December 2018

Wyoming State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Wyoming State Board of Pharmacy • 1712 Carey Ave, Suite 200 • Cheyenne, WY 82002
http://pharmacyboard.wyo.gov

New Executive Director at the Board of Pharmacy, Lisa V. Hunt, RPh, MBA-HM

By Samuel Blakeslee, PharmD candidate

The Wyoming State Board of Pharmacy introduces its new executive director, Lisa V. Hunt. Lisa has been a staff member at the Board since 2015 when she was hired as the chief compliance officer. Before joining the Board, Lisa worked as a dispensing pharmacist; ran Oregon's state drug utilization review (DUR) program; and worked for Oregon, Washington, and Utah's Medicaid pharmacy programs, managing the Medicaid pharmacy DUR, pharmacy and therapeutics committees, and rebate programs. She has represented the agencies she worked for in administrative hearings and legislative hearings.

Lisa comes from a family of pharmacists, with both her uncle and grandfather running their own independent pharmacies. She graduated from Oregon State University, holds a master of business administration degree in health care management, and is a licensed pharmacist in four states.

Lisa has been involved in providing technical assistance for pharmacy-related legislation on issues ranging from naloxone, opioid addiction mitigation, and pharmacists' collaborative practice issues. Lisa has worked hard to protect the public and promote best practices for the pharmacy profession. She values the teaching opportunities associated with her previous position and is excited to continue being a student preceptor.

Looking forward, Lisa already has several projects and goals she is working to complete. Multiple Board software programs and other systems are being updated to ensure the quick processing of applications and licenses. Additionally, updates to the WORx prescription drug monitoring program to track delegates and allow access to interstate data sharing are in progress. Lisa notes that we are seeing a lot of changes in the pharmacy profession today. Telehealth is now common and "pharmacists are taking a more active role in providing new types of patient care services." Lisa looks forward to continuing to meet with and answer questions for all the pharmacists and pharmacy technicians in Wyoming.

Wyoming's Response to the Opioid Crisis – An Update on the Opioid Addiction Task Force

By Alexander Carter, PharmD candidate

Opioid abuse and addiction continue to make headlines across the United States. Organizations such as the Centers for Disease Control and Prevention and the National Safety Council have published numerous articles and studies promoting changes that they believe could end the opioid crisis, or at least reduce its impact on the American people. In response to these efforts, many states have begun drafting and enacting new legislation concerning controlled substances (CS). Wyoming is no exception. On March 16 of this year, Governor Matt Mead signed Senate Bill 78, establishing the Opioid Addiction Task Force. The 14 appointed members of the task force include legislators, health care professionals, law enforcement personnel, and others who are tasked with developing legislation that protects the legitimate and safe use of controlled medications while reducing dangerous and illicit use.

The Opioid Addiction Task Force met on August 29, 2018, to discuss a number of proposed bills that could impact pharmacists. These included opioid and addiction continuing education (CE) requirements, new limitations for Schedule II prescriptions, and requiring the use of electronic prescriptions for controlled medications.

As health care professionals, we are part of a field that is ever changing. New studies are published every day, guidelines are regularly updated, and best practice

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National Pharmacy Compliance News

December 2018

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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.*

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constantly evolves. Current CE requirements are in place to help pharmacists stay up to date on these changes and shore up any areas we may be deficient. The proposed bill would require CE on topics such as CS prescribing, managing pain patients, and treating substance abuse disorders. Pharmacists, doctors, nurses, dentists, and all other practitioners who hold a Wyoming CS registration would be required to meet these new CE standards in addition to any requirements set by their respective boards. Nearly all members of the task force, as well as the community members in attendance, agreed that requiring these extra CE hours would be a beneficial change.

The topic of adding new limitations to opioid analgesic prescriptions was a more debated topic. The initial proposal included a limit on morphine milligram equivalents (MMEs) in addition to a seven-day cap for any acute pain narcotic prescriptions. Exceptions were noted for chronic pain cases, cancer patients, and other patients requiring larger doses or longer courses of these medications. A concern mentioned on multiple occasions was that these requirements would result in a disproportionately large number of "exception patients." An additional argument against this proposed bill was that requirements that directly regulate medical and pharmacy practice should instead be left to their respective boards as opposed to state statutes. An eventual compromise was made in which MME limits would not be regulated by the state, but opioid prescriptions for acute cases would be limited to a 14-day supply.

The proposal to require solely electronic prescriptions for CS was recognized as an expensive, but ultimately beneficial change. The predominant concern raised was that in various parts of the state – more rural areas in particular – providers may not be equipped to write electronic prescriptions. The programs that securely transmit prescriptions to a pharmacy can have substantial costs, which could have significant impacts on smaller clinics and offices. To better accommodate these providers, this change would not be enforced until 2022.

