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Kansas State Board of Pharmacy News

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Vaccination Reporting Reminder

Pharmacists who provide vaccinations are required to promptly report the immunization to the patient's primary care provider or to the physician who has entered into the vaccination protocol with the pharmacist, and to report the immunization to the appropriate state immunization registry. The Kansas Immunization Registry, also referred to as KSWebIZ, is a statewide immunization registry that consolidates immunization information among health care professionals, ensures adequate immunization levels, and helps avoid unnecessary immunizations.

The Kansas Department of Health and Environment has asked the Kansas State Board of Pharmacy to remind pharmacists of their responsibility to report immunizations. If a pharmacist has any questions in relation to the options for accessing KSWebIZ, please contact Brittany Ersery via email at bersery@kdheks.gov.

Electronic Prescribing of Schedule II Prescriptions

Effective February 13, 2015, all prescriptions can be transmitted electronically from the prescriber to the pharmacy. The Board adopted a regulatory change to K.A.R. 68-2-22 and K.A.R. 68-20-10a so that Schedule II prescriptions can be transmitted electronically along with all other prescriptions. Electronic prescribing should improve safety and patient care and reduce fraud and abuse. In order for prescribers or pharmacies to transmit and accept electronic prescriptions, their software vendor shall be certified by a third-party audit. This certification ensures that the software works in accordance with industry-accepted standards and federal and state law. If your software is certified, you may need to contact your vendor in order to enable your electronic prescribing functionality if it is not operating. Most software vendors have completed their certification and are obligated to provide the pharmacy with a copy of the certificate. Currently, the following software vendors have been certified: AdvanceNet Health Solutions; Best Computer Systems; CarePoint; Cerner Etreby; Computer-Rx; Creehan & Company; CVS/caremark mail; CVS/pharmacy; CVS/specialty; Digital Business Solutions; ExcelleRx; Express Scripts Home Delivery; FrameworkLTC by SoftWriters; Foundation Systems; H E B Pharmacy; Health Business Systems; Humana Pharmacy; Injured Workers Pharmacy; KeyCentrix; Kroger; Lagniappe Pharmacy Services (Alpha, InteRx, OpusRx, PPC, Rx-1, Synercom, Visual); Liberty Software; McKesson Pharmacy Systems (Condor, EnterpriseRx, PharmacyRx, Pharmaserv, Zadall); MDScripts; Micro Merchant Systems; Omnicare; OptumRx; Pd-Rx Pharmaceuticals; PDX; Pharmacy Systems, Inc; PharMerica; PioneerRx; Prodigy Data Systems; QS/1 Data Systems; Rite Aid; RNA-Helix; ScriptPro USA; SRS Pharmacy; SuiteRx; SuperValu; Thrifty White Pharmacy; Transaction Data Systems; VIP Computer Systems; Walgreens; and Walmart.

Electronic prescriptions do not need to be printed out as a hard copy. Federal law states that once a prescription is created electronically, all records of the prescription must be retained electronically. As in the case of paper prescriptions, state law requires electronic prescriptions to be kept for a minimum period of five years.

A practitioner can print a copy of the electronic prescription, but it must be clearly labeled "Copy only – not valid for dispensing." If a pharmacist receives a paper or oral prescription that indicates it was originally transmitted electronically to another pharmacy, the pharmacist must check with the other pharmacy to determine whether the prescription was received and dispensed. If the pharmacy received the original electronic prescription but had not dispensed the prescription, then that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void. For more information on electronic prescribing, visit the Board's web

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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. *Email: ismpinfo@ismp.org.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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page under the link for "Statutes & Regs" and select the "Reports & Guidance Docs" link from the drop-down menu.

Fifty Years of Service

The Kansas State Board of Pharmacy congratulates the following pharmacists who were originally licensed in 1964, have continuously maintained their Kansas license, and have devoted a half-century of service to the public and the profession. The Board is grateful for their years of contributions to the profession.

George Addleman.....Oberlin, KS
Samuel Barbieri.....Arma, KS
Henry Brauer.....Mexico, MO
Norman Bresel.....Overland Park, KS
Edward Burrichter.....Lawrence, KS
Brenda Denton.....Garland, KS
Larry Denton.....Garland
Thomas Frazier.....Pratt, KS
John Gessler.....Overland Park
Fred Karban.....Wichita, KS
William Kenney.....Overland Park
Orville King.....Lawrence
Phyllis McAdoo.....Lawrence
Mason Ormsby.....Olathe, KS
William Padgett.....Flat Rock, NC
Patrick Porter.....Neodesha, KS
John Reed.....Lawrence
James Rosander.....Westmoreland, KS
Kenneth Stewart.....Lee's Summit, MO
Robert Super.....Topeka, KS
Harry Tishk.....Henderson, NV
Larry Wagerle.....Hutchinson, KS

K-TRACS Update

The number of pharmacy registrants and requests made by pharmacy registrants has increased substantially during the past year. The Board is proud of the increase in utilization of Kansas Tracking and Reporting of Controlled Substances (K-TRACS), and it is continuing to prove to be the most powerful patient care tool to prevent and deter prescription drug abuse. The Board is also pleased that Oklahoma is now using the National Association of Boards of Pharmacy® (NABP®) PMP InterConnect® so you are able to check Oklahoma's records as well as Kansas records.

