September 2014

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1199 Shoreline Lane, Suite 303 • Boise, ID 83702

Red Flags Video

The National Association of Boards of Pharmacy®, in collaboration with the Anti-Diversion Industry Working Group, has created a video that is intended to educate pharmacists and increase their awareness of potential red flags when filling controlled substance (CS) prescription drug orders. Please visit the Idaho State Board of Pharmacy's website and click on the link under "Hot Topics!" to view this helpful resource.

Tramadol Is Rescheduled a Schedule IV CS

Effective August 18, 2014, all tramadol-containing products were rescheduled federally to Schedule IV CS. Because the Board did not object, tramadol-containing products are also now scheduled in Idaho. Confirmation of this change will be codified in statute by the 2015 legislature. Federal regulation and Board rule require all Drug Enforcement Administration (DEA) registrants to take an inventory of all tramadol-containing products on the date of rescheduling and to treat all subsequent tramadol records and inventories as Schedule IV CS.

Counseling Requirements

As evidenced by the "Recent Board Discipline" portion of this *Newsletter,* the Board is concerned with a lack of required counseling, offers to counsel, and counseling documentation. The Board believes counseling to be a pillar of the profession of pharmacy and a safeguard of public safety. Previously, the Board has only heard cases involving counseling violations that are in conjunction with dispensing errors. The Board has directed the Board's staff, including the Board's inspectors and investigators, to strictly enforce the following counseling law.

54-1739(2) states:

> Before dispensing a prescription for a new medication, or when otherwise deemed necessary or appropriate, a pharmacist shall counsel the patient or caregiver. In addition to the counseling requirements provided in section 54-1705, Idaho Code, counseling shall include such supplemental written materials as required by law or as are customary in that practice setting. For refills or renewed prescriptions, a pharmacist or a technician shall extend an offer to counsel the patient or caregiver. If such offer is accepted, a pharmacist shall provide such counseling as necessary or appropriate in the professional judgment of the pharmacist. All counseling and offers to counsel shall be face to face with the patient or caregiver when possible, but if not possible, then a reasonable effort shall be made to contact the patient or caregiver. Nothing in this section shall require a pharmacist to provide counseling when a patient or caregiver refuses such counseling or when counseling is otherwise impossible. Patient counseling shall not be required for inpatients of a hospital or institutional facility when licensed health care professionals administer the medication.

Rule 105 states, "Documentation must be created and retained sufficient to evidence compliance with the offer to counsel and counseling requirements of the Idaho Pharmacy Act."

Future Board Meeting; Potential 2015 Statute and Rule Changes

The following dates are subject to change. Meeting times and locations are yet to be determined. Please check the Board's website for potential updated information. 2015 Draft Statute & Rule Changes language is currently posted to the Board's website under "Hot Topics!"

October 22 and 23 in Boise, ID. October 22 will be the last day of the official open public comment period on the Board's proposed rules that print in the October *Idaho Administrative Bulletin,* and will be available on the Board's website in September. The Board will take such public comment on October 22, and deliberate upon it on October 23. Please take an active role in rule promulgation and the process of changing Idaho Code by reviewing and commenting. Pursuant to federal law changes and/or federal agency guidance documents, the following topics are being considered for rule promulgation and/or statute change: biosimilar substitution, outsourcing facility registration and practice standards, compounding, repackaging of previously dispensed prescription drugs into unit-dose packaging by another pharmacy, and wholesale drug distribution. The Board is considering clarifying the following topics via rule promulgation: standard prescription drug labeling, technician-in-training renewal limitations, foreign pharmacist graduate experience hours, nonresident pharmacist practice standards, annual CS inventory dates, pharmacy authorized entry, and pharmacy security. The Board is considering updating rules and/or statutes addressing telepharmacy, discipline, the prescription monitoring program, immunizations, sterile product preparation, and fingerprinting. The Board is considering promulgating new rules that address compounding, sterile product preparation, hazardous drugs, labeling, and the distribution of compounded drug product by a pharmacy for "office use."

