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News

Wyoming State Board of Pharmacy

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New Office Assistant at the Board

By Alec Richards, 2017 PharmD Candidate

There is a new face at the Wyoming State Board of Pharmacy, and she is going to be the first one you see or talk to at the office. Carmen Orla-Bukowski is the new office assistant at the Board. She is the first point of communication with the Board, although she does much more than that. Originally from Peru, Carmen moved to Cheyenne, WY, in 2009 from San Francisco, CA, to raise her kids. When she is not at the Board, Carmen likes to spend time with her kids. They enjoy local activities such as hiking, spending time in nature, and going to museums, as well as exploring the area. When asked what her favorite part about working for the Board was, without hesitation Carmen answered the people she works with. Carmen enjoys being a part of the team at the Board and loves being able to have an impact on people. She also loves learning about pharmacy and its many different aspects. After spending some time with Carmen, I can tell she is a great addition to the Board. Welcome to the team, Carmen.

Telehealth and Concerns With the Practice

By Rachel Nerud, 2016 PharmD Candidate

The Board recently met for its quarterly meeting. At this meeting, the Board of Pharmacy was joined by the Wyoming Board of Medicine and Wyoming State Board of Nursing in discussing the topic of telemedicine. Telemedicine has raised some questions across the state with pharmacists as they are unable to confirm if there is a practitioner-patient relationship. The pharmacist asks the patient the name of the practitioner who prescribed his or her medication and the patient does not know; this leaves the pharmacist to call the number provided to speak to the practitioner to confirm if there is a legitimate practitioner-patient relationship. The pharmacist may be unable to reach anyone after calling the number provided or unable to talk to the practitioner. Another issue has been when the patient reports that he or she is talking to a practitioner in Minnesota, but the practitioner's address on the prescription shows Wyoming.

Wyoming Pharmacy Act Rules and Regulations Chapter 2, Section 14(b) states:

> It shall be unprofessional conduct for a resident or non-resident pharmacy, or a pharmacist, to dispense, sell, or offer to sell prescription drugs to persons located within the State, or any other state, on the basis of a prescription generated solely through an Internet questionnaire physician consultation.

This citation is why there is a legitimate concern by the pharmacist to make sure there is a practitioner-patient relationship.

In the discussion with the Boards of Medicine and Nursing, it was explained that there are three ways for a practitioner-patient relationship to be established for telehealth:

(1) An established face-to-face relationship that is supplemented by telehealth follow-up. This can include a physician in another state who has seen the patient in person, with follow-up through phone or video.

(2) A video link with a physician for a service appropriate for telehealth, such as psychiatry, dermatology, etc, and where appropriate history and physical are performed.

(3) A specialist who is asked to consult at the request of the primary care physician.

The practitioner who is routinely offering to see and diagnose a patient through telehealth must be licensed in the state where the patient is located. The boards are preparing a guideline for telehealth in Wyoming.

Recent Disciplinary Actions

L.F., Pharmacist License #2406: Probation of license and administrative penalty of $1,000 due to disciplinary action in another state.

D.L., Pharmacist License #3321: Administrative penalty of $200 for failing to obtain 12 hours of continuing education (CE) in 2015. Additional CE is required in 2016, including three hours on pharmacy law.

Pharmacy License #52-03473: Failure to transmit all dispensed controlled substance (CS) prescriptions in Schedules II, III, and IV to Wyoming's prescription drug monitoring program, the Wyoming Online Prescription Database (WORx), and failure to correct errors in a timely manner. Administrative penalty of $2,000 and submission of a written plan to ensure correct transmission.

Pharmacy License #R10027: Failure to transmit all dispensed CS prescriptions in Schedules II, III, and IV to WORx. Administrative penalty of $2,000 and submission of a written plan to ensure correct transmission.

FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

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.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

1. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med.* 2005;165(16):1842-1847.
2. Mesteig M, Helbostad JL, Sletvold O, Røsstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. *BMC Health Serv Res.* 2010;10:1.
3. Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm.* 2008;65(15):1451-1457.
4. Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc.* 2014;89(8):1042-1051.
5. Kanaan AO, Donovan JL, Duchin NP, et al. Adverse drug events after hospital discharge in older adults: types, severity, and involvement of Beers criteria medications. *J Am Geriatr Soc.* 2013;61(11):1894-1899.
6. American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch.* March 2015.

USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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Take-Back Programs Achieve Long-Standing Success

By Nathan Holcomb, Meghan Kolf, and Dane Pebler, 2016 PharmD Candidates

According to Drug Enforcement Administration (DEA), "Rates of prescription drug abuse in the U.S. are at alarming rates, as are the number of accidental poisonings and overdoses due to these drugs." This, combined with a lack of available methods for patients to safely dispose of unused medications, makes for a large number of medications available for improper disposal into public water reservoirs and misuse or abuse by unintended parties.

In Casper, WY, a local pharmacist works with the help of law enforcement and pharmacy students to ensure unneeded or expired medications can be dropped off by the general public and disposed of or recycled properly. Every six to eight weeks, drugs that have been dropped off by individuals, medical offices, and law enforcement are sorted for destruction or redistribution. Expired or used medications are designated for destruction, while unit dose or manufacturer-packaged medications that are intact and unopened with at least three months before expiration are sent to the Wyoming Medication Donation Program for redistribution to various medication assistance programs for patients in need. CS are also separated, counted, and documented on a DEA Form 41 before destruction to ensure lawful procedure is followed. For example, on August 10, 2015, medications were sorted, and over 18 eight-gallon containers of medication were designated for incineration and two tubs of CS were held at the police station to be counted and documented prior to destruction. When weighed, this drop-off totaled 260 pounds. This brings the total number of medications disposed of at this location to over 13,500 pounds in the past eight years.

Wyoming is unique in that there are 38 medication drop-off locations throughout the state, covering all 23 counties. In particular, there are three such locations at police stations in the Casper area available for anyone to anonymously bring unused medications. On October 22, 2016, DEA will be having a National Prescription Drug Take-Back Day from 10 AM to 2 PM, and specific locations for this take-back will be listed on the DEA website. According to DEA, "The National Prescription Drug Take-Back Day aims to provide a safe, convenient, and responsible means of disposing of prescription drugs, while also educating the general public about the potential for abuse of medications." The agency also states, "In the previous nine Take-Back events nationwide from 2010-2014, 4,823,251 pounds, or 2,411 tons of drugs were collected."

On the April 2016 Take-Back Day, a record was set with 893,498 pounds collected (about 447 tons) from almost 5,400 sites spread through all 50 states. As health care professionals, pharmacists and pharmacy technicians can help their patients dispose of medications safely by educating them about proper disposal programs and locations in their areas. For a list of locations where your patients can drop off their medications, you can visit *www.wyomedicationdonation.org*.

New 'Scam' Alert

Someone is telephoning prescriptions for ibuprofen plus promethazine/codeine cough syrup into pharmacies and claiming to be an emergency department practitioner. After the prescriptions are filled, a phone call is received to "transfer the prescriptions to California as the patient has gone home." A fax and/or phone number for the California pharmacy is provided. Upon further checking, pharmacists determined the patient was not seen in the emergency room, and sometimes the practitioner was not even on duty. Kudos to pharmacists who stop the scam.

School Districts Receive Funds From Administrative Penalties

According to Wyoming Statute 33-24-113, any administrative penalty assessed by the Board is paid to the county treasurer to the credit of the public school fund of the county in which the violation occurred.

Influenza Season Recommendation

The Advisory Committee on Immunization Practices of the United States Centers for Disease Control and Prevention recommended on June 23, 2016, that FluMist® not be used in any setting for the 2016-2017 influenza season.

Board Meeting Schedule

Meetings begin at 1 PM on the first day and continue through the morning of the second day.

- ♦ September 7-8, 2016, at 500 S 3rd Street, Laramie, WY
- ♦ December 7-8, 2016, at 2211 King Blvd, Casper

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