



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Announcements

- ◆ The Kansas State Board of Pharmacy has named Carly Haynes, RPh, as the new director of compliance. Carly has been with the Board for over 14 years. She is licensed as a registered pharmacist in Kansas and as a doctor of pharmacy in Oklahoma. She has completed specialized training in United States Pharmacopeia Chapter <797> from CriticalPoint, LLC, and Campbell University, and she holds credentials in sterile compounding and advanced inspector/investigator training.
- ◆ More new regulations coming soon! The Board is considering several new and amended regulations, which will be available for public comment. To stay up to date, visit the following page on the Board website: <http://pharmacy.ks.gov/statutes-regs/proposed-changes>.
- ◆ Visit www.PreventOverdoseKS.org for the most up-to-date information from the Centers for Disease Control and Prevention (CDC) about prescription drug overdose and misuse in Kansas.
- ◆ The Board is adding a part-time pharmacy compliance inspector position in the Johnson and Wyandotte County areas. The detailed announcement and job description can be found at www.admin.ks.gov/services/state-employment-center/job/job-postings?id=187604.

K-TRACS Statewide Integration

The Board, along with the Kansas Department of Health and Environment (KDHE), is pleased to announce a new partnership with Appriss Health to provide interoperability services for all prescribers and pharmacists in Kansas to access K-TRACS, the Kansas prescription drug monitoring program, through PMP Gateway. PMP Gateway allows authorized prescribers and pharmacists to access K-TRACS data through an integrated approach with electronic medical/health records and pharmacy management systems. The project is funded by a grant from the CDC awarded to KDHE. Grant funds will support PMP Gateway connection costs for each Kansas electronic health records and pharmacy management system approved for integration.

For more information and to request integration, please visit <http://pharmacy.ks.gov/k-tracs/k-tracs-statewide-integration>. Integrations must be approved by the Board and will require reporting to the Board regarding such connections.

2018 Retail Dealer Renewals

Board retail dealer permits expire **February 28, 2018**. Permits may be renewed either online or by mail from mid-January 2018 through February 28, 2018. For renewal instructions, visit <http://pharmacy.ks.gov> and click “Retail Dealer Renewal.”

Online: Use the Board’s secure online payment portal to renew each permit. If you do not have a username and password from 2017, or have forgotten yours, click “Sign-Up” under “Existing Licensee Registration” and create a username and password. Log in to your account and select “Renew License,” which will bring you to a page where you can complete your renewal, pay the renewal fee of \$10 (plus a transaction fee) by credit/debit card or electronic check, and **immediately print your 2018 permit**. Electronic renewals must be date/time-stamped on or before 11:59 PM CST on February 28, 2018.

Mail: Paper forms can be found on the Board’s website and filled out electronically for individual or multiple permits. The forms must be postmarked or hand-delivered no later than February 28, 2018, to the Board office along with a check or money order made payable to the **Kansas State Board of Pharmacy**. Please allow 10 business days for the Board to process your renewal. To verify that your renewal has been processed, visit the License Verification page on the Board’s website and check for the updated expiration date.

Failing to renew on or before 11:59 PM CST February 28, 2018, will result in your permit being canceled. You will then be required to complete a new application. The facility cannot sell nonprescription medications until the new application is submitted and approved by the Board.

.Pharmacy Domain Signals Safety on the Web



With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced “dot pharmacy”) is part of a website’s address like “.com” or “.biz”: www.safe.pharmacy. It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval™ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit www.safe.pharmacy/apply.

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

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.

As health care organizations move toward a “Just Culture,” one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to “negligent” or “criminal” conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- ◆ educate patients about safe use of prescription opioids;
- ◆ remind patients to store medications out of children’s reach in a safe place; and
- ◆ talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at www.ama-assn.org/opioids-disposal. Options for disposing of medications safely are available in the Initiatives section of the NABP website at www.nabp.pharmacy under AWAR_xE®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

News to a particular state or jurisdiction can only be ascertained such state or jurisdiction.

