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Kansas State Board of Pharmacy News

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Multiple Prescriptions of a Schedule II CS

The federal rule allows a practitioner to provide a patient with multiple prescriptions on the same day for the same Schedule II controlled substance (CS) to be filled sequentially. There is no federal or state limit on the amount a prescriber can prescribe, but when a prescriber issues multiple prescriptions of the same drug on the same day, the combined amount shall not exceed a 90-day supply. It is up to the prescriber to determine how many separate prescriptions to write. For example, a prescriber may issue three 30-day Schedule II prescriptions to cover the 90 days, or he or she may issue nine 10-day Schedule II prescriptions to cover the 90 days. Each prescription must be individually written on a separate prescription. Once the prescription is filled, the inspector would expect to find either three separate canceled prescriptions or nine canceled prescriptions.

Inventory Requirements When a Drug Is Scheduled

Tramadol became a federally controlled Schedule IV drug beginning August 18, 2014. Pursuant to 21 CFR §1304.11, a pharmacy is required to take an inventory of any CS that is added to the list on the effective date of the rule. Thereafter, the substance needs to be included in each inventory made by the registrant.

Kansas requires an annual inventory of CS. Each inventory of Schedule II CS and all products containing hydrocodone require an exact count. Make sure you designate on the inventory whether it was taken at the beginning or close of business.

The Kansas State Board of Pharmacy has taken steps to have tramadol removed from the Kansas Tracking and Reporting of Controlled Substances (K-TRACS) drugs of concern regulation. Tramadol will need to be reported to K-TRACS now that it has been federally scheduled.

Treatment of Obesity Using CS

The Kansas State Board of Healing Arts has a specific regulation related to the treatment of obesity. K.A.R. 100-23-1 states that prescribers shall not dispense or prescribe CS for the treatment of obesity unless certain requirements are met. Specifically, the treating physician shall not dispense or prescribe more than a 30-day supply of CS at one time to treat obesity. This means that there can be no refills for CS diet drugs. Schedule III and IV CS prescriptions can be phoned in, faxed, or electronically submitted to the pharmacy.

Registration Renewals for Pharmacy Technicians

Renewal notices will be sent to pharmacy technicians the first week of September 2014. The Board will open its website on September 15, 2014, for online renewals. Even-numbered permit numbers will expire on November 30, 2014, at which time a late fee will be added. Pharmacists-in-charge (PICs) need to be checking the registration status of pharmacy technicians to ensure no unregistered technicians are performing pharmacy functions. The Board is holding the PIC responsible, so make sure the technicians in your pharmacy have an updated registration and that the pocket card is on display at the pharmacy.

Next Board Meeting

The Board will hold its next meeting on October 16-17, 2014. The meeting will be held at Via Christi Hospital St Joseph, 3600 E Harry, Third Floor, Conference Room A, Wichita, KS. The meetings begin at 9 AM each day and are open to the public. Administrative hearings will be heard on Friday, and there may be instances where the public is not permitted in the hearing. You may obtain up to eight hours of continuing education (CE) for attending a Board meeting.

Pharmacist Vaccinations

According to the Kansas Department of Health and Environment's Bureau of Epidemiology and Public Health Informatics, 34 individuals died directly from influenza in Kansas last year, and 380 patients died as a direct result of pneumonia. Many more died as an indirect result of these two illnesses. The Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention provided that influenza and pneumonia together are the fifth leading cause of American deaths. Immunizing for these two diseases is the most cost-effective preventive measure, and pharmacists can play a key role in making sure that patients are educated about immunizations.

As flu season approaches, Kansas pharmacists are reminded to review the present statute regarding immunizations administered by pharmacists in K.S.A. 65-1635a. Pharmacists and supervised interns may administer vaccinations to patients 18 years of age and older, and may administer flu vaccines to patients six years of age or older. The supervising pharmacist and the intern must have successfully completed a course of study and training on vaccination storage, protocols, injection techniques, emergency procedures, and record keeping that is either Accreditation Council for Pharmacy Education- or Board-approved. The immunization training given by the University of Kansas (KU) School of Pharmacy has been Board-approved. The pharmacist or intern must also maintain a current CPR certificate that is available upon inspection to the Board inspectors. You must have a protocol with a physician before you can administer a vaccine.

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.

