December 2017

News

Wyoming State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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

New Inspector/Compliance Officer, Matthew Martineau

By Danielle Weiss, PharmD Candidate

There is a new face at the Wyoming State Board of Pharmacy, Matthew "Matt" Martineau, PharmD. With a variety of experience, Matt is familiar with the many types of pharmacies he will be inspecting. While a student at the University of Wyoming, he had many of his advanced pharmacy practice experiences (APPEs) at larger hospitals in Wyoming and Colorado. After graduation, he became a clinical pharmacist for Chadron Community Health, a small hospital in Nebraska. He then moved to Cheyenne, WY, where he quickly worked his way up at Walgreens, from float pharmacist to staff pharmacist to pharmacy manager. Before coming to the Board, he worked at Albertsons/Safeway as well. With this background, Matt will be able to bring a well-rounded view to the Board.

Matt has wanted to become an inspector/compliance officer for some time now. His interest started when he had an APPE at the Board while he was a student during the legislative session that year. He likes the puzzles that the law can present, along with the logic and problem-solving required. He is looking forward to anticipating what changes will need to be made in the future as pharmacy evolves. He believes that as technology becomes increasingly dominant in the world of pharmacy, we need to continue to adapt, especially when it relates to patient safety. Matt states that he is a perpetual student, as he enjoys reading, listening to podcasts, and watching lectures online for anything that piques his interest. He also likes to travel and hike with his wife, Beth. He has been to five of the seven continents, and he hopes to continue to add stamps to his passport. It is safe to say he is a welcome addition to the team at the Board.

Recent Disciplinary Actions

L.H., Pharmacist License #1727: Failed to complete 12 hours of continuing education (CE) in 2016. Fine of $300 plus required to complete 12 extra hours of CE, including three hours on pharmacy law.

Pharmacy License #06-80401: Medication error plus delay in providing prescriptions to a nursing home patient. Fine of $2,000 plus submission of plans to prevent future such issues.

Pharmacy License #R10149: Medication error. Fine of $500 plus submission of a plan to prevent future such medication errors.

Addressing the Use of Cannabidiol and Hemp Extracts in the State of Wyoming

By Andrew Cox, PharmD Candidate

In a country plagued with a current opioid/opiate abuse epidemic, a lot of people are looking for alternative ways to treat their pain. This has led to a rise in the use of the hemp extract cannabidiol, or CBD. CBD is claimed to provide relief for an individual's pain while remaining devoid of the psychoactive effects that are seen with the compound tetrahydrocannabinol (THC). While CBD may be a potential option to treat pain in the pharmacotherapy future, studies are currently lacking to provide evidence of the safety and efficacy of the product. Therefore, the claims being made by the several manufacturers of CBD products have not been evaluated by Food and Drug Administration (FDA). In addition, FDA has sent out warning letters to several manufacturers of CBD products that had been tested and found not to contain the amount of CBD that was claimed by the manufacturer. The claim that a product is devoid of THC leaves people with the assumption that these products are legal to possess and use in the state of Wyoming. However, Wyoming has outlined in legislation the only certain instance in which the use and possession of hemp extracts like CBD is in fact legal. Unless the product comes with a certification of analysis, it cannot be proven to be completely free of THC (most oils contain a low amount of THC). This article will highlight key points on CBD use in the state of Wyoming.

To begin with, according to Wyoming Statute (W.S.) 35-7-1803, the only exemption from criminal and civil penalties for the medical use of hemp extract is if the individual

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.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.safe.pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval℠ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply.*

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

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.*

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal.* Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR$_X$E®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.*

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health,* discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at *www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.*

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm549679.htm,* FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at *www.fda.gov/safety/medwatch.*

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit *atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.*

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team,* contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.*

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at *www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.*

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possesses the hemp extract only for the individual's or the individual's minor child's intractable epilepsy. The individual or the legal parent or guardian of the minor must be a holder of a valid hemp extract registration card, issued by the Wyoming Department of Health under W.S. 35-7-1802, and must provide, through a certificate of analysis or otherwise, evidence that the hemp extract meets the percentages for tetrahydrocannabinol and cannabidiol. According to the statute, intractable epilepsy is defined as follows: "epilepsy that, as determined by a neurologist, does not respond to other treatment options overseen by the neurologist." In addition, registration cards will only be issued based upon approved criteria: the individual must be at least 18 years of age, be a resident of Wyoming, and provide a statement to the Department of Health that is signed by a neurologist and specifies that the individual or minor suffers from intractable epilepsy and may benefit from the treatment with hemp extract. The submitted application must be approved and the assessed fee paid. The approved formulation of the extract must be no more than 0.3% tetrahydrocannabinol by weight and must contain at least 15% cannabidiol by weight. In addition, the substance cannot contain any other psychoactive substance.

While the statute addresses who can possess CBD, it does not address how it can be obtained. Currently, it is illegal to sell cannabis products in the state of Wyoming. Therefore, an individual would have to procure the CBD in a state that has legalized cannabis products. Because of interstate commerce laws, it would be illegal for this product to be shipped from another state into Wyoming. Thus, an individual would have to travel to retrieve the CBD. Any product purchased must contain a certificate of analysis to verify the appropriate concentration.

It is important to keep up to date on current Wyoming law before considering the use of CBD for Wyoming-approved uses. It is best to avoid possessing CBD, recommending CBD, selling CBD, or compounding products with CBD in Wyoming. CBD may have a place in the future of pharmacotherapy in Wyoming, but for now, unless in the clearly defined cases of intractable epilepsy, it remains illegal.

