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Idaho State Board of Pharmacy News

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2015 Changes to Idaho Code

Please note that 2015 administrative rule changes were detailed in the March 2015 *Newsletter*. Idaho Code allows for the scheduling of controlled substances (CS), as per federal scheduling changes, if the Idaho State Board of Pharmacy does not object within 30 days. The Board did not object to the scheduling of perampanel as a Schedule III CS, suvorexant as a Schedule IV CS, or tramadol as a Schedule IV CS. Additionally, the Board did not object to the rescheduling of all hydrocodone combination products into Schedule II. House Bill (HB) 9 updates Idaho Code pursuant to such earlier scheduling. The bill passed with an emergency clause, so it is currently effective. The following changes to Idaho Code will become effective on July 1, 2015.

- HB 4 grants the Board statutory authority to restrict a CS registration, to fine a CS registrant, and to enforce such Board orders. The bill includes many additional changes that are deemed housekeeping, such as separating the definition of "dispense" into "dispense," "prescribe," and "administer," as well as creating harmony in the various statutes that list requirements for CS registration: manufacturing, distributing, prescribing, administering, dispensing, and conducting research.
- HB 5 waives the fingerprinting requirement for reinstatement applicants who have lapsed licenses or registrations of less than one year.
- HB 6 separates Idaho Statute 54-1733 into a Validity of Prescription Drug Orders section and 54-1733A, Transmission of Prescription Drug Orders. Most of the change is stylistic in nature; however, the bill also contains the following substantive changes. A valid prescription drug order for a non-controlled drug may now be transmitted to a licensed pharmacy electronically by a licensed practical or professional nurse in an institutional facility for a patient of that facility via a secure, interoperable information technology system that exchanges data accurately, effectively, and in compliance with applicable laws. Please note that Drug Enforcement Administration (DEA) will not allow a CS to be transmitted electronically unless in compliance with federal law. Additionally, a valid prescription drug order may be transmitted verbally by a licensed practical or professional nurse for a hospice patient, and a hospice agent may fax a valid prescription drug order for a hospice patient. If such order was originally received verbally by a licensed practical or professional nurse, the faxed document shall include the name of the prescriber, the name of the nurse, and the name of the person who faxed the order. Please note that such allowance for hospice nurses and agencies was added to existing law that allows for such transmissions by nurses and institutional facilities; however, DEA will only allow agents of the practitioner to transmit CS orders, as detailed in a 2010 regulation. DEA explains that if an agent is not an employee of the prescribing practitioner, then the practitioner must "manifest assent" to having a particular person act as his or her agent, and the agent must reciprocate manifesting assent. Please visit the following link on DEA's website for more information: *www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr1006.htm*.
- HB 7 updates the list of authorized individuals who can receive prescription monitoring program (PMP) data contained within Idaho's Controlled Substance Database. The bill clarifies that a lawful order of competent jurisdiction must be issued by the presiding judge and not just an attorney.
- HB 8 was initiated to strike Idaho Code that has been preempted by Congress within the federal Drug Quality and Security Act. States can no longer require the tracking of drugs through the distribution system. For example, states can no longer require prescription drug pedigrees. Please note that the federal government is now regulating transaction documentation, and it will be releasing new requirements periodically over the next decade. In reviewing pertinent sections of the Idaho Wholesale Drug Distribution Act and the Idaho Pharmacy Act, much housekeeping was performed, such as updating the list of persons who can possess prescription drugs in the absence of a prescription drug order. It is now a criminal and administrative offense for a pharmacy to distribute drugs or devices to a wholesale distributor. Please note that returns to the original wholesale distributor are allowed. Additionally, a wholesale distributor is prohibited from purchasing prescription drugs from pharmacies or practitioners. A wholesale distributor must also monitor purchase activity of customers in order to identify suspicious ordering patterns that identify potential diversion or criminal activity related to CS.
- HB 108 was not run by the Board; however, the Board actively supported it. The bill allows pharmacists to prescribe opioid antagonists, namely naloxone. Numerous sections of Idaho Pharmacy Code were changed to allow this provision. Pharmacists must counsel those to whom they dispense an opioid antagonist, including the mandatory provision of the administrator contacting emergency services once the opioid antagonist has been administered. The bill also requires the Idaho Department of Health and Welfare to create and maintain an online education program for laypersons and the general public on matters pertaining to opiate-related overdoses.
- HB 189 was not run by the Board. It provides statutory authority for prescribing via telemedicine within the scope of license and consistent with the standards of the profession as defined by the individual medical licensing Boards. Therefore, the individual prescriber licensing boards are required to promulgate rules before the practice can be established. The bill does clarify that treatment based solely on an online questionnaire does not constitute an acceptable standard of care. In the near future, it will be legal to dispense a prescription that was issued via telehealth services if it complies with applicable state and federal law, such as the Ryan Haight Act.

