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Wyoming State Board of Pharmacy News

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New Board Member: Janet Shatto, RPT, CPhT

By Bethany Reasch, PharmD Candidate

Jan Shatto is from Cheyenne, WY. She received her bachelor's degree in both animal science and secondary education from the University of Wyoming. Currently, she and her husband, Gary, own Shatto's Frontier Drug in Douglas, WY, where she works as a pharmacy technician. Jan wanted to become a member of the Wyoming State Board of Pharmacy because she felt she had valuable knowledge and experience to offer. Along with bringing the technician perspective, she also feels that she will be able to provide the point of view of independent pharmacies. When asked how she can contribute to the Board, Jan said that she felt she could get the other members to think about the bottom line and how the decisions made will help make the profession better. She hopes to be able to get the Board thinking about all types of pharmacy and how best to implement any changes made for each aspect of the profession. Regarding the future of pharmacy, Jan hopes that individuals will gain a better understanding of the profession and see the true value pharmacists have to the health care system. Currently in the state, there are many underserved communities in regard to pharmacy services. Her hopes are that more independent pharmacies will open to help better serve the residents of Wyoming and fill that void.

Jan's hobbies include dancing, going to the mountains, and spending time with her grandkids.

CE Audit for CPE Earned in 2013

The random audit for continuing pharmacy education (CPE) earned in 2013 was accomplished by reviewing records for pharmacists and pharmacy technicians whose license number ends in "5." This included 112 pharmacists and 52 pharmacy technicians. CPE Monitor®, the National Association of Boards of Pharmacy® (NABP®) service for tracking continuing education (CE) obtained from Accreditation Council for Pharmacy Education (ACPE)-accredited providers, was reviewed first to see if the records were complete. More than 50% of the pharmacist records were in CPE Monitor, so those pharmacists were not contacted at all. Therefore, mailing, faxing, and sorting through certificates were eliminated, which has increased efficiency to licensees, as well as Board staff. For those who did not have a complete CPE Monitor profile, letters were mailed requesting certificates of completion. Disciplinary action was initiated for those who could not provide the required hours (12 hours for pharmacists and six hours for pharmacy technicians). You are reminded to visit *www.myCPEmonitor.net* to set up an NABP e-Profile ID and register for CPE Monitor, and record all of your ACPE-approved hours there. Rules, Wyoming Pharmacy Act, Chapter 6 for pharmacists and Chapter 10 for pharmacy technicians, lists the approved CE providers in addition to ACPE. Before you list the hours earned on your renewal for 2015 licenses, be sure to have enough hours earned and documented.

Transfers of Controlled Substances

By Michael Hardy, PharmD Candidate

There seems to be confusion on the procedure when transferring controlled substances (CS) to a physician's office. Frequent issues culminate around whether or not prescriptions are required, what type of invoice to use, and how to transfer or transport the CS. In this article, the Board hopes to provide the tools and information necessary to successfully navigate a transfer from your pharmacy to a medical office.

Everyone knows the five percent rule, but what about "minimal quantities?" There is a clear-cut five percent rule when transferring or selling prescription drugs from pharmacy to pharmacy with the premise of not becoming a distributor. But what about selling prescription drugs or CS to licensed practitioners for office use? In Chapter 8 of the Wyoming Pharmacy Act Rules and Regulations, manufacturing and distributing regulations are given. There are also exemptions on what wholesale distribution does not include. Relating to this topic, wholesale distributing is **not** "the sale of **minimal quantities** of prescription drugs by retail pharmacies to licensed practitioners for office use." Although there is no current definition of "minimal quantities" in the rules and regulations, keep in mind that the five percent rule is a good one to go by. Also take note of the definition, which is **"5% of total prescription drug sales revenue."**

Are prescriptions needed to transfer CS from registrant to registrant? No CS prescription should be used for office use, per federal and state regulations. It is important to use an invoice when selling CS to practitioners. Transfers of Schedule III through V CS must be documented, in writing, with the following required information: the drug name, dosage form, strength, quantity, and date transferred, along with signatures of the pharmacist-in-charge or his or her designated agent, and the name, address, and registration number to whom the CS were distributed. The transfer of Schedule II CS requires a separate Drug Enforcement Administration (DEA) Form 222 or the electronic equivalent with the corresponding information on that form. All CS invoices and DEA Form 222s need to be separated and kept on file for two years.

