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Wyoming State Board of Pharmacy News

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Board Welcomes New Inspector/ Compliance Officer Craig Frederick

Craig Frederick, PharmD, RPh, joins the Wyoming State Board of Pharmacy after spending most of his career in the retail pharmacy setting. He owned his own independent pharmacy for nearly 18 years in the town of Guernsey, WY. Craig also has experience working in critical access hospitals, chain retail pharmacies, and telepharmacy. Along with practicing community pharmacy, he has spent the last five years serving as the executive director of the Wyoming Pharmacy Association. In this role, he has gained experience in legislative and regulatory processes.

Craig is an alumnus of the University of Wyoming School of Pharmacy and is an avid Wyoming Cowboys sports fan. He enjoys spending time with his family, being involved with community organizations, and golfing. Craig loves Wyoming and is ready to meet all the people who are serving their communities through pharmacy practice.

Craig is excited about using his pharmacy knowledge and experience in a different capacity in his new role as an inspector/compliance officer.

X-Waivers for Buprenorphine Prescribing

By Rachel Sato, PharmD Candidate

Buprenorphine is a medication used for opioid use disorder (OUD) and does not require the strict in-patient methadone clinic requirements. This medication is safer than methadone because it is a partial agonist and has a ceiling dose, which limits the toxicity. Buprenorphine works by binding to the opioid receptors more tightly than another opioid, and by occupying that receptor it still has some of the pain benefits and decreases the craving for opioids. The only downside is that because buprenorphine is only a partial agonist, it can still precipitate withdrawal. Therefore, patients should have already made the decision to quit and be in the early stages of withdrawal before starting buprenorphine. This medication is also sometimes combined with naloxone – called Suboxone® – which prevents the medications from being crushed and either injected or inhaled via nasal route.

Buprenorphine is a medication that until recently required an X-waiver to be prescribed for OUD. The X-waiver required prescribers to undergo eight hours of training and submit an application to the Substance Abuse and Mental Health Services Administration. Once granted approval, prescribers could take on a maximum of 30 patients for the first year, then after that year, apply to serve up to 100 patients, and then increase to serve a maximum of 275 patients.

Recently, the United States Department of Health and Human Services eliminated the requirement that physicians with a Drug Enforcement Administration registration number need to apply for a separate waiver to prescribe buprenorphine. The elimination of the X-waiver applies only to physicians and no other qualifying practitioners. The elimination also applies to drugs or formulations covered under Title 21 US Code §823(g)(2)(C), such as buprenorphine, but does not apply to methadone. Physicians using the exemption shall place an "X" on the prescription and clearly identify that the prescription is being used for OUD. Physicians using the exemption will also be limited to treating a maximum of 30 patients. Emergency department physicians who need to use the medication for emergency withdrawal are exempt from the limit, however, as they do not engage in long-term treatment relationships with the patients. The physicians are also limited to treating patients in their own state where they are licensed. This exemption also does not bar them from obtaining a waiver or further training to feel comfortable prescribing this medication.

The recent progress toward making treatment options more accessible for patients with OUD should also help reduce the stigma surrounding the disorder and help providers reach a larger population of people. Although this recent movement only affects the physician's requirement for an X-waiver,

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).* The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by 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.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.[1] However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan[2]and the American Society of Health-System Pharmacists (ASHP)[3], to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
2. *www.mipedscompounds.org/*
3. *www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx*

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons,* reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting *www.journalacs.org/article/S1072-7515(20)32336-X/fulltext.*

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

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there is still interest in relaxing the requirements further and making OUD therapy easier to access to prevent additional loss of life.

With the recent change in policy regarding X-waivers, there could be an increase in patients visiting pharmacies to fill their OUD medications. Pharmacists can help stay on top of the changing policy by developing treatment plans, coordinating care, monitoring adherence, counseling, and communicating with patients. The National Association of Boards of Pharmacy® expects that the pharmacist's role will become more important as the X-waiver is no longer required for physicians. The pharmacist's role will definitely expand as OUD treatment progresses in the future.

Shoulder Injury Related to Vaccine Administration

By Dick Rappleye, PharmD Candidate

Whenever there is an increase in the administration of vaccinations, be it seasonal or during a pandemic, it remains important for those who administer vaccinations to practice proper vaccination administration procedures. A higher volume of vaccinations can lead to a rushed immunization process and increase the risk of patient injury. This risk may be further compounded by unconventional administration settings such as drive-through vaccination services. Although vaccinating the population as quickly as possible is ideal, we must ensure that we do so safely.

