June 2017

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Announcements

- Facility permits are eligible for renewal through June 30, 2017. Use eLicensing to renew each permit individually, pay using the secure portal, and immediately print the 2017 permit. If additional copies are needed later, log back in and print/download a copy.
- The Kansas State Board of Pharmacy and staff want to express sincere appreciation to David Schoech, RPh, and Jim Garrelts, PharmD, for eight years of outstanding service to the Kansas pharmacy community while serving as members of the Board. They will be missed, but the Board looks forward to welcoming two new members soon!
- **CDC STEADI Fall Prevention:** The Centers for Disease Control and Prevention (CDC) launched a new training initiative, Stopping Elderly Accidents, Deaths, & Injuries (STEADI): The Pharmacist's Role in Older Adult Fall Prevention, developed in collaboration with the American Pharmacists Association. CDC is excited to be working specifically with pharmacists; as some of the most accessible members of the health care team and as medication experts, pharmacists can play a pivotal role in helping older Americans prevent falls. The free, interactive online training, accredited by the Accreditation Council for Pharmacy Education (ACPE), is designed to provide pharmacists with the knowledge and resources to screen older adults for fall risk, assess modifiable risk factors such as medication use, and intervene to improve older adults' health and reduce falls. Pharmacists are encouraged to take a look at a video trailer on CDC's STEADI training page. It is CDC's hope that you will find this training useful and help disseminate it to your partners.

Facility Inspection Reports

The Board is pleased to announce the newest enhancement to its eLicense program, with completion of the inspection data migration and reformatting of the inspection forms, reports, and processes. As part of this enhancement, Board inspectors have already begun utilizing electronic inspection forms while conducting inspections. At the conclusion of an inspection, reports will be sent to the facility via email. The new inspection forms and reports are more detailed, include 13 different facility types, and are source-referenced using federal and state laws and regulations, which allows for a thorough and comprehensive review of compliance and a facility-focused inspection.

Examples of blank inspection forms are now available on the Board website under "Business and Facilities." Please reference the forms to familiarize facility staff with the compliance measures that will be assessed at your next inspection. Facilities may use the inspection forms as a tool to conduct self-inspections or research details about certain expectations or violations.

Another enhanced feature is that a facility will now have 24/7 online access to its inspection reports with print/download capabilities. This functionality has been added in each facility's eLicense portal, which can be accessed with the same login credentials used for facility permits and renewals. Please note that inspection reports are only available for inspections conducted after April 1, 2017.

Pharmacist Renewals

Pharmacist licenses expiring June 30, 2017, are now eligible for renewal. To renew, visit the eLicensing portal on the Board website to set up a username and password, review and update contact information and other required items, answer the disciplinary history questions, and complete the renewal certification. Use the secure payment processing portal to submit your payment by credit card, debit card, or electronic check. Online renewals must be date/time-stamped on or before 11:59 PM CDT on June 30, 2017. All other renewals will be considered late and will require payment of the late fee, and pharmacists are not authorized to practice until the renewal (and late fee) are submitted to the Board office.

Pharmacists are required to have completed 30 hours of continuing pharmacy education (CPE) between July 1, 2015, and the date of their renewal (no later than June 30, 2017). Hours reported to CPE Monitor® do not need to be submitted to the Board. Other certificates of completion for CPE must be submitted to the Board prior to renewal. Submissions can be made by mail, fax, or email to pharmacy@ks.gov. There is no grace period for completion of CPE.

To verify your renewal has been received, visit the Board's License Verification page and check for the updated

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DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

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expiration date. You should also receive a confirmation email when renewing online.

If you have any questions regarding the renewal process, visit the Board website and review the renewal instructions for your license/registration type and the Board's frequently asked questions. If after reviewing this information, you are still unable to resolve your issue, please email the Board at pharmacy@ks.gov and a staff member will respond as soon as possible.

