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News

Wyoming State Board of Pharmacy

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Butalbital Schedule Status in Wyoming

Wyoming Statute §35-7-1018(c)(iii) in the Wyoming Controlled Substances Act lists "[a]ny substance which contains any quantity of a derivative of barbituric acid or any salt thereof" as a Schedule III controlled substance (CS). While there are butalbital products on Drug Enforcement Administration's (DEA's) list of exempted prescription products, including Fioricet (butalbital/acetaminophen/caffeine), Wyoming does not have a similar list of exempted products. All butalbital-containing products, therefore, are Schedule III CS in Wyoming and must be treated as such.

Emergency Rule – Chapter 16: Immunization Regulations

The Wyoming State Board of Pharmacy held a special meeting on November 19, 2020, to consider an emergency rule adding vaccines for the coronavirus disease 2019 (COVID-19) to the Wyoming Pharmacy Act Rules and Regulations Chapter 16: Immunization Regulations. During the December 2, 2020 Board meeting, Board members considered additional changes to the chapter that would better allow pharmacists to provide immunizations during the COVID-19 public health emergency. The emergency rule deletes the definition of private space and the requirement that the individual receiving a vaccine be seated in a chair with back support. It also adds vaccines for COVID-19 that are approved by Food and Drug Administration (FDA) under an emergency use authorization and any vaccine for COVID-19 that completes the FDA approval process. The emergency rule has been approved by Governor Mark Gordon.

Requests for copies of the emergency rule may be addressed to the Board executive director at 1712 Carey Avenue, Suite 200, Cheyenne, WY 82002, or to bop@wyo.gov. The emergency rule is posted on the Board's website and the Wyoming Secretary of State website.

Rules Revisions Signed by Governor Gordon

The changes to the Wyoming Controlled Substances Act Rules and Regulations were approved and signed by Governor Gordon on September 16, 2020. Chapter 6 was repealed, and Chapter 10 was created to simplify, modernize, and reorganize the information that was previously in Chapter 6. The new Chapter 10 also provides exemptions to the requirement that all CS be electronically prescribed under Wyoming Statute §35-7-1030. The updated chapters have been posted in the Laws section of the Board's website. They can also be found on the Wyoming Administrative Rules website at *rules.wyo.gov.*

Notice of Intent to Amend Rules

The Board proposes to amend **Chapter 17: Sterile Compounding** of the Wyoming Pharmacy Act Rules and Regulations. This is being done in order to simplify and reorganize the information that was previously incorporated by reference in United States Pharmacopeia General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.

The Board is also proposing to revise Chapter 10 of the Controlled Substances Act Rules. The Board has been made aware that pharmacies within federal jurisdictions in Wyoming are unable to receive electronic CS prescriptions from practitioners outside of the federal system. Given that these pharmacies are unable to receive electronic prescriptions, the proposed revision would exempt CS prescriptions that are to be dispensed from a pharmacy within a federal jurisdiction from the electronic prescribing requirement found in Wyoming Statute §35-7-1030.

Requests for copies of the proposed amendments may be addressed to the Board executive director at 1712 Carey Avenue, Suite 200, Cheyenne, WY 82002. The proposed amended rules and new chapters are posted on the Wyoming Secretary of State website. Comments may be submitted to the Board by mail or to bop@wyo.gov on or before 5 PM MST on February 13, 2021.

Happy Retirement to David Wills!

David "Dave" Wills retired from his position as data management specialist on November 13, 2020. He joined the Board staff in October 2008. Dave helped manage Wyoming's prescription drug monitoring program (PDMP),

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National Pharmacy Compliance News

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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.

FDA Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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titled the Wyoming Online Prescription Database (WORx), and helped develop and shepherd the program during his time with the Board. He was instrumental in the transition of WORx online, with implementation of a pilot program testing online access in 2009 and full 24/7 access finalized in 2013. Dave also developed good working relationships with Wyoming's practitioners, pharmacists, interns, members of law enforcement, and other state PDMP coordinators. Recently, Dave worked on connecting the database with other states' PDMPs, and WORx is now connected to and sharing data with 21 states. The Board wishes Dave a long and happy retirement!

WORx Enhancements

By Keith Bennett, PharmD, RPh, Inspector/Compliance Officer

WORx continues to evolve as an effective tool to aid in the identification, intervention, and prevention of substance abuse and/or diversion of CS. Two growing features of WORx involve sharing data with other states through NABP PMP InterConnect® and integration with electronic health records (EHRs) and retail pharmacy software systems.

During the 2020 budget session, Senate File No. SF0077 amended Wyoming Statute §35-7-1060(c) in the Wyoming Controlled Substances Act to allow the Board to establish data sharing agreements and release information to participating states. Wyoming Statute §35-7-1060(c)(vii) enables the Board to continue to increase the number of states with which WORx data is shared through PMP InterConnect. Currently, Wyoming's database is linked with 21 states in addition to the Military Health System (Department of Veterans Affairs and Indian Health Service). The continued growth and utilization of this feature in WORx will provide for a more effective method to mitigate drug diversion and abuse nationwide.