Collaborative Practice

Many of you have asked about specifics of the new collaborative practice statute that became effective July 1, 2014. The Board appointed Dr James Garrelts to chair the committee. The Board also appointed voting members of the committee. They are Lyndsey N. Hogg, PharmD, BCACP; Tiffany R. Shin, PharmD, BCACP; and Rick Couldry, MS, BS. The Board of Healing Arts will appoint three voting physician members to the committee. It plans to make its appointments in October. Once the committee has been established, the group will meet so that they can draft regulations related to collaborative practice requirements. All questions related to collaborative agreements will be directed to this committee.

'Red Flags' Video

It is undeniable that prescription drug abuse is on the rise. The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group, a consortium of pharmaceutical manufacturers and distributors, created an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS. The video, entitled "Red Flags," was released by NABP at its 110th Annual Meeting, and it has been made available to each state. Please take a few minutes to look at the video on the Board's web page. NABP recognizes that this video is helpful, but that pharmacists may be looking for more guidance. NABP will be holding a Task Force on Prescription Drug Abuse to explore this issue further so that it can provide tools to help pharmacists in determining whether a prescription is for a legitimate medical purpose.

Board Officers Named

The Board voted on officers at its July Board meeting. The Board elected Robert Haneke, PharmD, as Board president and Chad Ullom, RPh, as vice president. Michael Lonergan, RPh, will serve as the Board's investigative member, and John Worden, PharmD, will serve as investigative member for conflict cases. The Board elects new officers on an annual basis.

Pharmacy Technician Education

The Board has been fielding numerous questions about the status of pharmacy technician certification in Kansas. It has been confusing because there was a lot of activity at the Kansas Legislature the last couple of years and the language was modified several times. For instance, in 2013, the pharmacy technician bill was filed in the Committee on Vision 2020 and it required a pharmacy technician registered in Kansas to take and pass a national pharmacy technician certification examination. The bill had language that would allow the Board to grant exemptions or grandfather, and it allowed for a technician trainee registration. This bill did not make it out of the Committee, so it died.

In 2014, another bill was filed in the same committee, but it was modified. It required a pharmacy technician to pass an examination. The Board would have been able to determine which examinations were acceptable, including any national examination. There was no language related to grandfathering, exemptions, or CE. This bill passed out of the Committee and the House of Representatives. However, it did not pass out of the Senate Committee on Public Health and Welfare. Many pharmacists thought that the issue was over when it did not get through the Committee. What happened next was that language was amended into a new bill that was debated on the Senate floor. The new bill was Senate Substitute for House Bill 2146. The new language stated that the Board would draft new regulations that would identify one or more examinations that technicians would be required to take, and the Board would identify when the test had to be passed. All criteria related to the test would be done through regulations. The technicians were also required to obtain CE.

Board Member David Schoech, RPh, is on the committee that will draft the regulations. Throughout this process, it was evident that not every practice setting had the same needs. The Board has made sure that there are members of Kansas Pharmacists Association, Kansas Independent Pharmacy Service Corporation, Kansas Council of Health-System Pharmacists, Kansas Association of Chain Drug Stores, mail order pharmacies, PBA Health, KU School of Pharmacy, and pharmacy technicians represented on the committee. This committee will meet in the fall and will report back to their respective associations. This legislation is a prime example of why pharmacy advocacy is important and how association advocates ensure that your interests are served. There are many policy decisions that could impact your profession, so if you have questions about the technician requirements, contact your professional association. Once again, the bill that passed did not contain any specific language related to grandfathering, temporary permits, trainees, or specific technician duties.

Prescription Drug Monitoring Program Drugs of Concern

The Board will have a public comment period on October 16, 2014, during its regularly scheduled Board meeting related to the K-TRACS regulations and drugs of concern. The Board is proposing an amendment to the regulations that would remove carisoprodol and tramadol as drugs of concern. Both drugs have been federally scheduled, so all dispensing of these drugs should now be downloaded into K-TRACS.

The other change is that prescriptions containing pseudoephedrine will be tracked as a drug of concern through K-TRACS. Over-the-counter pseudoephedrine will continue to be tracked through the National Precursor Log Exchange electronic logging system. The Board will also consider adding promethazine with codeine as a drug of concern that will be tracked in the K-TRACS system. If you have concerns or comments about these changes, you may publicly comment at the Board meeting, send an e-mail to the Board at pharmacy@pharmacy.ks.gov, or send written correspondence to the Board office prior to the October hearing.

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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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