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Kansas State Board of Pharmacy News

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Board Launches New Web Site

The Kansas State Board of Pharmacy is pleased to announce the release of its new Web site, designed with a fresh new look and user-friendly navigation. It will be updated with the latest information on proposed regulations and laws, Kansas Tracking and Reporting of Controlled Substances (K-TRACS) information, and applications for licensing and programs. The new design allows users to quickly find the information they need to see. The Board hopes you enjoy browsing its new site, finding more information each time, and that it will be a useful tool for everyone. The Web site can be found at *www.pharmacy.ks.gov.*

New K-TRACS Director for Prescription Monitoring Program

The Board welcomes Marty Singleton to the Board staff as the assistant director and K-TRACS program director. Marty was previously with the Kansas Department for Children and Families and he has a degree in electrical engineering from Kansas State University. Marty has a diverse background including an emphasis in information technology. Marty immediately began working with the Board's new PMP AWAR$_X$E™ software that was developed by the National Association of Boards of Pharmacy® (NABP®) to provide greater flexibility and more services to the Board's K-TRACS program. The software is intended to work seamlessly with NABP PMP InterConnect®. The Kansas Board was the first state to launch the PMP AWAR$_X$E software on July 1, 2013. Marty has been busy making sure that the Board transitions to the new software with ease. The Board is pleased to have someone with Marty's skills join its team.

Change of Address

All licensees of the Board are required to provide a proper and current residence address to the Board and to notify the Board within 30 days of changing that address by giving both the old and new address. Licensees must designate an "Address of Record" that is the address to which all licenses, license and permit renewals, and correspondence from the Board are mailed.

Failing to provide a reliable address does not comply with pharmacy law and can result in the renewal notice not being received by the licensee. Failure to renew in a timely manner may result in the loss of licensure due to nonrenewal, and subsequent cancellation of the license.

Components of Proper Prescribing

The following article has been retracted in the June 2017 Newsletter.

To be effective, a prescription shall be issued for a legitimate medical purpose by a practitioner or mid-level practitioner acting in the usual course of professional practice. While the Kansas State Board of Healing Arts determines whether a physician has met the essential components of proper prescribing, each pharmacist has a corresponding liability in using his or her professional judgment to determine that there is a proper prescriber-patient relationship. Generally, a prescriber should perform and document a physical examination that includes obtaining a legitimate medical history, engaging in sufficient dialogue to form a treatment opinion, determining the risks and benefits of the drug or treatment regimen, scheduling follow-up appointments to assess therapeutic outcome, and maintaining an adequate and accurate medical record before prescribing any medication for the first time. Telephone interviews, Internet questionnaires, or online consultations are not appropriate or acceptable and fail to meet the minimum components of an appropriate examination since they cannot with any certainty provide enough information to make a verifiable diagnosis.

Telemedicine that provides consulting services to assist the primary care physician in rendering a diagnosis using live interactive video or the transmission of diagnostic images, vital signs, and/or video clips along with the patient data or remotely collecting and sending data remotely for interpretation that provides peer-to-peer support are acceptable.

If you receive an Internet prescription, it is incumbent on the pharmacist to determine whether the components of proper prescribing are present. If the prescription is based solely on a telephone or Internet questionnaire it would not be appropriate to fill the prescription. If you have concerns about a prescription, contact your Board inspector.

Licensing and K-TRACS Staff

The Board has two new licensing and K-TRACS staff to assist in any licensing or prescription monitoring program needs. KariAnn Wootan and Kathleen Deeter joined the Board office in November. They both have college degrees and experience that will make them great assets to the agency. They will be working diligently to complete their training and get up to speed as quickly as possible.

From the Board Inspectors: Words to the Wise or at Least a Little Advice

Pharmacist-in-Charge Changes

The regulations require the **resigning** pharmacist-in-charge (PIC) to:

- Notify the Board within five days of resignation. The letter may be mailed or faxed (K.A.R. 68-2-5). The notification must

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Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA's MedWatch Program. More information about this recall is available on the FDA Web site at *www.fda.gov/Safety/Recalls/ucm357909*.

Barcoding Technology for Community Pharmacy

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.*

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology[1] and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies.

Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 2006[2] study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for **not** implementing barcode scanning for product verification, other than cost, included uncertainty regarding the "right" vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy's readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.[3] Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at *www.ismp.org/AHRQ/Default.asp?link=sa.*

[1]*Cochran GL, Jones KJ, Brockman J, Skinner A, et al. "Errors prevented by and associated with barcode medication systems." Joint Comm J Qual Pt Safety. 2007;33(5):293-301.*

Ukens C. "New study sheds light on medication errors." Drug Topics. 2002;146(21):33.

[2]*Skrepnek GH, Armstrong EP, Malone DC, Abarca J, et al. "Workload and availability of technology in metropolitan community pharmacies." J Amer Pham Assoc. 2006; 46(2):154-160.*

[3]*American Hospital Association, Health Research and Educational Trust, Institute for Safe Medication Practices. "Pathways for medication safety: assessing bedside bar-coding readiness." 2002. Accessed on October 15, 2010 at:* www.ismp.org/selfassessments/PathwaySection3.pdf.

ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new *ISMP Medication Safety Alert!* publication, *Long-Term Care Advise-ERR,* as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With *ISMP Medication Safety Alert!* publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at *www.ismp.org/newsletters/longtermcare.*

FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen. "This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications," said Sharon Hertz, MD, deputy director of FDA's Division of Anesthesia, Analgesia, and Addiction Products. "However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal." The full consumer update is available on the FDA Web site at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm363010.htm.*

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm*.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP's VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors – a growing segment of the pharmaceutical wholesale industry – to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit *www.nabp.net/programs/accreditation/vawd.*

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians' offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of "health care provider," and thus may not obtain NPI numbers. The clarification also states that "Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently." CMS also notes that "if a veterinarian fulfills the definition of 'health care provider' in a profession other than furnishing veterinary services," such as if they are also a nurse practitioner, "the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI."

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include the name and address of the pharmacy and the **date** of the last day serving as PIC.

- Return the original registration to the Board office (leave a copy posted).
- Take a final inventory of **all** controlled substances (CS) **(date** and sign) (K.A.R. 68-7-11(o) and 68-7-12(e)).

The regulation (K.A.R. 68-1-2a(b)) requires the pharmacy owner to:

- Obtain a new PIC within 30 days (K.A.R. 68-1-2a(b)). This includes notification and payment of fees to the Board. The date of the new registration must be within the 30 days as there is **no** grace period for this process. **One extension** may be requested.

The regulations require the **incoming** PIC to:

- Pass a PIC test **before** the registration may be issued if the incoming PIC has never served as PIC. This process must be completed in the 30-day period as required (K.A.R. 68-1-2a(a)).
- Take a beginning inventory of **all** CS **(date** and sign) (K.A.R. 68-7-11(p) and 68-7-12(f)).

Technician Training

Per K.A.R. 68-5-15, documentation must be maintained to show that a technician has been adequately trained for his or her job functions. Training manuals and check-off sheets should be available for review by your inspector during inspections. Technician training is required to be documented yearly.

If the technician participates in sterile compounding, there should be specific training information that indicates the type of training the technician was given.

Expiration Dates

- Labels – Prescription labels must have an expiration date/use by date on the label (K.A.R. 68-5-1(a) and 68-7-14(a)(7)). The expiration date should not exceed one year or the manufacturer's expiration date, whichever is **less.**
- Products on shelves – Be sure to run your stock shelves, as a dispensed expired drug is considered adulterated and misbranded.

CQI

This is a quarterly event. At the end of March, June, September, and December, the pharmacy **shall** have a meeting to review **all** reportable incidents. Please refer to the *Kansas State Board of Pharmacy Newsletters* of December 2008 (Changes in Incident Reporting) and September 2009 (Continuous Quality Improvement) (K.S.A. 65-1695 and K.A.R. 68-19-1). The documentation should indicate:

- The **date** the meeting was held.
- **Who** attended the meeting (the PIC shall be in attendance).
- The **type** of reportable incidents with applicable prescription numbers (ties back to incident report).
- **What** preventive step(s) will be used to prevent further incidents of this type. The preventative steps must be **progressive.** This is an opportunity to review whether high prescription volume, distractions, shortage of support personnel, look-alike/sound-alike drug names, inadequate opportunity to counsel, illegible handwriting, or fatigue are contributing to errors. It would be helpful to know whether the errors occurred during peak times, shift changes, or during slower periods when boredom may contribute to a lack of attention. If the preventive step is merely to "slow down," it needs to be accompanied with an analysis of why this was the problem. Continuous quality improvements (CQIs) are required regardless of the number of staff in the pharmacy.

Immunizations

(K.S.A. 65-1635a)

- Is your CPR certification up to date?
- Do you have a signed protocol with a medical doctor or a doctor of osteopathic medicine?
- Have you signed the immunization administration record form indicating which arm was injected and the **lot** number of the vaccine?

Licenses and Registrations

Please post technician registrations and pharmacist licenses where they may be seen. Posting means that they should be hanging conspicuously on the wall (K.S.A. 65-1641 and 1645(e)).

PSE Certification

Is your pseudoephedrine (PSE) certification up to date? Drug Enforcement Administration (DEA) requires pharmacies selling PSE and ephedrine to self-certify that they have trained any employee selling over-the-counter (OTC) drugs that contain PSE or ephedrine. The certification expires yearly and the date is located in the upper right-hand corner of the certificate. Everyone that sells OTC products shall be using the National Precursor Log Exchange (NPLEx) electronic logging system. Failure to use the NPLEx will result in fines for the pharmacy.

Documentation

If it is **not documented, it was not done.**

Cessation of Operations

Per K.A.R. 68-2-10, return registration and provide a written explanation of the disposition of drugs and notation of the relocation of the closed prescription files within five days after termination of operations. All prescription records, electronic files (patient profiles, invoices, and prescriptions), a current inventory of dangerous drugs and devices, and acquisition and disposition records must be maintained for at least five years.

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

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.

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