Staff Additions

The Board welcomes Mr Fan Xiong, who joined the staff as its Kansas Data-Driven Prevention Initiative epidemiologist. Fan graduated from Berry College in Georgia with a bachelor of science degree with honors in political science and government. He then moved on to the University of Georgia (UGA) College of Public Health, where he graduated with a master of public health degree in epidemiology and a certificate in disaster management. While at UGA, he was certified as a ham radio operator and completed various certifications related to disaster management and crisis communication. Fan was also a member of the Cancer Research Working Group, where he worked on the mortality and incidence of brain cancer disparity in Georgia. After graduating, he was accepted and has recently completed his requirements to graduate as a member of the Council of State and Territorial Epidemiologists and CDC Applied Epidemiology Fellowship for the Class of XIII. During his fellowship at the Kansas Department of Health and Environment, he focused on developing public health surveillance capacity in prescription drug epidemiology. Fan has also presented on various topics related to prescription drug epidemiology at local, state, and national conferences. In his free time, he likes to visit art galleries and indulge in watercolor, acrylic, and oil painting with his wife, play in competitive chess tournaments, and tackle difficult mathematical and philosophical questions.

Notice on Telehealth Prescriptions

Recent reports to the Board indicate that reliance on an article from the December 2013 *Kansas State Board of Pharmacy Newsletter* titled "Components of Proper Prescribing" has been cited by Kansas pharmacists in declining to fill prescriptions written by Kansas-licensed prescribers operating under the telehealth model. Unfortunately, this has inadvertently resulted in frustration and obstacles for health care consumers in Kansas. Please note that there is **no** provision in the Kansas Pharmacy Practice Act that prevents filling telehealth prescriptions as long as they otherwise comply with all state and federal law, including the Ryan Haight Online Pharmacy Consumer Protection Act. To assuage concerns regarding compliance with the Pharmacy Practice Act, the Board hereby retracts the aforementioned article.

Statewide Protocol for Dispensing Naloxone

Thanks to a multiprofessional workgroup, legislation was introduced and passed in the Kansas Legislature that establishes requirements for a licensed pharmacist to dispense emergency opioid antagonists to patients and bystanders pursuant to a statewide protocol adopted by the Board. The law allows for a first responder, scientist or technician operating under a first responder agency, or a school nurse to possess, store, and administer emergency opioid antagonists as clinically indicated, provided they receive adequate training. In addition, any individual who, in good faith and with reasonable care, dispenses or administers an emergency opioid antagonist pursuant to the new law is not subject to civil liability, criminal prosecution, or any disciplinary action by a professional licensure entity. House Bill 2217 will go into effect on July 1, 2017, and adoption of the associated regulations and protocol will follow shortly thereafter. Copies of the draft regulation and protocol are available for review on the Board website at *http://pharmacy.ks.gov/statutes-regs/proposed-changes* and are open for public comment. This law will not impact the availability of naloxone through traditional provider prescriptions.

Pharmacy Updates From the 2017 Legislative Session

The Kansas Pharmacy Practice Act was updated to mirror the federal Drug Supply Chain Security Act, including definitions, registration categories, and requirements for third-party logistics providers, outsourcing facilities, and repackagers, as well as adjustments for wholesale distributors and manufacturers. Board authority has been expanded to allow discipline for misdemeanors of moral turpitude or gross immorality, false or fraudulent attempt to obtain licensure/registration, failure to comply with a Board order/directive, and violation of any provision of the Prescription Drug Monitoring Program Act. In addition, the Board now has authority to regulate sterile and nonsterile compounding and is currently reviewing regulations to bring Kansas up to speed with United States Pharmacopeia requirements. Other changes include requirements for pharmacy technician name tags and passage of a certification exam; regular and timely updates to the Board for pharmacist, technician, and intern employment and contact information; and biological product exchange/interchange.

Annual updates to the Kansas Controlled Substance Act include:

- Schedule I
  - AH-7921
  - Beta-hydroxythiofentanyl
  - Butyryl fentanyl
  - Furanyl fentanyl
  - O-desmethyltramadol
  - U-47700
  - Etizolam
- Schedule II – Thiafentanil
- Schedule IV – Cannabidiol, when comprising the sole active ingredient of a drug product approved by Food and Drug Administration
- Schedule V – Brivaracetam

The Board was granted an expansion of its emergency scheduling authority for analogs of controlled substances scheduled in Kansas and substances posing an imminent hazard to the public safety. The Board may initiate the scheduling process on its own motion or upon report from another individual or organization. Scheduling expires on July 1 of the following calendar year and requires a report to the legislature for consideration of permanent scheduling.

Pharmacy advocates were successful in gaining additional immunization authority for Kansas pharmacists. Effective

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July 1, 2017, 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 ACPE-accredited course in vaccination storage, protocols, injection technique, emergency procedures, and record keeping and has a current CPR certificate. Please provide notice of such certification to the Board to have your license reflect that you are "Immunization Certified." Also, make sure to update the immunization protocol with a physician to provide additional immunizations to minors ages 12-18.

Complete copies of all new laws and pending regulations can be found on the Board's website at *http://pharmacy.ks.gov/statutes-regs/proposed-changes.* An update to the Word and pdf versions of all Board statutes and regulations will be available July 1, 2017, at *http://pharmacy.ks.gov/statutes-regs/statutes-regs.*

Pharmacy Technician CE

In the fall of 2016, the Board adopted new regulations requiring 20 hours of continuing education (CE) for pharmacy technicians to renew a registration in Kansas.

The CE you complete may be approved for pharmacists or pharmacy technicians or may be earned for national certification. However, all CE must be approved by one of the following:

(1) ACPE. To receive credit, register through CPE Monitor.

(2) Another state board of pharmacy. To receive credit, submit a copy of your certificate of completion to the Kansas Board within 30 days of course completion.

(3) The Kansas State Board of Pharmacy. To get CE approval from the Board, submit a request for approval to the Board at least 10 days prior to the course using the E-200 Request Form. A list of pre-approved Kansas CE courses is also available on the Board website. To receive credit, submit a copy of your certificate of completion to the Board within 30 days of course completion.

For registrations expiring **October 31, 2017,** only 10 hours of CE are required for renewal. This CE must be earned between September 1, 2015, and the date of renewal.

For registrations expiring **October 31, 2018,** 20 hours of CE are required for renewal. This CE must be earned between September 1, 2016, and the date of renewal.

K-TRACS Confidentiality and Records Release

One of the highest priorities for Kansas Tracking and Reporting of Controlled Substances (K-TRACS) is the security and confidentiality of an individual's prescription records. Please remember to not copy and share anyone's K-TRACS report. The Board understands that while speaking with a prescriber regarding a patient, it is easy to say you will send the prescriber a copy. Instead of forwarding the information, please encourage the prescriber to enroll in K-TRACS and acquire the information through his or her own account. When dealing with law enforcement, do not give them a copy of the profile. Instead, inform the officer/detective/agent to acquire a subpoena for said records and forward that document to the K-TRACS office. Remember, Kansas Statutes Annotated (K.S.A.) 65-1693(b) states, "A person authorized to have prescription monitoring information pursuant to this act who knowingly discloses such information in violation of this act shall be guilty of a severity level 10, non-person felony." However, the statute does not prevent the dispenser and prescriber from discussing an individual so that said patient can obtain the best possible care. K.S.A. 65-1693(e) states, "It shall not be a violation of this act for a practitioner or dispenser to disclose or use information obtained pursuant to this act when such information is disclosed or used solely in the course of such practitioner's or dispenser's care of the patient who is the subject of the information."

Upcoming Events

August 4, 2017

Prescription Monitoring Program Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka, KS

August 17, 2017

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

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® (NABPF®) 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 NABPF or the Board unless expressly so stated.

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