While uncommon, shoulder injury related to vaccine administration (SIRVA) can be a debilitating safety concern when administering vaccinations. SIRVA is caused by the injection of a vaccine into the capsule of the shoulder joint rather than into the deltoid muscle. This results in pain and inflammation of the joint, decreased range of motion, weakness, and a decreased quality of life. The symptoms present within 48 hours of the injection and may persist for months. Furthermore, pain is typically not relieved with over-the-counter analgesics, instead requiring corticosteroid injections. SIRVA can be avoided by utilizing the proper vaccine administration technique.

Tips for proper vaccine administration:

- Ensure that you are at the same level of the patient while administering vaccinations; preferably, you and the patient should both be sitting. Standing while administering a vaccine to a sitting patient increases the risk of injecting into the capsule of the shoulder joint. Avoid administering a vaccine to a standing patient as this increases the risk of physical injury to both you and the patient if the patient faints.
- Expose the patient's shoulder completely. This should be done by rolling the sleeve up over the shoulder rather than pulling the neck of the shirt down. If the sleeve cannot be rolled up high enough to fully expose the shoulder, the arm must be pulled out of the sleeve or the shirt must be removed altogether.
- Needle length should be chosen based on the body build and weight of the patient. A 16-mm (5/8-inch) needle should be chosen for patients weighing less than 60 kg (130 lbs). A 25-mm (1-inch) needle is appropriate for patients weighing 60 to 70 kg (130 to 152 lbs). Women weighing 70 to 90 kg (152 to 200 lbs) or men weighing 70 to 118 kg (152 to 260 lbs) should receive injections with either a 25-mm (1-inch) or 38-mm (1.5-inch) needle. A 38-mm (1.5-inch) needle is necessary for women weighing more than 90 kg (200 lbs) and men weighing more than 118 kg (260 lbs).
- Use the landmarking technique, never "eyeball." Landmark the injection site by identifying the acromion process (the bony protrusion at the top of the shoulder), then measure two or three finger widths down from the acromion process. Inject into the area above the beginning of the patient's armpit and below the measured finger widths from the acromion process. To avoid injecting too far to either side, create a "V" with your thumb and forefinger to outline the deltoid muscle and inject within the limits of the "V."
- Always insert the needle for intramuscular vaccines at a 90-degree angle.
- If, after inserting the needle, you suspect that you may have entered the capsule of the shoulder joint, do not inject the vaccine. Remove the needle from the patient's arm, replace it with a new needle, recalibrate the injection site, and administer the vaccine again.

Proper vaccination administration technique will help to avoid causing SIRVA. If you suspect the occurrence of SIRVA, refer the patient to their primary care provider for diagnosis and treatment. All instances of SIRVA should be reported to your workplace event reporting system. The Centers for Disease Control and Prevention also recommends reporting any vaccine administration errors, including SIRVA, to the Vaccine Adverse Event Reporting System (VAERS). The VAERS website is available at *www.vaers.hhs.gov/index.*

Scam Alert – Impersonating Investigators

The Board office has received reports that pharmacists and practitioners are receiving calls that appear to come from the Board office's main phone number, and that the caller identifies themself as an agent with the Board or as a federal

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investigator. The caller is often able to confirm some of the individual's information, such as license number, National Provider Identifier number, and place of employment.

In some cases, the caller accuses the individual of having committed a violation, that their license may be suspended or revoked, and that they will be arrested if they do not cooperate. In some cases, the caller alleges that the individual was involved in prescription drug trafficking. Some individuals have reported that the caller becomes aggressive and demanding, threatening to have the Federal Bureau of Investigation arrest them if they do not comply.

The Board will not contact or interact with you in this manner.

Please keep the following in mind to protect your information:

- If you receive a phone call that shows the Board's phone number on your caller ID, ask for the person's name, let them know you are busy, and that you will call them back.
- The names and pictures of the Board's staff can be verified on the Board's website.
- Do not share your personal information over the phone as the Board already has your information.

Ultimately, the scam appears to be designed to ask for a transfer of funds. No Board staff member will ever contact a licensee via telephone to demand money or any other form of payment over the phone. The Board **cannot** take funds over the phone or through bank transfer/wiring of funds.

If an inspector/compliance officer comes to your pharmacy, please verify their identity by asking to see their badge/ID.

If you receive such a phone call, please report it to the Federal Communications Commission at 888/225-5322 or contact the Board.

CE Opportunities on the Responsible Prescribing of Controlled Substances

In 2019, the Wyoming Legislature amended Wyoming Statute 33-24-121 to require that pharmacists obtain one and one-half hours of continuing education (CE) related to the responsible prescribing of controlled substances (CS) annually. There are many different courses available to meet this requirement. Programs such as Nebraska's InforMed offers courses that focus on opioids like "Opioid Analgesics in the Management of Acute and Chronic Pain" for a fee, while the College of Psychiatric and Neurologic Pharmacists offers an OUD Education Program that is available free of charge. Courses on the responsible prescribing of other CS may also meet this requirement.

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