Financial and Professional Regulation (IDFPR) 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 IDFPR unless expressly so stated.