Many other bills that addressed pharmacy-related topics were introduced, received a hearing, or were vetoed by the governor. Look

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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:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) 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 AWAR$_X$E® 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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for a revised form of most of the following bills to return to the 2016 legislature: medication synchronization; naturopath prescriptive authority; psychologist prescriptive authority; cannabidiol extract from the marijuana plant to be used for various conditions, including childhood epilepsy; and a pharmacy audit bill run by the Idaho State Pharmacy Association that would also regulate pharmacy benefit managers and address pharmacy reimbursement.

CS Inventories and Distribution Reporting

Board Rule 206 requires each CS registrant to annually conduct a physical inventory of its stocks of CS on hand. A complete CS inventory is also required in the event of a change of pharmacist-in-charge (PIC) or director by the first day of employment of the incoming PIC or director, and within 48 hours of the discovery of a reportable loss of a CS. Additionally, on the effective date of an addition of a substance to a schedule of the Controlled Substances Act, each registrant that possesses the CS must take an inventory of the substance on hand. Therefore, most pharmacies must have inventoried tramadol and hydrocodone combination products on the appropriate dates in late 2014. While computer-generated on-hand quantities can assist the pharmacist in completing these duties, simply printing a report of on-hand quantities does not satisfy the inventory requirements. A physical count of all quantities on hand is required. Please note that while all CS that are stored in a hospital may not be physically located in the institutional pharmacy, all CS that are stored within the hospital must be included in the CS inventory. Additionally, pharmacies that supply emergency kits to nursing homes retain ownership of the drugs in these kits; therefore CS contained in such kits must be included in CS inventories, too. Newly promulgated Rule 615 mandates that pharmacies must report certain data on CS distributed (dispensed CS continue to be reported to the PMP daily) at least monthly to the Board, except when distributing intracompany. Such data should be submitted to ellen.mitchell@bop.idaho.gov by the 15th of each month, listing the following data on the previous month's distributions: transaction date, drug name, drug strength, package size, quantity, practitioner name, practitioner address, practitioner professional license number, and practitioner DEA registration number.

Passing of a Former Board Senior Compliance Officer

The Board is lamenting the loss of Marion Clark Bowen, who served as the senior compliance officer for the Board from 1986 to 1996. Ms Bowen was a 1952 graduate of Idaho State University College of Pharmacy, where she received the Pharmacy Professional Achievement Award in 1994. She served on a number of different association boards, including being past president of the Idaho State Pharmacy Association. She was extremely active in her community, and volunteered for numerous groups, including the Board of Directors for the American Heart Association of Idaho. Ms Bowen had the courage to be "the first" woman in so many different endeavors. She will be missed by all who knew her.

Recent Board Discipline

A.L., PharmD: License and CS registration revoked for diversion.

T.R., PharmD: License and CS registration conditioned as to require compliance with Pharmacist Recovery Network (PRN) contract.

A.M., RPh: $500 fine for failing to maintain counseling documentation, and 18 credit hours of continuing pharmacy education (CPE) for failing to follow the instructions of a prescriber.

T.S., PharmD: $500 fine for failing to counsel and/or failing to maintain counseling documentation, and 18 credit hours of CPE for failing to follow the instructions of a prescriber.

D.G., Certified Technician: $250 for failing to maintain certification.

T.A., Certified Technician: $250 fine for failing to maintain certification.

D.H., Certified Technician: $250 fine for failing to maintain certification.

E.H., Certified Technician: $250 fine for failing to maintain certification.

C.R., Certified Technician: $250 fine for failing to maintain certification.

S.T., MD: CS registration conditioned as per State of Idaho Board of Medicine order.

D.D., MD: CS registration conditioned as per State of Idaho Board of Medicine order.

D.A., CRNA: CS registration conditioned as to require compliance with PRN contract.

T.W., DDS: CS registration conditioned for inventory, reporting, disposal, and record keeping violations, as well as delivering a CS to oneself.

M.M.D.S., DME: $2,000 fine for the unregistered distribution of durable medical devices into Idaho.

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them filed in your pharmacy, preferably in your *Idaho Pharmacy Law Book,* for future reference.

The *Idaho State Board of Pharmacy News* is published by the Idaho 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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