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Kansas State Board of Pharmacy News

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Change of Address

All pharmacists, technicians, and interns must notify the Kansas State Board of Pharmacy in writing within 30 days of a change of address. Online updates through the license renewal page are also accepted. The Board is required to send notifications to your last known address, so please remain diligent in keeping your information updated.

Treat a Veterinarian Prescription Exactly as You Would a Physician Prescription

If you are filling veterinary prescriptions and you have questions or concerns about the drug prescribed, it is important to contact the veterinarian for clarification. Lowering or raising the dosage or substituting medication may seriously compromise an animal's health. Do not make changes to veterinary prescriptions without first contacting the prescriber because drugs affect animals much differently than humans. After contacting the veterinarian, clarification or any changes made to the original prescription should be documented on the back of the original prescription.

Compounding Issues

Last year's deadly outbreak of fungal meningitis linked to spinal injections of a pain-relieving steroid product produced by the New England Compounding Center in Massachusetts raised serious questions about the oversight of compounding pharmacies and the appropriate role for federal and state regulators. The Kansas State Board of Pharmacy and Kansas Department of Health and Environment participated in a Food and Drug Administration (FDA) intergovernmental meeting on December 19, 2012. There was discussion on whether the states had the resources to provide oversight of pharmacy compounding and whether there was a way to rebalance federal and state participation in the regulation of pharmacy compounding that would better protect the public health.

The Board is very concerned about whether federal preemptions will be enacted that could possibly undermine the Board's authority by removing its oversight in this area. The Board has implemented a plan that includes the adoption of rules and regulations for compounding. The regulations have been approved by the Department of Administration and are currently at the Office of the Attorney General for review. The Board has asked the Office of the Attorney General to expedite these regulations. The inspectors are going to receive additional training related to compounding, and the Board is going to work with the National Association of Boards of Pharmacy® and other states to share its limited resources. The Board has also requested that Board staff seek approval for hiring an additional pharmacist inspector.

If you hold a nonresident permit in another state, be advised that your pharmacy may get an additional inspection from the state in which you are licensed. Make sure that you know the laws of each state that you are registered in related to office use because many states do not allow this practice. The Board will cooperate with any state that wants an additional inspection of your premises.

It is the Board's goal to address the compounding issues in order to adequately protect the public's health, welfare, and safety.

Pharmacies Participating in KHIN Health Information Exchange

The Kansas Health Information Network (KHIN) welcomed its first pharmacy to the KHIN network in December 2012: Funk Pharmacy in Concordia, KS. This is an important milestone as pharmacies are critically important in the development of a statewide health information exchange. Participation of Kansas pharmacies in KHIN improves the health of Kansas patients by ensuring safe and effective medication use and supports the pharmacist's optimized role in health care delivery. KHIN supports pharmacists in improving patient care through the following:

- Pharmacists who utilize KHIN can search for their patients across all participating KHIN providers resulting in more current chronic disease and medication-related data for their patients.
- Pharmacists can improve communication among health care team members through KHIN's secure clinical messaging/DIRECT with over 2,700 KHIN prescribing provider members.
- Participation by pharmacists results in more accurate medication data in KHIN. This supports all KHIN par-

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

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.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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ticipating providers in improving the quality and safety of care.

- Pharmacy participation in KHIN ensures that pharmacist administered immunizations are exchanged electronically with other health care providers and the state immunization registry.

KHIN is a Kansas not-for-profit organization that was established by the Kansas Medical Society, the Kansas Hospital Association, and the Wichita Health Information Exchange in 2010.

Fees for joining KHIN are $100 annually per pharmacist. For more information regarding KHIN, please contact KHIN Executive Director Laura McCrary, EdD, at lmccrary@khinonline.org or visit the KHIN Web site to download the necessary paperwork for eligible providers to join KHIN: *http://khinonline.org/files/Physician_and_Eligible_Provider_Final_Participation_Agreement_2013.pdf.*

Pharmacy Technician National Certification

Last year the Kansas Pharmacy Summit, sponsored by the Kansas Pharmacists Association, was held at the University of Kansas School of Pharmacy. The Pharmacy Summit gives pharmacists, in all practice settings, an opportunity to discuss emerging issues or concerns in the practice of pharmacy.

One of the areas of concern was the need to increase technician training and education. Currently the Board registers pharmacy technicians before they can work in a pharmacy. Approximately 18% of technicians do not renew their permit each year, so there is a very high turnover. National certification would not only increase the pharmacy technician's knowledge and reduce on-the-job training, but it would improve job satisfaction and provide a more qualified work force.

Linda Radke, RPh, a member of Kansas Society of Health-System Pharmacists, gave an informational presentation to the Board recommending that the Kansas Pharmacy Act be amended to require national certification of technicians. Mike Larkin, of the Kansas Pharmacists Association, agreed to chair a task force so that legislation and regulations could be drafted with the necessary requirements. In order to accomplish this task, a broadly drafted bill was filed in the 2013 Legislative Session with amendments to be developed by the task force. The task force will now meet and discuss all issues related to pharmacy technician certification and educational requirements. The task force meetings are open to everyone and your opinion is important to this group. If you cannot attend the meetings but would like to provide input, notify Mike Larkin at Mike@kpha.org. This group will discuss related items such as pharmacy technician ratio and whether to grandfather current pharmacy technicians, so please let us know where you stand on these issues. The Board supports the endeavors of these groups and would like to make sure that everyone is involved in the process because it will affect everyone's practice.

Compliance Issue

Community pharmacies are once again being solicited to fill invalid prescriptions generated over the Internet. One company is faxing pharmacies offering pharmacy owners a chance to fill 100 prescriptions a day and to act as a fulfillment partner. These prescriptions are generated over the Internet, solely on the basis of an online questionnaire, without benefit of a legitimate patient-prescriber relationship. The Kansas Pharmacy Act specifically addresses these relationships as a violation of the law and falling below the standard of care.

Board Meeting Dates

Board meetings are open to the public. You can receive continuing education credit for attending a Board meeting. The Board will meet next at the following locations:

March 28 and March 29.....University of Kansas School of Pharmacy
2010 Becker Dr
Lawrence, KS

June 6 and June 7.....800 SW Jackson, Lower Level
Topeka, KS

September 18 and 19.....Location to be announced

November 21 and 22.....Via Christi Hospital
3600 E Harry
Wichita, KS

Useful Contact Information

Kansas State Board of Pharmacy.....785/296-4056
1-888/792-6273

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

FDA Center for Drug Evaluation and Research.....1-855/543-3784

Kansas Pharmacists Association.....785/228-2327

Kansas Pharmacists Recovery Network.....785/217-7091

Kansas Tracking and Reporting of Controlled Substances 785/296-6547

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