June 2013

# Kansas State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

800 SW Jackson St, Ste 1414 • Topeka, KS 66612 • *www.kansas.gov/pharmacy/*

## Lewis and Clark Information Exchange Partners With Kansas State Board of Pharmacy

The Kansas State Board of Pharmacy is excited to have entered into an agreement with the Lewis and Clark Information Exchange (LACIE) to provide approved providers access into the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) reporting system. "This will be a tremendous benefit to the providers and organizations that we serve," stated Mike Dittemore, RN, executive director of LACIE. LACIE will act strictly as a conduit to help expedite information that resides in the K-TRACS system to approved providers.

Pharmacists are a critical link to the health care delivery chain. LACIE provides them with medical information from a variety of providers that they may not normally have easy access to, such as current medications, immunizations, allergies, medical/discharge history, problem lists, lab results, and clinic visits. This improves the opportunity for them to proactively intervene with the care of the patients they serve. LACIE plans to work directly with the Board to ensure the information that is provided through its exchange provides optimum value to participating pharmacists as well as meeting the minimum data sharing requirement as defined by the Health Insurance Portability and Accountability Act.

LACIE, through their partnership with Cerner, has actively been sharing data between discrepant organizations for more than three years. Based in Kansas City, KS, LACIE is governed by a collaborative board that consists of The University of Kansas Hospital, Olathe Medical Center, Shawnee Mission Medical Center, Children's Mercy Hospitals and Clinics, Heartland Health, Truman Medical Centers, Cerner Clinics, as well as a federally qualified health center safety net clinic and consumer representative. LACIE covers the whole state of Kansas as well as parts of Missouri.

For a view-only portal connection to LACIE there is a one-time connection fee of $200 and a monthly unlimited use fee of $10. For pharmacists that would prefer to pay once annually, the unlimited use fee for the view-only connection is $100. For more information on LACIE or to join, please visit their Web site *www.lacie-hie.com* or contact Mike Dittemore, BS, eMBA, RN, LACIE executive director, at 816/214-6894.

## Reporting Staff Drug-Related Issues

State boards of pharmacy have been encouraged by the National Association of Boards of Pharmacy® Task Force on the Control and Accountability of Prescription Medications to add regulations to state pharmacy acts requiring the pharmacists-in-charge (PICs) to report any termination of employment of pharmacy staff for drug-related reasons. Examples of this could include adulteration, abuse, theft, or diversion. At this time, the Kansas Board does not find it necessary to create new regulations for this purpose but would like to remind each PIC to report to the Board any employment termination of pharmacists, interns, or technicians due to drug-related reasons. Information about PICs who have been terminated for these reasons should be reported by the pharmacy permit holder and/or pharmacy owner. The Board would also like to encourage PICs to complete at least three hours of continuing education every renewal period that details the legal responsibilities of a PIC, including diversion prevention.

## Kansas Medication Disposal Program

The Board has completed a year of the voluntary medication disposal program in collaboration with Kansas Department of Health and Environment (KDHE). Approximately 57 pharmacies are participating statewide so that they can dispose of medications generated by households, long-term care facilities, and hospice care facilities. The Board and KDHE conducted a survey during the months of April and May to determine whether pharmacies viewed this program as a benefit and what barriers existed to keep them from participating. It was clear from the survey that pharmacies want to destroy drugs in a more environmentally friendly way and to remove the burden of medication disposal from the patient.

However, there were many questions related to how a pharmacy could sign up for the program and once signed up, how to dispose of the medications once they have been collected. Therefore, the Board is updating the information on the Web page so that it can provide relevant information that relates solely to a pharmacy. This program is entirely voluntary and there is no fee associated with signing up. The Board would like this process to be efficient so that you can provide additional services to your patients without requiring additional work on the pharmacy end.

In order to sign up, a pharmacy can go to the Board Web page at *www.kansas.gov/pharmacy* and scroll down to the bot-

*Continued on page 4*

## 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*.

*Continued from page 1*

tom of the page to the link for "Kansas Medication Disposal Program." This will take you to the KDHE Web page. Under the section titled "Pharmacy Program Information" there is a link for the "Pharmacy participation application." The first step in taking back drugs for disposal is to fill out this application. You can either fax the application to 785/296-1592 or mail the application to KDHE, Bureau of Waste Management, 1000 SW Jackson, Ste. 320, Topeka, KS 66612. Once again, there is no fee.