Recent Board Discipline

A.W., PharmD: License and CS registration revoked for dispensing and possessing legend drugs, including CS, without valid prescription drug orders, and falsifying pharmacy records.

J.H., PharmD: License restricted for diversion pursuant to Arizona State Board of Pharmacy order.

C.W., Pharmacy Technician: Registration revoked for diversion pursuant to voluntary surrender.

P.B., Pharmacy Technician-in-Training: Registration suspended for three years pursuant to Washington State Pharmacy Quality Assurance Commission order.

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examini

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments were accepted until July 31, 2014.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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D.G., Certified Technician: Registration revoked for a lack of fitness for professional practice and intoxication, impairment, or consumption of drugs while on duty.

M.H., RPh: $200 fine for engaging in the practice of pharmacy while failing to renew her pharmacist license.

A.O., RPh and Pharmacist-in-Charge (PIC): $100 fine for allowing an unlicensed pharmacist to practice.

J.V., PharmD and PIC: $100 fine for allowing an unlicensed pharmacist to practice.

K.S., PharmD: $200 fine for engaging in the practice of pharmacy while failing to renew her pharmacist license.

T.Z., Pharmacy Technician: $100 fine for working unregistered in a pharmacy.

A.L., PharmD and PIC: $200 fine for allowing an unregistered technician to work in the pharmacy.

C.B., RPh and PIC: $400 fine for allowing two unregistered pharmacists to dispense CS.

B.G., PharmD: $200 fine for dispensing CS while failing to renew his CS registration.

M.W., RPh: $200 fine for dispensing CS while failing to renew her CS registration.

W., Pharmacy: $1,000 fine for allowing an unlicensed pharmacist to practice.

L.H., PharmD and PIC: $1,000 fine for allowing an unlicensed pharmacist to practice.

G.H., RPh: $2,000 fine for engaging in the practice of pharmacy while failing to renew her license.

J.S., PharmD: $1,000 fine and six additional continuing pharmacy education (CPE) hours for misfilling a prescription and failing to counsel.

P.A., RPh: $1,000 fine and six additional CPE hours for misfilling a prescription and failing to offer counseling.

C.D., RPh: $500 fine and six additional CPE hours for failing to affix to the label of a dispensed prescription cautionary information and failing to dispense a Food and Drug Administration-required Medication Guide.

E.R., RPh: $500 fine and six additional CPE hours for misfilling a prescription.

D.M., PharmD: $1,000 fine and six additional CPE hours for misfilling a prescription and failing to counsel.

B.S., Wholesale Distributor: $2,000 fine for furnishing CS to a prescriber who did not hold an Idaho CS registration.

J.H., MD: CS registration revoked pursuant to State of Idaho Board of Medicine order.

D.B., MD: CS registration revoked pursuant to State of Idaho Board of Medicine order.

J.H., DO: CS registration revoked pursuant to State of Idaho Board of Medicine order.

M.M., MD: CS registration canceled pursuant to voluntary surrender of DEA CS registration.

R.B., DO: CS registration canceled pursuant to voluntary surrender of DEA CS registration.

S.S., DO: CS registration restricted pursuant to State of Idaho Board of Medicine order.

S.H., MD: CS registration canceled pursuant to State of Idaho Board of Medicine order.

L.R., OD: CS registration restricted as to not dispense or administer CS for diversion.

T.C., DDS: CS registration restricted as to not dispense or administer CS for diversion.

Ralph Merrill 'Moon' Wheeler Passes Away

Mr Wheeler was a pharmacist who owned Rockland Pharmacy in American Falls, ID, for 34 years and a politician who spent 39 years in elected offices, including the Idaho State House of Representatives and Senate. Mr Wheeler was an active Idaho State University supporter, serving on the alumni board and dean's advisory council. His life was one of commitment and contributing to the profession of pharmacy and his family, community, town, county, state, and country. He will be missed.

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.

Mark D. Johnston, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager