



# Kansas State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **K-TRACS Education and Best Practices**

The Kansas prescription monitoring program (PMP), better known as Kansas Tracking and Reporting of Controlled Substances (K-TRACS), has seen a steady increase in use in 2016. Data collected by K-TRACS is a valuable tool to help prescribers and pharmacists treat patients using accurate and timely controlled substance (CS) prescription information. Therefore, it is essential that the quality of the information reported to K-TRACS is accurate and complete. There are many instances where data is entered into the wrong field by the dispenser or simple data entry errors occur. Common examples include reporting the wrong patient gender, inverting numbers in a date field, adding extra characters to a patient name, or simply inserting the prescription fill date in the date of birth field. When considering the volume of data a pharmacy records in a single day, the data received by K-TRACS is usually useful and of good quality. However, any error may impact the care a patient receives.

To ensure quality care, it is imperative that dispensers are aware of the information contained in patient profiles. The two main reasons a patient cannot be confirmed in K-TRACS are variations in the patient's name or date of birth. It is a best practice to always use the patient's legal name instead of a nickname. Also, any notes or numbers in the patient's name will transfer to K-TRACS, which makes it difficult to guarantee you have the correct patient when querying the system and matching records. Similarly, if the pharmacy has an incorrect date of birth, problems ensue. This is sometimes done purposefully for insurance purposes, but please encourage the patient to correct this information with his or her insurance company so K-TRACS data may be reported accurately and effectively.

To guarantee K-TRACS contains correct data, please verify that the patient's name and date of birth are correct in the patient's profile before dispensing. Also, having a correct phone number is extremely helpful when

identifying a patient. Patients tend to maintain the same phone number over time, even when they have had changes in address, legal name, or other identifiers. Additionally, be cautious when entering the prescriber's information and Drug Enforcement Administration (DEA) number, as it is imperative that this information is correct.

Data accuracy checklist:

- ◆ Legal name
- ◆ Gender
- ◆ Date of birth
- ◆ Phone number
- ◆ Prescriber name
- ◆ Prescriber DEA number

Pharmacists should also consider what time of day the pharmacy reports data to K-TRACS. Once data is reported, it cannot be corrected or deleted from K-TRACS. If the pharmacy reports all "fills," K-TRACS may show prescriptions that were never dispensed to the patient. This can create an inaccurate prescription history for a patient who has a CS prescription filled but never picks it up from a pharmacy. This can be resolved either by reporting to K-TRACS only at the point of sale or by backing out a transaction that is not picked up **prior** to the pharmacy's electronic system reporting to K-TRACS for that 24-hour period.

With your assistance in entering and transmitting complete and accurate data to K-TRACS, it will continue to be a valuable tool for both prescribers and dispensers to ensure each patient has the best possible health care.

## **2016 Technician Renewals**

Pharmacy technicians with licenses expiring October 31, 2016, can renew online beginning September 6.

Renewal instructions are as follows:

- ◆ Visit <http://pharmacy.ks.gov> and click "[Technician Renewal](#)."

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## **FDA Calls for Review of Opioids Policy, Announces Action Plan**

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- ◆ Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- ◆ Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- ◆ Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- ◆ Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- ◆ Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- ◆ Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- ◆ Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- ◆ Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm).

## **More Selected Medication Safety Risks to Manage in 2016**



*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](http://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](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

## **Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags**

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as  $154 \text{ mEq}/0.9\% = x/3\%$  and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag ( $77 \text{ mEq}/0.9\% = x/3\%$ ).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

## **Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications**

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,<sup>1-5</sup> and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.<sup>6</sup> The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

most of these errors happened within the first 14 days after discharge.<sup>5</sup> The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).<sup>4</sup>

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

## References

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## USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings*, has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at [www.usp.org](http://www.usp.org) in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium*.

## FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, “Emergency Preparedness – Keeping Medications Safe,”

pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

## FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency’s effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency’s approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery).

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA’s Drug Safety Communication announcement, available at [www.fda.gov/Drugs/DrugSafety/ucm489676.htm](http://www.fda.gov/Drugs/DrugSafety/ucm489676.htm).

## FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus’ facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at [www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm](http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm).

- ◆ Under New User Registration, click “Sign-Up” and create a username and password.
- ◆ Log in to your new account and select “Renew License.”
- ◆ Review and update information, answer disciplinary questions, and submit the renewal.
- ◆ Use the Kansas State Board of Pharmacy secure online payment portal to pay \$20 plus a small transaction fee by credit/debit card or electronic check, **or** follow the instructions to print and mail a \$20 check or money order to the Board.
- ◆ Allow 10 business days for the Board to process your renewal.
- ◆ Visit the Board’s [License Verification](#) web page to check for an updated expiration date.

**Failing to renew on or before 11:59 PM CDT on October 31, 2016, will result in the registration being canceled.** Canceled technicians will be required to complete a new application and fingerprint card to continue working (\$68 cost).

Pharmacies utilizing/employing technicians with canceled registrations will be in violation of the Kansas Pharmacy Practice Act and may be disciplined by the Board.

### **Staff Additions**

Reyne Kenton recently accepted the position of K-TRACS program manager at the Board office in Topeka, KS. Reyne has been with the Board for 14 years as a pharmacy compliance inspector in the western Kansas region. She brings to K-TRACS a knowledge of pharmacy not only from the regulatory side, but from the retail side as well. Reyne will be responsible for managing K-TRACS and working with the PMP Advisory Committee to continue enhancing and improving the tools and resources in Kansas.

The Board welcomes Kayla Jones as the new pharmacy compliance inspector for western Kansas. Kayla is a native of Larned, KS, and worked in law enforcement for over six years prior to entering the pharmacy world. She is a certified pharmacy technician with more than six years of experience in the pharmacy setting and was most recently an assistant manager for a national retail pharmacy chain. Kayla will be covering the western Kansas counties from Morton to Cheyenne to Smith to Barber and back to Morton.

### **Board Adopts New Regulations**

At its meeting on July 14, 2016, the Board adopted several regulations on automation, exam scores, intern registration fees, and continuing education (CE) for pharmacists and technicians, which can be found on the Board website at <http://pharmacy.ks.gov/statutes-regs/proposed-changes>. These regulations became effective on August 19, 2016. The following are short summaries of the regulations.

#### **K.A.R. 68-1-1b. Continuing education for pharmacists.**

- ◆ Creates additional requirements for pharmacists to obtain CE hours during the previous two-year licensure period and to provide proof of such to the Board.
- ◆ All continuing pharmacy education (CPE) appearing on CPE Monitor® will be automatically uploaded and available to the Board without any additional requirements for pharmacists. CPE Monitor is a collaborative service from the National Association of Boards of Pharmacy® (NABP®) and the Accreditation Council for Pharmacy Education (ACPE).
- ◆ Adds new requirements for non-ACPE-accredited CE to be submitted to and approved by the Board and for CE providers to distribute certificates of completion to pharmacists.

#### **K.A.R. 68-5-18. Continuing education for pharmacy technicians.**

- ◆ Adds new 20-hour CPE requirement for all technicians for each biannual renewal period.
- ◆ All CPE appearing on CPE Monitor will be automatically uploaded and available to the Board without any additional requirements for technicians.
- ◆ Adds new requirements for non-ACPE-accredited CE to be submitted to and approved by the Board and for CE providers to distribute certificates of completion to technicians.
- ◆ Creates requirements for non-ACPE-accredited CE to be submitted to and approved by the Board and for CE providers to distribute certificates of completion to technicians.
- ◆ Guidelines for future renewal groups:
  - ◇ 2016 renewals – no hours required
  - ◇ 2017 renewals – 10 hours required, earned between September 1, 2015, and October 31, 2017
  - ◇ 2018 renewals – 20 hours required, earned between September 1, 2016, and October 31, 2018

**K.A.R. 68-1-1f and 68-1-1g. Foreign graduates and the Test of English as a Foreign Language Internet-based test (TOEFL iBT).** This regulation outlines the requirements, including passing the TOEFL iBT, for graduates of foreign pharmacy programs who are seeking licensure in Kansas. The amendments update the passing scores to comply with NABP standards, as well as requiring the TOEFL be internet-based.

**K.A.R. 68-11-3. Fees.** Beginning September 1, 2016, this regulation sets the fee for an intern registration at \$20.

**K.A.R. 68-7-10. Pharmacy-based drug distribution systems in long-term care facilities.** This regulation is amended to allow and regulate automated drug delivery systems in long-term care facilities.

**K.A.R. 68-9-2. Automated drug delivery systems in pharmacies.** This regulation is amended to allow and regulate automated drug delivery systems in pharmacies.

**K.A.R. 68-9-3. Automated drug delivery system to supply drugs for administration in certain facilities.** This new regulation sets forth the requirements for automated drug delivery systems in medical care facilities, institutional drug rooms, and long-term care or nursing facilities. The regulation includes duties, responsibilities, and standards for the pharmacist-in-charge (PIC), regulates who may access the system, and establishes criteria for the drugs that may be stored in an automated system and the process for tracking, monitoring, and managing the system.

### **Old Forms Out, New Forms In**

Beginning August 1, 2016, the Board began accepting only current versions of Board forms. Old forms will be returned (with payment) directly to the sender without processing. Visit the Board's [Forms page](#) for the new, updated, electronically fillable forms – all in one central location! The Board even has a new, quick “Change in PIC” form. Make sure you are using the most up-to-date version by checking the “Revised” date in the bottom right-hand corner of each form!

### **PIC Notification Requirements**

According to the Kansas Pharmacy Practice Act, each resident and nonresident pharmacy, health department, family planning clinic, and institutional drug room shall have a designated PIC. A PIC is the pharmacist who is responsible to the Board for the pharmacy's compliance with Kansas laws and regulations pertaining to the practice of pharmacy, manufacturing of drugs, and distribution of drugs. The PIC shall supervise the pharmacy on a full-time or part-time basis and perform duties relating to supervision of the pharmacy as outlined by the Board.

Each pharmacist ceasing to serve as the pharmacy's PIC shall notify the Board within five days of his or her last day of work. The easiest method is to use the “Change

in PIC” form ([BA-50](#)) in conjunction with the employer/pharmacy; however, letters of resignation containing the required information will also be accepted. The outgoing PIC is also required to complete an inventory of all CS, unless terminated for cause.

Each pharmacy (resident or nonresident) that operates for more than 30 days without a PIC is subject to discipline. This 30-day deadline includes making proper notification to the Board of the PIC change ([Form BA-50](#)) and the new PIC completing any required exam. Each incoming PIC is also required to complete an inventory of all CS within 72 hours of starting. Failure to comply with these requirements may result in disciplinary action against a license or registration. See K.S.A. 65-1626, 65-1637, and 65-1643, and K.A.R. 68-1-2a, 68-2-5, 68-7-12, and 68-7-12a.

### **Upcoming Events**

#### **October 28, 2016**

PMP Advisory Committee Meeting  
800 SW Jackson, Lower Level, Topeka

#### **November 3, 2016**

Board of Pharmacy Quarterly Meeting  
Via Christi Hospital St Joseph  
Third Floor, Conference Room A  
3600 E Harry, Wichita, KS

#### **January 12, 2017**

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