Pharmacy Compliance Corner

By Lisa Hunt and Matt Martineau, Board Inspectors/ Compliance Officers

Pharmacy inspections for 2017 have been focusing on compounding. Whether you are in retail and only do a few nonsterile compounds a year or you practice in an institutional setting and prepare many sterile compounded products, you will be asked if documentation exists for compounding competencies for all pharmacists and pharmacy technicians who assist pharmacists in compounding.

Inspectors frequently look for documentation that shows each pharmacist and technician has passed an observed test demonstrating that he or she can accurately and safely compound. Observed tests must reflect the type of compounding that the pharmacy actually performs. Wyoming Pharmacy Act (WPA) Rules, Chapter 10, Section 7(a) requires documentation of certain elements, but does not limit to only those skills. Sterile aseptic technique is required for sterile compounding. Observed testing may include, for example, observing if compounding staff can appropriately gown and garb, calculate the correct intravenous flow rate, or measure and add the correct dose to the correct bag of normal saline.

Nonsterile compounding also requires annual compounding competency testing. Example documentation questions may include: Can compounding staff accurately measure out 80 mL of viscous lidocaine 2%? Or, can compounding staff measure out 60 mg of hydrocortisone powder?

Documentation should include the name of the person observing the testing, the date and time the competency was assessed, and the results. It is important that every individual who participates in the compounding process undergo annual competency testing, required for both technicians and pharmacists. Documentation of the testing must be available for review.

For more information on competency requirements see WPA Rules Chapter 13, Section 4(b); Chapter 10, Section 7(a); and Chapter 17 (on United States Pharmacopeia (USP) Chapter <797>).

New Board Website

In October 2017, the new Board website went live at *http://pharmacyboard.wyo.gov.* The photograph of Fremont Lakes near Pinedale, WY, at the top of the home page was provided by Katrina Roberts, RPh, a 2017 University of Wyoming graduate. The information on the website has been revised and updated.

WPA Rules Revisions

Governor Matt Mead signed rules revisions under the WPA in Chapters 2 (General Practice), 8 (Wholesale Distributors), 14 (Telepharmacy), and 18 (Prescribing by Pharmacists) on October 27, 2017. A summary of changes is included below.

Wyoming Rules Revisions Signed by Governor Matt Mead on October 27, 2017

Rules WPA Citation	Topic	Change
Chapter 2 - General Practice of Pharmacy	General	Spelling, numbering, format corrected throughout. Some sections changed numbers.
Chapter 2, Section 4 - Definitions	Ancillary Kit	New name for emergency drug kits for nursing homes, hospices, etc.
Chapter 2, Section 4 - Definitions	Single Unit Dose and Unit of Use	Changed definitions from Unit Dose Package and Unit of Issue Package to match USP.
Chapter 2, Section 5	Pharmacist Licensure by Exam	Updates to new North American Pharmacist Licensure Examination® and Multistate Pharmacy Jurisprudence Examination® regulations for retakes.
Chapter 2, Section 7	Prescription Balance	No longer required to have a balance or electronic scale if the pharmacy does not compound.
Chapter 2, Section 10	Transfers	Clarification of transfers.
Chapter 2, Section 15	Return of Unused Prescription Drugs	For donation under W.S. 35-7-1601 or returned for quarantine/destruction after error.

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Rules WPA Citation	Topic	Change
Chapter 2, Section 24	Fees	Fees for new licenses such as outsourcing facilities, third-party logistics providers. Adds late fees for renewals of pharmacy interns, medical oxygen, outsourcing facilities, others.
Chapter 2, Section 25	Ancillary Drug Supply	Revised rules for nursing homes, hospices, extended-care facilities permits.
Chapter 2, Section 34	Electronic Records	Regulations regarding electronic storage of prescription records.
Chapter 2, Sections 35, 36, and 37	Incorporation by Reference	References for drug disposal by patients, the "Orange Book," disposal of controlled substances.
Chapter 8	Wholesale Distributors	Entire chapter revised to comply with the federal Drug Quality Security Act.
Chapter 14	Telepharmacy	Revised due to statute changes in 2017. Allows "traditional dispensing," 10-mile limits (or none). Describes audio/video communication with the parent pharmacy, regulations for delivery and storage of drugs.
Chapter 18 (new)	Prescribing by Pharmacists	Emergency rules for naloxone prescribing and dispensing due to statute changes in 2017.
Chapter 18, Section 4	Definitions	Opiate antagonist, opiate overdose.
Chapter 18, Section 6	Naloxone Prescriptions	To whom: person at risk, person who can assist a person at risk, what risk means.
Chapter 18, Section 6(b)	Naloxone Counseling	What information must be provided by a pharmacist when dispensing naloxone.
Chapter 18, Section 6(c)	Naloxone Allergy	Do not dispense if known hypersensitivity.
Chapter 18, Section 6(d)	CE Required	One hour of CE specific to the use of naloxone.
Chapter 18, Section 6(e)	Naloxone Prescription	Generate a written or electronic prescription.
Chapter 18, Section 6(e)(iii)	Report Naloxone to Wyoming Online Prescription Database (WORx)	Requires reporting of naloxone prescriptions dispensed to WORx, the Wyoming prescription drug monitoring program.

The *Wyoming State Board of Pharmacy News* is published by the Wyoming State Board of Pharmacy and the National Association of Boards of PharmacyFoundation® (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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