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at www.cdc.gov/dhbsp/pubs/docs/ccl-pharmacy-guide.pdf.

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health*, discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at www.fda.gov/Drugs/DrugSafety/ucm549679.htm, FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- ◆ A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- ◆ A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- ◆ A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and

18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

- ◆ A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at www.fda.gov/safety/medwatch.

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*, contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at www.cdc.gov/dhbsp/pubs/docs/CPA-Team-Based-Care.pdf.

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide*, which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.

Board Adopts Amended Regulations

At its meeting on November 8, 2017, the Board adopted several amended regulations, which are summarized below.

Kansas Administrative Regulation (K.A.R.) 68-1-3a relates to the number of intern hours a pharmacist applicant is required to have for licensure in Kansas. This regulation is amended to increase the number of hours to 1,740 clock hours. This change is consistent with national standards and current training requirements for the University of Kansas and University of Missouri–Kansas City schools of pharmacy.

K.A.R. 68-7-12a deals only with nonresident pharmacies. Amendments require each nonresident pharmacy to designate a pharmacist-in-charge (PIC), who must be licensed as a pharmacist in Kansas, and require all practicing pharmacists employed by or under contract with that nonresident pharmacy to be licensed in the state where that pharmacist is practicing. The Board will give sufficient time for nonresident pharmacies to comply with the new PIC licensure requirements, and additional details will be provided in the near future. The amendments require each nonresident pharmacy to provide the Board with a satisfactory inspection conducted within the previous 18-month period by the nonresident pharmacy's state board of pharmacy. If no state inspection is available, the nonresident pharmacy may, at its own expense, contract with a Board-approved third party for an inspection. An example of a Board-approved third party might be the National Association of Boards of Pharmacy's® Verified Pharmacy Program®.

K.A.R. 68-7-15 governs the prepackaging and repackaging of drugs in the pharmacy. This regulation is being amended to allow pharmacists to dispense and repack a prescribed medication with an ingestible event marker designed to ensure medication adherence. With a valid prescription for each, a pharmacist can repack the prescribed medication and the Food and Drug Administration-approved device in the same capsule, so they can be ingested simultaneously. The device then communicates with a patch on the patient's body, which transmits data to an app and can be viewed by the patient, prescriber, and pharmacist. The device monitors medication adherence, including when and whether a patient is taking the drug as prescribed, and further communicates heart rate, steps, and other physical metrics.

The Board is amending **K.A.R. 68-7-20** to require each pharmacy participating in shared services to be actively engaged in operating its pharmacy.

Amendments to **K.A.R. 68-11-2** are in response to House Bill 2055, passed during the 2017 legislative session, which included new facility registration categories based on the federal Drug Supply Chain Security Act, including third-party logistics providers, outsourcing facilities or virtual outsourcing facilities, repackagers, and automated dispensing systems. In addition, the fee for retail dealers is being rounded to the nearest dollar amount (\$10).

Intern Authority to Administer Immunizations

Any pharmacist or intern may administer an influenza vaccine to a person six years of age or older and may administer any other vaccine to a person 12 years of age or older pursuant to a protocol if he or she has successfully completed a Board-approved or Accreditation Council for Pharmacy Education-accredited course in vaccination storage, protocols, injection technique, emergency procedures, and record keeping and has a current CPR certificate. At a recent continuing pharmacy education event, a question arose about whether the intern's supervising pharmacist was also required to be "immunization certified." The answer is: Yes, if an intern is certified to administer immunizations, the intern's supervising pharmacist must also be certified in order to properly supervise the intern. Please note that interns have their own, independent authority to administer immunizations, so this is not a "delegation" of the pharmacist's function. It is merely a matter of proper supervision: a pharmacist cannot properly supervise an intern providing immunizations if that pharmacist is not also certified to provide immunizations.

Upcoming Events

March 8, 2018

Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka, KS

June 14, 2018

Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka

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