



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>

NTSB Request for Safety, Counseling Patients

The National Transportation Safety Board (NTSB) is an independent federal agency charged by Congress with investigating every civil aviation accident in the United States. On September 9, 2014, the NTSB adopted a safety study, *Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment*. This study can be accessed at www.ntsb.gov, by searching for report number SS-14-01. New recommendations were issued to the 50 states, including Wyoming, as follows.

Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation. (I-14-1)

Use existing newsletters with . . . pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation. (I-14-2)

The Wyoming State Board of Pharmacy members discussed this request at a recent meeting. Because the NTSB study shows a large increase in the use of at least one drug in the study for fatally injured pilots, it becomes even more important to actually counsel rather than just make the offer. Simple questions such as what is your pain level; are you having side effects; and what did the prescriber tell you; as well as advising patients to be careful with other drugs or alcohol, may prevent a fatal accident. Overall, the most common potentially impairing drug pilots had used was diphenhydramine. In the most recent five years studied, eight percent of all pilots tested positive for controlled substances (CS), and hydrocodone and diazepam each accounted for 20% of the positive findings. Aviation is the only transportation mode in which a fatally injured operator (pilot) routinely undergoes extensive toxicology testing. Given the general increase in drug use in the population, it is likely that there has been a similar trend in drug use among operators across all modes of transportation. Even though pharmacists and technicians routinely add a warning sticker to the prescription label, counseling is the last best opportunity for a pharmacist to make a difference in compliance and outcomes. Making the offer to counsel for Schedule II prescriptions is mandatory for each fill because they are new prescriptions (Wyoming Pharmacy Act, Rules & Regulations, Chapter 9, Section 5). As mentioned in previous *Newsletters*, counseling is the right thing for the patient, protects the pharmacist's license, and is required by regulation.

50-Year Pharmacist

The Board congratulates Lloyd Scott of Worland, WY, for remaining licensed in Wyoming for 50 years, holding pharmacist license number 1663. He will be honored at the Awards Dinner and Benefit

Auction at the 98th Annual Wyoming Pharmacy Association/Wyoming Society of Health-System Pharmacy Convention in Cody, WY, on Saturday, June 13, 2015.

Board Officers

At the March 2015 meeting in Cheyenne, WY, the following were elected to officer positions: Bessie McGirr, RPh, president; Kerri Kilgore, RPh, vice president; and John McPherson, DDS, secretary-treasurer. They will serve two-year terms through February 2017.

Wyoming Legislative Update: Controlled Substances Act

The Wyoming Controlled Substances Act was revised by the 2015 State of Wyoming Legislature with an effective date of January 1, 2016. Instead of the current requirement for pharmacies to report CS prescriptions to the Wyoming Online Prescription Database (WORx) "no more than 7 days after dispensed," the new Wyoming Statute (W.S.) 35-7-1060 states, "**no later than the close of business on the business day immediately following the day the controlled substance was dispensed.**" This will provide more current information for prescribers and pharmacists who access jwr.WORXpdm.com for reports.

Another revision will allow for delegates to be appointed by practitioners or pharmacists to assist in obtaining reports from WORx. The rules process will be used to define who can be appointed as a delegate. The current statute states only practitioners or pharmacists may have access to the information in WORx.

Wyoming Legislative Update: Wyoming Pharmacy Act

The legislature enacted changes to the makeup of the Board as of July 1, 2015. A fifth pharmacist will be added, the pharmacy technician member will become a voting member, and the Board members will have daily payroll during Board activities the same as legislators. Language was updated to allow for electronic examinations, and interns will not have to notify the Board of each change of rotation site. Two sections of the statutes dealing with poison sales and records were repealed. Visit the governor's website to apply for the open Board member position.

W.S. 33-24-136 was revised as follows: "Every person who prepares, compounds, processes, packages or repackages, dispenses, fills or sells or offers for sale, at retail . . . any prescription, shall place the written memorandum or electronic record . . . in a separate file marked and kept for that purpose . . . Each prescription record shall be maintained and available for inspection by agents of the board for a period of two (2) years." The rules process will be used to write regulations to ensure that the electronic records will be secure. This change from paper prescription records to electronic was

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at www.fda.gov/RegulatoryInformation/Guidances/default.htm.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

 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.

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

- Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
- Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- ◆ Explain the weekly dosing schedule.
- ◆ Explain that taking extra doses is dangerous.
- ◆ Have the patient repeat back the instructions.
- ◆ Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at www.ismp.org/AHRQ/default.asp).

To read all of the best practices, visit www.ismp.org/Tools/BestPractices/default.asp.