K-TRACS staff have been working with its technology vendor to provide unsolicited patient alerts on the website through the use of the prescription monitoring program (PMP) software system PMP AWAR$_X$E. K-TRACS will alert the pharmacy with a history of those patients who have been identified as users of multiple pharmacies and prescribers. This will take the place of the threshold letters that are currently mailed to pharmacists and prescribers.

K-TRACS users will also see an improved error description for National Drug Codes that do not match and that are rejected. There will be a better description, and the errors will be easier to fix.

The Board will have an easier time determining whether a pharmacy that dispenses controlled substances (CS) or drugs of concern to patients in Kansas is delinquent in uploading or providing zero reports. The Kansas law requires data to be submitted within 24 hours of the dispensing.

Continuing Education

The pharmacist renewal period is quickly approaching. Make sure that you have your 30 hours of continuing education (CE) taken between July 1, 2013 and June 30, 2015. There is no grace period for CE. The Board is auditing all CE through CPE Monitor® service. The audit will not be conducted until the final date that documents any CE taken on June 30, 2015.

All CE that has been Accreditation Council for Pharmacy Education (ACPE)-accredited will be uploaded in CPE Monitor by the vendor. The only CE that will not be in CPE Monitor is CE that has been Board-approved. Individuals who have CE that was Board-approved will be required to submit their certificates upon request. A list of Board-approved CE is on the Board web page.

If you have not accessed CPE Monitor and are not using it, you will be required to provide copies of your certificates to the Board. To eliminate sending paper certificates in the future, you must first set up an NABP e-Profile, obtain your NABP e-Profile ID, and then register for CPE Monitor by entering your Kansas license information.

The Board regards the failure to comply with the CE rules and regulations requirements for licensure as a serious issue. With the large number of home study, web-based, and live programs available, achieving 30 hours within a two-year period is not viewed as a burden. Accordingly, the penalties assessed by the Board for failure to comply with the CE requirements are far worse than the effort required to complete the minimum 30-hour requirement.

The Board does not accept continuing medical education unless it has been submitted to the CE Committee for approval at least 30 days prior to the event. Likewise, any non-ACPE-accredited CE must have been approved by the CE Committee prior to the event for credit to be awarded. Do not wait until the last day to obtain your CE because if there are software or Internet malfunctions and you are unable to have a properly dated CE certificate, it will not be accepted. For further review of the Board's CE policy and requirements, visit the Board's web page

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under the link for "Licensing & Registration" and select "Pharmacists" from the drop-down menu.

Pharmacy Technician Registration

The Board has updated its web page so that pharmacy technicians may obtain an application online. They may also request a fingerprint card via the Board's website under the link for "Licensing & Registration" and selecting "Pharmacy Technicians" from the drop-down menu. The Board has updated the application and will no longer accept outdated or older technician applications. The new application meets the requirements for information currently required under Kansas law.

Pharmacy technician national certification regulations have been drafted and are currently under review. The new regulations will soon require all pharmacy technicians to obtain CE. The CE will be required regardless of whether the technician has been nationally certified.

Theft or Loss of Controlled Substances

The Board receives Drug Enforcement Administration (DEA) Report of Theft or Loss of Controlled Substances forms (DEA Form 106) each month. The Board has noticed an increase in forms reporting the loss of one bottle of a Schedule II CS. The reason cited is that the bottle was accidentally thrown out in the trash or that the incorrect amount was accidentally dispensed when filling a prescription. The Board has also seen an increase in the theft of Tylenol® with codeine since hydrocodone combination products are now Schedule II CS.

The Board is very concerned about these losses and considers such losses to be unacceptable. It is the pharmacist-in-charge's responsibility to draft policies that prevent the loss of drugs from the pharmacy. The Board suggests a perpetual inventory be taken for Schedule II drugs and that a reconciliation be performed more frequently. Discrepancies discovered during reconciliation should be reported to DEA on the DEA Form 106, available on the DEA website. DEA requires notice within one business day of discovery when the loss is significant (Title 21 Code of Federal Regulations §1301.76 (b)). DEA views "upon discovery" to mean that notification should occur immediately and without delay. Regarding significant loss, there is no single objective standard that can be established and applied to all registrants to determine whether a loss is significant. Pharmacies need to examine their business activities and external environment and implement strong site security. This may require limited authorized access for CS, applying proper drug handling procedures, and utilizing stringent employee screening practices. Please be aware that the most common ways employees divert CS are by short-count dispensing, theft from stock, self-dosing on the premises, bogus written or phoned-in prescriptions, pulling old prescriptions and authorizing refills, and putting filled prescriptions or bottles in the trash or in other items that leave the pharmacy.

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

DEA (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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