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Arkansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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New Web Site – PharmacyBoard.Arkansas.Gov

The Arkansas State Board of Pharmacy has a new Web site: *http://pharmacyboard.arkansas.gov.*

Inspection Findings

The following are common issues noted by Board inspection staff as points of noncompliance and concern for routine pharmacy inspections:

- Combat Methamphetamine Epidemic Act certificate expiration
- Failure to update immunization protocols or immunization protocols that also contained medications other than vaccines/immunizations such as B12
- Failure to have proof of CPR available for review (as a reminder, your immunization certification is printed on your pharmacist license if it is current with the Board)
- Failure to have a technician order entry procedure that is available to and easily found by technicians
- Controlled substance (CS) inventories that are either not up to date or are not complete (eg, missing over-the-counter Schedule V products, missing tramadol or tramadol-containing products)

Board Plans for Move of Board Offices – Update

The Board is planning to change locations in the summer of 2013, with its current plan reflecting a move in mid- to late-July. Once again, this move will allow the Board to have more functional space that can be better used for its Board meetings as well as collaborating with interprofessional workgroups on issues such as prescription drug abuse, prescription drug take-back programs, law tests, law reviews, and educational opportunities delivered from the Board staff. The Board will also have a conference room that will function very well for smaller meetings with its staff and committee meetings for the Board. While its current space has served it very well, the Board is truly looking forward to the opportunities this move will give it in delivering more services to the public as well as its permit holders while remaining in downtown Little Rock, AR. With this move, the Board anticipates updating all permit holders with the Board in respect to its new address once its moving date is confirmed.

Arkansas Prescription Monitoring Program Update

By Denise Robertson, PD, PMP Administrator, Arkansas Department of Health

Act 304 of 2011, as adopted by the Arkansas General Assembly, established the Arkansas Prescription Monitoring Program (AR PMP) to be implemented under the direction of the Arkansas Department of Health in the spring of 2013 if funding was available. Currently, the program is operational through federal grants.

The goals and benefits of a PMP are set forth in the legislation:

- To enhance patient care by providing prescription monitoring information that will ensure legitimate use of CS in health care
- To help curtail the misuse and abuse of CS
- To assist in combating illegal trade in and diversion of CS
- To enable access to prescription information by practitioners, law enforcement agents, and other authorized individuals and agencies

Prescription drug abuse has become a major problem in the United States. Statistics for Arkansas alone are shocking. Arkansas ranked among the second highest group of states nationally in overall drug overdose deaths in 2008, with 5.1 per 100,000 deaths resulting from non-medical use of opioid pain relievers.[1] Arkansas ranked among the highest group nationally in the rate of kilograms of opioid pain relievers sold per 10,000 people in 2010.[2] Abuse of prescription drugs has not eluded our youth. Nearly 20% of Arkansas teenagers have abused prescription drugs by the time they are seniors in high school.[3] PMPs were created to assist health care practitioners in the battle against prescription drug abuse.

The AR PMP collects Schedule II through V prescription dispensing data. Pharmacies are now reporting this data to the AR PMP weekly for the previous Sunday through Saturday reporting period. Direct access to the database should be available to pharmacists and prescribers in June 2013. At that time, you will be able to create an access account via the AR PMP Web site at *www.arkansaspmp.com.* Access will allow you to better assess patient use of CS. Questions about the program can be directed to Denise Robertson, PD, at denise.robertson@arkansas.gov or 501/683-3960.

References:

1. Centers for Disease Control and Prevention. Vital signs:1999-2008. MMWR.2011; 60(43):1487-1492.

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FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

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2. Clark T, Eadie J, Kreiner P, Strickler G. Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices. 2012.
3. Arkansas Department of Human Services Division of Behavioral Health Services. 2011 Arkansas Prevention Needs Assessment Student Survey.

Renewals Closed

Renewals have closed for the following permits/registrations, which expired December 31, 2012: pharmacy technicians, charitable clinic pharmacies, charitable clinic pharmacy technician permits, institutional pharmacies, wholesale distributors, List 1 chemical distributors, hospital pharmacies, and durable medical equipment permits. Any of these permits that were not renewed by April 1, 2013, are now void and are no longer subject to renewal. As a note, of the 7,984 pharmacy technicians permitted by the end of last year, 2,220 did not renew, indicating that they should no longer perform pharmacy technician duties. As a reminder to our pharmacists, whenever an unregistered person has performed technician duties in the past, the Board has offered consent agreements with a $500 penalty to the pharmacist-in-charge and a $1,000 penalty to the pharmacy. Please make sure that you are not allowing unregistered employees to perform duties that require registration.

Prescription Drug Take-Back and ARTakeBack.Org

At the time of writing this *Newsletter,* the Board had been working diligently with other partners to prepare for the April 27, 2013 drug take-back event. In addition to these preparations, the Board has also partnered with State Drug Director Fran Flener's office, the local Drug Enforcement Administration, and Benton Police Department Chief Kirk Lane's office to upgrade and update the *www .artakeback.org* Web site to serve our medical professionals and the public much better in sharing information on the importance of our Monitor, Secure, and Dispose program for prescription drugs as well as statistics and related sites for issues dealing with drug abuse. This new site will also continue to serve as a resource to identify take-back locations and drop boxes throughout Arkansas. The Board hopes that you will take a chance to visit this site as well as promote it to your patients for their consideration in the storage and destruction of their prescription drugs.

Newsletter/Notification Changes

The Arkansas State Board of Pharmacy periodically sends out updates, *Newsletters,* current topics, and notifications by mail and/or e-mail. During the June 2012 meeting, the Board voted to phase out the mailing of these *Newsletters* in favor of sending electronic reminders of current issues as well as links to the quarterly *Newsletter* as posted on the Board Web site. As a part of this process, it is important to ensure that your contact information is current with the Board office including your e-mail address as a point of contact.

If you would like to check your contact information, you may do so through the Board Web site by clicking on the License Maintenance link. Once you reach that screen enter your license number, which includes PD as a designator for pharmacists and PT for technicians, followed by a five-digit number. If your license only has four numbers, then put a zero in front of those four digits such as PD01234 for the number 1234. Also, do not forget to update your information if you move or change jobs. Printed *Newsletters* will end after this *Newsletter* and will switch to electronic format, which will be available on the Board's Web site.

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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