Paper prescriptions, which have traditionally been one of the few ways Schedule II drugs could be prescribed, are subject to a multitude of issues. Forgeries, prescription alterations, and even stolen prescription pads all account for ways paper prescriptions can lead to the improper dispensing of narcotics. Additionally, e-prescriptions offer an additional level of convenience for pharmacists, prescribers, and patients. Per Chapter 6, Section 13 of the Wyoming Controlled Substances Act, pharmacists are unable to change various aspects of a Schedule II prescription, including easily forgotten things like the date. An erroneous e-prescription can quickly be corrected and resent following a quick phone call and would not require the patient to return to the prescriber.

Wyoming is taking an active role in combating the opioid crisis. Late 2017 saw the addition of Chapter 18 to the Wyoming Pharmacy Act, which allows pharmacists to prescribe and dispense naloxone. Now, Wyoming health care professionals are working alongside legislators to develop and pass new statutes they believe will help reduce the impact of the opioid crisis. It is important to recognize that new legislation can have a significant influence on how we practice pharmacy in Wyoming and ensure we are prepared to adapt as necessary.

FDA Approves First Marihuana-Derived Medication: Epidiolex

By Hannah Thorfinnson, PharmD candidate

On Monday, June 25, 2018, Food and Drug Administration (FDA) granted approval to GW Pharmaceuticals for the first medication to be derived from the marihuana plant. Epidiolex® (cannabidiol) is an oral solution of pure, plant-derived cannabidiol that was approved through the orphan drug development process for the treatment of Lennox-Gastaut syndrome and Dravet syndrome, which are two rare but serious epilepsy conditions. The mechanism behind the antiepileptic properties of Epidiolex is unknown, but it has demonstrated low affinity for cannabinoid receptors and is therefore thought to illicit an anticonvulsant mechanism via alternative pathways. Cannabidiol is an extract obtained from the flowering portion of the cannabis plant, and while it is a chemical component of the plant, it is not responsible for the intoxicating and euphoric effects of its illicit parent drug. Psychotropic effects of marihuana are attributed to another chemical component of the marihuana plant, tetrahydrocannabinol (THC). The newly approved Epidiolex is pure cannabidiol and does not contain any amount of THC.

Lennox-Gastaut and Dravet syndrome are two very rare and very severe forms of epilepsy that begin in childhood. The seizures experienced with these forms of epilepsy are difficult to control with medication, leading to delayed development and learning disabilities. Prolonged seizures resulting in status epilepticus are possible in both conditions and can be fatal. Epidiolex is the first approved treatment of Dravet syndrome, which was previously treated with a combination of off-label antiepileptic drugs.

FDA designated priority review of Epidiolex due to the dire need for effective treatment. Priority review meant that all available resources would be prioritized to review

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and approve this medication. Epidiolex was also granted orphan drug status by FDA for both conditions. The Orphan Drug Designation program is a way FDA incentivizes the development of treatment for rare disease states/disorders. Additionally, Epidiolex received fast-track designation for the treatment of Dravet syndrome to facilitate the development of the drug and expedite FDA's review process.

There are currently three completed clinical trials that were randomized controlled, double-blind, and consisted of 516 patients with either Lennox-Gastaut syndrome or Dravet syndrome. Each trial compared the safety and efficacy of Epidiolex, both high and low dose, compared to a placebo. Study subjects were documented to have refractory epilepsy syndromes characterized by the failure of multiple antiepileptic drugs. The inclusion and exclusion criteria of these studies were quite extensive, lowering the generalizability of their findings. The primary endpoint of these studies was the percentage change from baseline in the number of drop seizures experienced by individual patients. All trials show a statistically significant decrease in the percentage of drop seizures when taking Epidiolex as compared to placebo.

With FDA approval of a medication derived from the marihuana plant, it is important to note that THC is still an illicit substance in the state of Wyoming. Products containing THC are not to be sold or purchased with the exception of FDA-approved products. See Wyoming Statute (W.S.) Annotated Title 35-7-1031(c), which states in pertinent parts (Bold added for emphasis):

> It is unlawful for any person knowingly or intentionally to possess a controlled substance **. . . With the exception of any drug that has received final approval from the United States food and drug administration . . .** as listed in W.S. 35-7-1018(h), and notwithstanding any other provision of this act, no practitioner shall dispense or prescribe marihuana, tetrahydrocannabinol, or synthetic equivalents of marihuana or tetrahydrocannabinol and no prescription or practitioner's order for marihuana, tetrahydrocannabinol, or synthetic equivalents of marihuana or tetrahydrocannabinol shall be valid **unless the prescription is for a drug that has received final approval from the United States food and drug administration . . .**

The future of cannabidiol is not limited to GW Pharmaceuticals. There are several companies anxiously awaiting Drug Enforcement Administration's decision on how it is going to schedule marihuana and its derivatives. CURE Pharmaceuticals, an innovative drug delivery and development company, is researching cannabinoids for the treatment of several different sleeping disorders. Therapix Biosciences is another company that specializes in drug development based on synthetic cannabinoids for the treatment of Tourette syndrome, pain management, mild cognitive impairment, obstructive sleep apnea, traumatic brain injury, and various infectious diseases. The promising times ahead for cannabis research may give patients with rare and currently untreatable conditions new hope.

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