Recent Disciplinary Actions

M.H. Pharmacy Technician-in-Training Permit #2105: Order to revoke permit due to diversion of CS from employer.

B.R. Pharmacist License #2457: Letter of Admonition for dispensing a prescription drug product other than what was ordered by the

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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.

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practitioner. Additional CE required, plus must submit a plan to improve medication safety.

C.T. Pharmacist License #3325: Failure to obtain the required number of hours of CE in 2013. Additional hours of CE required, plus administrative penalty of $200.

'Red Flags' Video

NABP produced a video called "Red Flags" to present situations that a pharmacist should consider as possible intent to obtain CS in a fraudulent manner. Bessie McGirr, Board vice president, provided the introduction to the film. As well as showcasing situations such as "pill mills" and people who keep detailed records of which pharmacies they have targeted, the video reminds pharmacists and pharmacy technicians of the importance of obtaining identification of the patient who presents a prescription for a CS. Wyoming Controlled Substances Act, Rules and Regulations, Chapter 6, Section 4(a) states, "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, **but a corresponding responsibility rests with the pharmacist who fills the prescription."** The film premiered at the Board meeting in June and also at the Wyoming Pharmacy Association Annual Convention.

Safeguarding Techniques and Tips for Pharmacists and Pharmacy Technicians Regarding CS Prescriptions

By Rebecca Pullos, PharmD Candidate

Currently in the United States, prescription drug abuse is an enormous issue and a topic that medical providers must be conscious of every day. Misuse, abuse, diversion, and addiction are growing problems affecting both public health and safety. Every day in the US, more than 2,500 youth (ages 12-17) will abuse a prescription pain reliever for the first time. Research has indicated that prescription drug abuse often leads to heroin use; nearly half of young people who inject heroin report that abusing prescription opioids was the first step in their addiction. According to the Centers for Disease Control and Prevention, more people die from prescription opioid overdose than from all other drugs combined, including cocaine and heroin. To reduce the likelihood of prescription drug abuse, diversion, and forgery of prescriptions, here are some safeguarding techniques, tips, and patient education points for pharmacists and pharmacy technicians that may aid in decreasing the number of prescription opioids diverted and prescription forgery.

- Call prescribers to validate CS prescriptions when a concern arises.
- Always obtain a signature from the patients picking up a CS prescription.
- Use a telephone book or electronic directory rather than the number on the prescription to contact the prescriber.
- Monitor prescriptions for shadows due to photocopying and check security features on the prescription as required by law.
- Do not dispense a prescription you suspect is forged, altered, or counterfeited, and contact the police.
- Instruct patients to follow proper disposal guidelines to prevent diversion *(www.fda.gov)*.
- Educate patients to take their medications as prescribed and not to share them with others.
- Provide patients with an educational brochure about prescription drug abuse and their role in helping to prevent it. Some sources for patient information include *www.nlm.nih.gov/medlineplus/druginformation.html* and *www.drugabuse.gov/PDF/PrescriptionDrugs.pdf*.

Compliance Corner

The Board inspectors report they are finding instances where the pharmacy technician wall certificate is not in the pharmacy. The Pharmacy Technician Certification Board certificate is **not** a license. Contact the Board office to get a duplicate wall certificate and display it with the current annual renewal notice as required.

Special Notice About This Newsletter

The *Wyoming State Board of Pharmacy Newsletter* has been designated as the official method of notification to pharmacists and pharmacy technicians licensed by the Wyoming State Board of Pharmacy. Please read these *Newsletters* and keep them for future reference. These *Newsletters* will be used in hearings as proof of notification. *Newsletters* are available for review on the Board web page at *http://pharmacyboard.state.wy.us* or at *www.nabp.net/publications/state-newsletters* under Wyoming.

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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