



Kansas State Board of Pharmacy

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NTSB Medication Safety Recommendations

The National Transportation Safety Board (NTSB) provided the Kansas State Board of Pharmacy with medication safety recommendations for pharmacists and other health care providers. To see the pharmacist recommendations and the safety study titled “Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment,” visit the Board’s website at <https://pharmacy.ks.gov>, and click on the “NTSB Medication Safety Recommendations” link located under the “News” section.

Direct Access to the Pharmacy

By Maggie Blowey, PharmD Candidate

Prescription drug diversion is a serious issue that is a growing concern throughout the nation. There are various ways in which these diverters illegally obtain medications, including counterfeit prescriptions, doctor shopping, and theft.

However, diversion by an outside individual is not the only point of concern. Employees and even family members who have access to restricted areas within the pharmacy can pose an equal threat. Internal theft, along with external diversion, can be prevented through diligent practices and proper security procedures.

According to K.A.R. 68-2-11, “Each premises for which a pharmacy registration is issued, except medical care facilities, shall be constructed so that the pharmacy can be secured to prevent access to prescription-only drugs when a pharmacist is not on duty.”

One way to prevent access to prescription-only drugs and to minimize potential loss is by limiting keys to appropriate personnel or limiting access to pharmacy areas through separate keys or employee-specific alarm access codes.

As stated above, appropriate personnel who should be allowed access to the pharmacy or dispensing area would be limited to the pharmacist(s) currently employed.

CE: What You Need to Know

By Maggie Blowey, PharmD Candidate

Quick Facts:

- ◆ Ten contact hours of continuing education (CE) equals one continuing education unit (CEU).
- ◆ Three CEUs are required during each licensure period.
- ◆ Accreditation Council for Pharmacy Education (ACPE)-approved programs are approved by the Board.
- ◆ Hours are not allowed to be carried forward to the next renewal period.
- ◆ Attendance at a scheduled Board meeting is acceptable for CEU credit (0.1 CEUs for two hours of attendance).

- ◆ A maximum of 0.8 CEUs, or eight contact hours, of a non-ACPE-approved program or attendance at a Board meeting can be counted toward total CEUs per biennial licensing period.
- ◆ The CEU period runs from July 1 through June 30 of each year. There is no grace period.
- ◆ Current Board-approved non-ACPE programs can be found on the Board’s web page at <https://pharmacy.ks.gov>.

The process for approval of a non-ACPE-approved CE program can be found on the Board website under the link for “Licensing & Registration” and by selecting “Pharmacists” from the drop-down menu. Currently, the Board does not require CE for pharmacy technicians, but it is currently drafting rules and regulations that will address the requirement for technicians. There are two [CE Approval Request Forms](#) available that must be filled out at least 30 days in advance either by the individual or the provider requesting to have his or her CE program approved. The criteria described in K.A.R. 68-1-1b will be taken into consideration by the Board when determining approval. As a reminder, a CE program cannot include in-service programs, on-the-job training, job orientation, programs open to the general public, CPR or Basic Cardiac Life Support courses, emergency or disaster training, direct experience under a code blue, or testing out of courses. After determination of approval status by the Board, the individual requesting approval will be notified.

The current CE Committee members reviewing and approving CE are Bob Haneke, PharmD; Joan Kramer, PharmD; Barb Woods, RPh; Doug Funk, RPh; and Debra Billingsley, JD.

Pharmacy Inspections

Administrative agencies such as the Board are tasked with determining whether pharmacies are complying with state and federal laws and regulations, and as such, have the authority to inspect pharmacies. While the pharmacist-in-charge maintains most of the liability during an inspection, all other employees should be aware of the laws surrounding an inspection. Because there is a valid public interest in ensuring that the highly regulated industry of pharmacy maintains compliance, and by virtue of the state issuing a permit or license, it is proper that an inspector be given immediate and unannounced inspection access. Inspections are generally routine, but the inspector may be investigating a consumer complaint.

A pharmacy inspector will provide you with credentials when he or she asks for entry into the pharmacy. The inspector will leave you his or her business card with his or her contact information. If you have concerns that the inspector is not a legitimate inspector,

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DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register*. The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.

The announcement is available on the *Federal Register* website at <https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule>.

The mL-Only Standard for Liquid Dosing Gathers Steam

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

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white

paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications*, which is available at www.ismp.org/sc?id=337. The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals*, Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- ◆ Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- ◆ Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- ◆ Coach patients on how to use and clean measuring devices; use the “teach back” approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the “C-IV” designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every “DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d).” In addition, all “prescriptions for tramadol



or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014.”