Under the same link you will find a "Special Waste Authorization request form." This will also need to be sent to KDHE. Section I requires the pharmacist to provide his or her personal information and Section II requires the pharmacy contact information. In order to fill out the application, KDHE has offered the assistance of Tony Guy, who can be reached at 785/296-0681. Tony will walk you through the application process and tell you how to dispose of the drugs at your local Subtitle D landfill or transfer station that is located in your community. You can also use a professional take-back program. You will not dispose of medications at a hazardous household waste facility because they cannot take controlled substances (CS) and you may have some comingled CS in the collection container. Your local landfill can take both controlled drugs and non-controlled drugs, but you must contact them before you take any drugs to them for disposal. In the case of medications, the landfill has unique characteristics that restrict the number of employees involved with pharmaceutical waste and it is treated more securely than average household waste so that it cannot be stolen or diverted. You do not have to prepare the medications with water, other liquids, or kitty litter. In fact, that process is discouraged and takes too much of your time.

You may only need to take the waste to the landfill once a year depending on how much you are collecting. The landfill or the professional disposal company will weigh your drugs for you and provide you with an invoice that documents the weight of the disposed drugs. You need to maintain that invoice for five years in the pharmacy. You will also receive an e-mail from KDHE periodically asking you how much you have disposed of in weight. You do not have to segregate drugs or look through the drugs to remove CS. If you receive drugs in an unmarked container from the patient that does not identify the drugs as CS you may collect them. Your patients can always put the medications in a baggy and bring them to you and you can toss them in the disposal container for disposal.

The program should only take a minimal amount of your time. Some landfills will take your medications for disposal as a community service and may not charge you. Not every landfill is willing to do that, but some are offering to collaborate with the local pharmacy because they want to be responsible toward society and the environment.

The Board and KDHE understand that they need to provide better information to you with an easy step-by-step process. The Bureau of Waste Management is working to provide pharmacy-related "frequently asked questions" as well as clearly delineating the differences between a consumer disposing of medications as opposed to a pharmacy disposing of medications because the requirements are different. The Board wants the experience to be user-friendly and to prevent additional duties added to your work day.

The Board and KDHE look forward to seeing more pharmacies participate in community collection centers for prescription medications. The Board believes that your participation is not only good public relations but as a business model shows that through your actions you encourage a positive impact on the environment, consumers, employees, communities, and other members of the public sphere.

## *Are You Canceling Your Schedule II Prescriptions?*

The Board has seen an increase in the number of complaints filed by the Kansas Medical Assistance Program. Many of the allegations are related to cancellation of the Schedule II prescriptions. Pursuant to K.A.R. 68-20-19 (e)(2), " . . . All written or emergency prescriptions for a controlled substance listed in schedule II shall be cancelled on the face of the prescription with the name of the pharmacist filling that prescription." The role of an audit is generally to detect fraud, waste, and abuse, but it is also used to validate data entry and documentation to ensure they meet the regulatory and contractual requirements. The Board recommends that you have a pharmacy technician check the Schedule II prescriptions for cancellation on a weekly basis to avoid paying a recoupment or having a complaint filed with the Board.

## *Incident Reports and Continuous Quality Improvement*

The Board reviewed several complaints recently whereby the PIC was unaware that an error had occurred and subsequently no incident report had been filed. Please make sure that your pharmacy technicians, staff pharmacists, PICs, and store managers understand that the PIC needs to be advised whenever a patient has complained about something that is a reportable offense. Failure to file an incident report will result in a fine against the pharmacy and/or the PIC.

## *Useful Contact Information*

**Kansas State Board of Pharmacy**.....785/296-4056
1-888/792-6273
**K-TRACS**.....785/296-6547
**Kansas State Board of Healing Arts**.....785/296-7413
1-888/886-7205
**Kansas Dental Board**.....785/296-6400
**Kansas State Board of Nursing**.....785/296-4929
**Kansas Board of Examiners in Optometry**.....785/832-9986
**Drug Enforcement Administration (Kansas City)**.....913/825-4200
**Food and Drug Administration, Center for Drug Evaluation and Research**.....1-855/543-3784
**Kansas Pharmacists Association**.....785/228-2327
**Kansas Council of Health-System Pharmacists**....785/271-0208
**Kansas Pharmacists Recovery Network**.....785/217-7091



The *Kansas State Board of Pharmacy News* is published by the Kansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, 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 the Foundation or the Board unless expressly so stated.

Debra L. Billingsley, JD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager