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News

Arkansas State Board of Pharmacy

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322 S Main St, Suite 600 • Little Rock, AR 72201 • Tel: 501/682-0190 • Fax: 501/682-0195

Save the Date for the 2014 Arkansas Prescription Drug Abuse Summit

The Arkansas State Board of Pharmacy hopes that you have arranged to join us at the 2014 Arkansas Prescription Drug Abuse Summit to be held in Little Rock, AR, September 9-10, 2014. This year's summit will have a plenary day at the Ron Robinson Theater on September 9, with various speakers highlighting issues surrounding prescription drug abuse in an interactive format, followed by an evening screening of "The Hungry Heart" documentary, including a question and answer session with the filmmaker at the conclusion of the showing.

The September 10 portion will be held at the Statehouse Convention Center and will offer an opportunity to obtain continuing education during a day-long conference structured to include breakout sessions for health care professionals to delve further into the problems associated with the abuse of and addiction to prescription drugs. Please watch *www.ArkansasAG.gov* and *www.CJI.edu* for details.

Board Elections

During the June 10-11, 2014 Board meeting, the Board elected the following new officers to lead the Board for the next year.

Larry Ross, MSEd, BA, a public member appointed by Governor Mike Beebe to the Board from Sherwood, AR, was elected to serve as the Board's president, a first for one of the Board's public members.

Lenora Newsome, PD, a pharmacist member from Smackover, AR, was elected to serve as the Board's vice president. Dr Newsome serves the Board as Governor Beebe's appointee based upon the advice and recommendation of the Pharmaceutical Section of the Arkansas Medical Dental Pharmaceutical Association.

Stephanie O'Neal, PD, a pharmacist member from Wynne, AR, was elected to serve as the Board's secretary. Dr O'Neal was appointed by Governor Beebe upon the advice and recommendation of the Arkansas Pharmacists Association (APA).

New Staff Member

The Board would like to say a special welcome to its new chief fiscal officer, Lana Broyles Whitmore. Many of you will recognize Lana from her previous time with the Board, as she previously worked for the Board from 1996-2006. To say the least, Lana has a very thorough knowledge of pharmacy and the Board is happy to have her back.

New Board Member

Former State Senator Percy Malone, PD, was appointed by Governor Beebe based on the advice and recommendation of APA, to finish out the term for pharmacist member Justin Boyd, PharmD. Dr Malone previously served on the Board prior to becoming a state legislator. Dr Boyd resigned as a Board member in April to concentrate on his upcoming duties serving the public as a member of the Arkansas House of Representatives beginning in January 2015.

Former State Senator Percy Malone served in the Arkansas Senate representing the 26th Senate District, which included all of Clark, Dallas, and Nevada Counties, and parts of Columbia and Ouachita Counties.

Senator Malone served as chairperson of the Senate Public Health, Welfare and Labor Committee; chairperson of the Administrative Rules and Regulations Committee; and chairperson of the Task Force on Abused and Neglected Children. He also held membership on numerous other committees and subcommittees, including the Joint Budget Committee, Arkansas Legislative Council, and the Senate Insurance and Commerce Committee, just to name a few.

He also served as State Representative for House District 36 from 1995 to 1999, which included parts of Clark and Nevada Counties. In this capacity, he served as co-chairperson of the Joint Budget Committee, as well as a member of the Insurance and Commerce Committee, the Public Health and Welfare Committee, and other important committees and subcommittees.

After receiving his pharmacy degree in 1965, Senator Malone began working with I.B. Fuller in Arkadelphia, AR. Mr Fuller became a mentor for Senator Malone's community involvement, which has ranged from serving on the Board of Directors of the Arkadelphia Chamber of Commerce, to serving as a delegate to Arkansas's Constitutional Convention in 1980, to being a member of the Arkansas State Board of Pharmacy.

Senator Malone was named one of Arkansas's Top 10 Legislators by the *Arkansas Democrat-Gazette* in 1999 and 2003. Throughout his legislative career, he has worked to support public education and health care initiatives, protect Arkansas consumers, and provide opportunities for economic growth.

Professionally, Senator Malone is president and owner of W.P. Malone, Inc, which includes a chain of Allcare Pharmacies across Arkansas. Senator Malone and his wife, Donna, are members of Third Street Baptist Church in Arkadelphia. He has two adult daughters, Amy Malone Norcross and Emily Malone Ervin, and five wonderful grandchildren.

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.

Regulation Changes

On March 19, 2014, the Board held a public hearing at the Arkansas State Board of Pharmacy, 322 South Main St, Suite 600, Little Rock, AR 72201. The following regulation changes were considered and approved for adoption. These changes were later reviewed by legislative council and had effective dates of May 31, 2014. Updated versions of these regulations are available on the Board's website.