The announcement is available on the *Federal Register* website at www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the “Warnings” and “Dosage and Administration” sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA’s website at www.fda.gov/Drugs/DrugSafety/ucm402240.htm.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy,

warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. “The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures,” states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision’s refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA’s MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA’s website at www.fda.gov/Drugs/DrugSafety/ucm405940.htm.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists’ process of patient care service delivery. “Pharmacists’ Patient Care Process” was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course’s website at www.sigmatech.com/BadAd. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

you may contact the Board office at 785/296-4056 at the time of inspection. The inspector is not a visitor and is not required to obtain permission to enter from Human Resources or the store manager, and he or she is not required to sign any documentation. The Board inspector will only show up during hours of lawful operation, which is why it is important that you provide the Board with your hours of operation. Further, the Board is not directly subject to the Health Insurance Portability and Accountability Act in regard to using or disclosing health care information; therefore, you would need to provide patient information when requested. If you do not have the record available when the inspector arrives, you would need to provide the requested information within the statutory requirements set out in the Kansas Pharmacy Act. If you are opening a new pharmacy or other registered business, you cannot operate without first having a registration. An inspector will always do a preopening inspection prior to the Board granting a permit. If the business conducts business prior to registration, it not only jeopardizes the issuance of a permit, but it also jeopardizes any future relationship that it may have enjoyed with the inspector. The applicant is presumed to have known that a permit is required prior to conducting business. This means that you shall have a permit on your wall before you open for business.

For the most part, inspections are a routine part of the pharmacy business. They are important to public safety and are required by the Kansas Pharmacy Act. Please be courteous to your inspector, and he or she will do his or her best to prevent any business disruption on his or her end.

What You Need to Know About Ebola

The Kansas Department of Health and Environment (KDHE) has important guidance documents for health care workers related to Ebola virus preparedness and recommendations for health care settings. It has a weekly phone call, frequently asked questions, and other important information that you may need to know. Visit KDHE's website at www.kdheks.gov and click on the link "What You Need to Know about Ebola." If you have concerns, you can send your questions to response2014@kdheks.gov.

K-TRACS Drugs of Concern

The Prescription Drug Monitoring Advisory Committee recommended that the Board change its regulation related to "drugs of concern" for Kansas Tracking and Reporting of Controlled Substances (K-TRACS) reporting purposes. These would be drugs that are not controlled substances in Schedule II-IV but are being tracked.

Each of the following drugs has been classified as a drug of concern that would have to be reported to K-TRACS:

- (1) Any product containing all three of these drugs: butalbital, acetaminophen, and caffeine;
- (2) Any compound, mixture, or preparation that contains any detectable quantity of ephedrine, its salts or optical isomers, or salts of optical isomers, and is exempt from being reported to the statewide electronic logging system for the sale of methamphetamine precursors (National Precursor Log Exchange (NPLEx));
- (3) Any compound, mixture, or preparation that contains any detectable quantity of pseudoephedrine, its salts or optical isomers, or salts of optical isomers, and is exempt from being reported to the statewide electronic logging system for the sale of methamphetamine precursors (NPLEx); and
- (4) Promethazine with codeine.

This regulation goes into effect on February 4, 2015. All point-of-sale cold products containing pseudoephedrine and ephedrine will still go through the NPLEx system. Do not report the over-the-counter point-of-sale items to K-TRACS. Only exempt prescriptions will now be tracked through K-TRACS.

Pharmacy Technician Education Update

The committee tasked with updating pharmacy technician education requirements has been working on drafting regulations that will set out the new requirements for pharmacy technicians. The committee is made up of representatives from each practice setting and includes pharmacy technicians. The committee has reviewed the psychometric process of national certification exams, and has reviewed potential grandfathering, exemptions, reciprocity, trainee requirements, and CE requirements. Once the committee has completed this process, it will make a recommendation to the full Board so that the Board can begin the regulation process. Nothing has been changed at this time, but once the regulations have been drafted, the Board will have a 60-day comment period for any person who would like to comment on the proposed changes. The Board will keep you updated on the progress of the committee.

Board Meetings

The next Board meetings are as follows:

- ◆ January 8-9, 2015 – Topeka, KS
- ◆ April 23-24, 2015 – Topeka
- ◆ July 16-17, 2015 – Topeka
- ◆ November 5-6, 2015 – Wichita, KS

The meeting locations are available on the Board's web page at <https://pharmacy.ks.gov> under the "Upcoming Events" section. All Board meetings and advisory board meetings are listed with the location and time. All meetings are open to the public. You can receive CE hours for attending the Board meetings.

KsPRN Program

Help is available to you or a colleague should you find yourself in a situation that seems hopeless as a result of substance abuse, aging issues, or mental disorders. Help is as close as a call to Vicki Whitaker, the program director of the Kansas Pharmacists Recovery Network (KsPRN) by calling 785/217-7091. You can also contact Vicki by e-mailing vicki@ksrx.org. All calls and e-mails are confidential.

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

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