Integration of WORx with EHRs is another important feature that can make it easier for providers to meet the statutory requirements to search the database for new CS prescriptions and search for prescribed opioids every three months. The Board is currently working with stakeholders to integrate WORx with the various pharmacy, hospital, and provider software that is utilized throughout the state. Pharmacies that either have integrated or are working on integration include Albertsons, CVS, Kroger, Walgreens, and Walmart. The database has also been or soon will be integrated with four hospital EHR systems, including Campbell County Memorial Hospital in Gillette, WY; Cheyenne Regional Medical Center in Cheyenne, WY; St John's Health in Jackson, WY; and Star Valley Health in Afton, WY. Additionally, the Board is working on integration with athenahealth, which is used by over 500 providers, multiple hospitals, and long-term care facilities throughout the state. The interoperability between WORx, EHRs, and pharmacy software is intended to reduce the clinical burden on providers and promote utilization of the database to the fullest extent possible.

WORx has proven to be a useful tool to combat abuse and diversion of CS for nearly 20 years. As data sharing with other states through PMP InterConnect and integration with EHRs throughout the state continue to grow over time, its effectiveness will become even more evident.

Kratom

By Haley LeFaivre, PharmD Candidate

Kratom is an easily accessible herbal supplement used to reduce fatigue, enhance mood, and provide pain relief. It is derived from the tropical evergreen tree *Mitragyna speciosa* in Southeast Asia, which has psychotropic and opioid-like properties. It has been linked to abuse due to its effects as a stimulant in low doses and as a sedative in high doses. Cases of psychosis from overuse have been reported with symptoms such as delusion, confusion, mania, and hallucinations. Other common side effects include flushing, itching, respiratory depression, hypertension, sweating, dry mouth, upset stomach, constipation, increased urination, tachycardia, and anorexia. Kratom is not currently scheduled in the Controlled Substances Act but is listed as a drug of concern by DEA.

FDA warns consumers not to use kratom out of concern that it appears to have properties that expose users to the risks of addiction, abuse, and dependence. There are no FDA-approved uses for kratom, and the agency has received concerning reports about its safety. FDA is actively evaluating all available scientific information on kratom. While FDA evaluates the available safety information about the effects of kratom, the agency encourages health care professionals and consumers to report any adverse reactions to FDA's MedWatch program.

As health care providers, it is important to understand the pharmacologic effects of kratom at different doses since the mechanism of action is not clearly defined. At low to moderate doses (1-5 g), a patient experiences stimulant-like effects. When taken in moderate to high doses (5-15 g), kratom produces opioid-like effects. Doses over 15 g are associated with sedation. With ingestion, it can take 10 to 15 minutes for onset and the effects can last two to five hours. Since standard urine drug screens do not detect kratom metabolites, it is important to recognize use and abuse in patients with substance abuse history, drug interactions, and side effects from the supplement. Early intervention and patient education may help reduce abuse and possible unintentional overdose. As pharmacists, we can identify patients that may be using herbal supplements like kratom and be their first intervention on using controversial therapies.

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Pharmacy Technicians and the Future of Pharmacy-Based Immunizations

By Bradley Robinson, PharmD Candidate

According to the Centers for Disease Control and Prevention, more than 65,000 Americans die from vaccine-preventable illness every year not including, of course, the COVID-19 vaccine. Twenty-five percent of children do not complete their primary series of vaccinations by the age of two. Furthermore, most adults are inadequately vaccinated against influenza, tetanus, diphtheria, hepatitis A and B, pneumococcal disease, shingles, and human papilloma virus. Pharmacies are the second most frequented location to receive immunizations. The demand for pharmacy-based immunization services continues to grow with the annual flu season and the recent arrival and rollout of the COVID-19 vaccines. Public health officials and manufacturers of flu vaccines are also planning for greater demand this year. Despite this growing demand, pharmacists in most states continue to find themselves spending more time administering vaccinations. This has created significant workflow issues for pharmacies.

Currently, four states have addressed this issue by allowing pharmacy technicians to administer vaccines. In 2017, Idaho became the first state to allow pharmacy technicians to administer vaccines under Idaho Rule 330.03. The rule requires a licensed pharmacy technician to complete an accredited vaccination administration program and become certified in CPR. This rule simultaneously made vaccine administration more accessible in the pharmacy setting and allowed technicians to step into a more valuable role in the health care team. In the first six months, pharmacy technicians administered 953 vaccinations with no adverse events reported. Colorado, Rhode Island, Utah, and the federal pharmacy system have also similarly made it possible for pharmacy technicians to administer vaccines.

In June 2020, the Pharmacy Technician Certification Board (PTCB) announced its collaboration with the American Pharmacists Association (APhA) to credential pharmacy technicians in vaccination delivery. APhA has worked to train pharmacists in vaccination administration for over 25 years. This new credential is offered to licensed pharmacy technicians who successfully complete the APhA/Washington State University Pharmacy-Based Immunization Administration by Pharmacy Technicians program. This program is comprised of two hours of self-study online education followed by four hours of live training. The program is designed to educate pharmacy technicians in all aspects of vaccination delivery.

Pharmacy technicians assist the pharmacist in many ways with data entry, insurance billing, inventory management, vaccine administration record forms, and filling prescriptions. This new credential offered by PTCB will count toward designation as an advanced certified pharmacy technician. The certification will help advance the role of a pharmacy technician while improving patient health care.

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