- **Regulation 01 – General Operations**

  Changes updated the physical address of the Board to 322 South Main Street, Suite 600, Little Rock, AR 72201.

- **Regulation 02 – Pharmacists**

  Changes clarified that the intern training requirements for pharmacist licensure by examination in Arkansas may be obtained as part of the school curriculum for the colleges of pharmacy under Board-approved conditions.

- **Regulation 04 – Pharmacy**

  Changes updated language regarding the electronic recording of legend or Schedule III, IV, or V controlled substance (CS) prescriptions transferred from a retail pharmacy to a central fill pharmacy. Changes also expanded the protocol for methadone clinics to utilize additional drugs in research, cleaned up language regarding electronic prescribing, and made technical corrections within the regulation.

- **Regulation 05 – Long-Term Care Facilities**

  Changes added language to allow licensed in-patient hospice facilities to have emergency kits with a limited supply of prescription medications for use in emergencies.

  This change will also require changes with Arkansas Department of Health regulations before facilities can fully implement this process.

- **Regulation 07 – Drug Products/Prescriptions**

  Changes allowed pharmacists to electronically receive and document prescriptions in accordance with Arkansas Act 1331 of 2013, and as allowed by federal regulations. Changes also updated language according to Arkansas Act 176 of 2013 to allow a pharmacist to manually enter information into the electronic tracking database when utilizing a military ID to purchase Schedule V ephedrine, pseudoephedrine, or phenylpropanolamine products, and updated language to clarify the option for a pharmacist to either enter verbal orders directly into the pharmacy's electronic prescription system or promptly reduce the verbal order to writing. Specifically, this would allow a pharmacist to accept a verbal order for a non-CS and enter it directly into the pharmacy prescription system for processing rather than reducing it to writing first. Any CS prescriptions must be reduced to writing immediately, according to federal regulations.

Hydrocodone Combination Products = Schedule II

Drug Enforcement Administration (DEA) recently announced that all hydrocodone combination products (HCPs) will become Schedule II as of October 6, 2014, and therefore should be inventoried with an exact count of all products before the start of business on that date to be added to your Schedule II inventory. DEA has published its final rule rescheduling all hydrocodone-containing products to Schedule II. This rescheduling has been discussed and debated for years, and has now been adopted after a public comment process that gathered some 600 public comments. While the majority of public comments supported rescheduling these products into Schedule II, it is worth noting that 60% of pharmacists who responded to the proposed rescheduling were opposed to this change.

This final rule becomes effective on Monday, October 6, 2014. The move will mean that all hydrocodone-containing products, including hydrocodone/acetaminophen, hydrocodone/ibuprofen, and hydrocodone-containing cough syrups, will require hard copy prescriptions, may not be phoned in, and will not be allowed to contain refills. While there are exceptions to some of these rules, such as emergency supplies of medication and medications for patients enrolled in hospice programs or in long-term care facilities, all prescriptions for products containing hydrocodone written on or after October 6, 2014, must be treated as a Schedule II prescription.

While this all may seem very straightforward, DEA has allowed for prescriptions written before October 6, 2014, to be treated as they currently are processed, meaning that "Any prescriptions for HCPs that are issued before October 6, 2014, and authorized for refilling, may be dispensed . . . if such dispensing occurs before April 8, 2015." In short, prescriptions for HCPs written before October 6, 2014, that have refills may be refilled in the same manner as they have been while in Schedule III. These prescriptions will continue to only be valid for six months from the date written, but may be refilled until their expiration, which will be sometime before April 8, 2015. For more information, please refer to the DEA news release on this issue at *www.justice.gov/dea/divisions/hq/2014/hq082114.shtml,* or the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2014-08-22/pdf/2014-19922.pdf.*

Prescription Drug Take-Back September 27, 2014, and ARTakeBack.Org

The April 2014 DEA-sponsored Prescription Drug Take-Back event resulted in a total of 22,373 pounds of unused medications being gathered in Arkansas, which once again surpassed its previous records. As a reminder when dealing with your patients, the Board partnered with the City of Benton Police Department, DEA, and State Drug Director Fran Flener on the *www.ARTakeback.org* website that has been and will continue to be updated with information surrounding drug disposal and destruction. The next DEA-sponsored Prescription Drug Take-Back event is scheduled for September 27, 2014, and the Board hopes that you will encourage your patients to participate. The Board would also encourage you to use the *www.ARTakeback.org* website to promote this event to your patients for their consideration in the storage and destruction of their prescription drugs as a resource to find the closest drug drop-off location to them. You may take note that there is a permanent drug drop-off location in every county in Arkansas now, with multiple locations in more populated areas.

Special Notice About the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office (501/682-0190) if you have questions about any of the articles in this *Newsletter.*

Arkansas Pharmacy Support Group Help Line
870/636-0923

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John Kirtley, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Deborah Zak - Communications Manager