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- ◆ The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- ◆ The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-



jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at www.fda.gov/Safety/Recalls/ucm433857.htm. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWARE® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at www.fda.gov/Drugs/DrugSafety/ucm431071.htm. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, www.nabp.net.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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. The latest Drug Info Rounds videos are as follows.

- ◆ In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- ◆ In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

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. These videos and previous Drug Info Rounds resources are available on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- ◆ **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- ◆ **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- ◆ **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at <https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf>.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at <http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326>.

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made because it no longer made sense to have computer-to-computer prescriptions that had to be printed, folded, stickered, and stored.

A bill (Senate File 0062) titled "Oral Chemotherapy Parity" was passed that states "No individual or group health insurance policy . . . shall require a higher copayment . . . than required for injected or intravenous chemotherapy." A bill (House Bill 0183) was passed regarding early refills of eye drops. If the renewal is requested by the insured by at least day 23 for a 30-day supply, day 45 for a 60-day supply, or day 68 for a 90-day supply, the insurance will cover the refill. One additional bottle for school or day care will also be covered by insurance every three months.

Recent Board Disciplinary Actions

S.B. Pharmacist License #2338: Suspension of licensure for three years with all but one year stayed, administrative penalty in the amount of \$2,000, and conditions on the license during the remaining suspension. Reasons included incomplete directions as ordered by the prescriber, dispensing in error, and returning a CS to stock for redispensing.

J.S. Pharmacist License #2942: As pharmacist-in-charge (PIC), allowed unlicensed practice by a pharmacy technician resulting in an administrative penalty in the amount of \$1,000 and requirement to submit a plan to verify licensure of all pharmacists, technicians, and interns.

B.R. Pharmacist License #2920: License conditioned with several requirements for a period of time to correspond to a Board order from Colorado for diversion of a CS.

J.A. Pharmacist License #3078: Conditions terminated from license due to compliance with all restrictions imposed by Office of Administrative Hearings Docket No. 12-039-059 C102. License restored to active status.

Rules Revisions in 2015

The Board would like volunteers to assist with revisions to the Wyoming Pharmacy Act Rules & Regulations in 2015. Review of Chapter 2 (General Practice Of Pharmacy Regulations), Chapter 17 (Sterile Compounding), and others will be done. A possible new chapter on hazardous waste will be considered. If anyone has a rule that he or she feels needs to be updated, corrected, or modified, please contact the Board office or any Board member. After rules are drafted by the Board, there is a 45-day public comment time period, then final adoption and review by the governor's office.

Newsletter by Email

This edition of the *Wyoming State Board of Pharmacy Newsletter* is being sent by email as a test of the Board's new licensing software. Savings in paper, mailing, and time are significant. If the Board does not have your email address on file, you will receive this

edition in the mail, prompting you to send your email address to the Board office at bop@wyo.gov. Each Wyoming licensed pharmacy will continue to receive a paper copy to be kept for reference. Past *Newsletters* are available on the Board's website and at www.nabp.net/state-newsletters.

Happy Trails to Richard Burton, Pharmacy Inspector/Compliance Officer

Richard Burton retired from his position as Board inspector/compliance officer on April 30, 2015. He joined the Board staff in 2004, and he claims to have traveled on every mile of paved highway in Wyoming during his tenure. In recent years he inspected the pharmacies in northern Wyoming, but earlier for over a year, he was the only inspector and traveled the entire state. Richard was the Board expert for many issues and the first to attend boot camp for sterile compounding. Richard also served on the Wyoming Board of Medicine Physician Assistant Advisory Council. His expertise and advice will be missed by all the pharmacists and pharmacy technicians in Wyoming, and the Board wishes him a long and happy retirement.

Verification of Licensure

As a result of the changes in laws and rules in various states and increased collaboration between multiple regulatory entities, there have been multiple disciplinary actions against licenses of out-of-state pharmacies, especially surrounding those pharmacies conducting compounding in unsafe conditions.

With these recent actions, it is important that we as pharmacy professionals educate our patients in Wyoming, as well as fellow health care providers, about the importance of only obtaining prescription medications from Wyoming licensed entities. This includes pharmacies, wholesalers, and manufacturers. As a reference point, the Board has a very useful verification tool on its website for anyone to use to check the status of a license/registration/permit. Click on the Verify License tab, enter either a license number or business name (not both), and click on Search. For example, under business name enter medvan* and then click Search. Medvantx Pharmacy Services in South Dakota and Medvantx Specialty Pharmacy in Kentucky will come up. Click on View Detail for information about license numbers, dates issued, and the PIC.

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