March 2021

# Kansas State Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## Announcements

- Regular updates regarding Kansas State Board of Pharmacy guidance and information on coronavirus disease 2019 (COVID-19) can be found on the Board website. This includes information about operations, waivers, renewals, exams, fingerprinting, inspections, pharmacy frequently asked questions (FAQs), and more. The Board has extended remote work options through June 2021.
- The University of Kansas School of Pharmacy is looking for pharmacist volunteers to participate in a research study. Licensed pharmacists over the age of 18 will be asked to complete a 60-minute interview and share views around corresponding responsibility. Pharmacist participation should cause no more discomfort than one would experience in everyday life. If selected, participants will receive a $50 ClinCard gift card. If interested, please contact Kristin Villa, MS, PharmD, PhD, RPh (kvilla@ku.edu) to inquire about participation.
- The 2021 Kansas Prescription Drug Monitoring Program (K-TRACS) Annual Report is available on the K-TRACS website under the section titled Advisory Committee.
- Follow the new K-TRACS Facebook page at *https://www.facebook.com/ktracs.*
- Follow the Board on Twitter @KSBOP or on Facebook *(www.facebook.com/KansasStateBoardOfPharmacy)* for news, updates, and more!

## Committee on Impaired Pharmacy Practice Seeks New Members

The Kansas Pharmacists Recovery Network (KsPRN), a confidential voluntary program established by the Board and administered by the Kansas Pharmacists Association and the Committee on Impaired Pharmacy Practice (CIPP), seeks members to serve on the committee.

CIPP monitors the program's participants and offers recommendations to the Board concerning participant progress in the program. KsPRN helps participants work toward overcoming impairment issues and assisting affected licensees with rehabilitation and recovery in a safe and confidential manner to protect the public safety and pharmacy profession.

Pharmacists and pharmacy interns struggling with impairment due to physical or mental disabilities, including deterioration through the aging process, loss of motor skill, or substance abuse are encouraged to seek treatment and rehabilitation while maintaining the confidentiality inherent in the KsPRN program. In many cases, the participant will be able to continue practicing pharmacy during their recovery process.

CIPP and KsPRN assures all participants complete confidentiality. In the case of self-referred participants, no one outside of KsPRN, not even the Board, will be notified of a self-referred pharmacist's condition, unless they fail to comply with the recommendations of KsPRN/CIPP and/or an evaluator.

Pharmacists interested in serving on CIPP should contact Leonard Allen, KsPRN manager, at leonard@ksrx.org or 785/228-2327. Members meet once per quarter and make a difference for an entire year.

Pharmacists or pharmacy interns struggling with impairment should also reach out for assistance. For more information, visit the KsPRN website.

## What Does Compliance Look Like?

### How to Locate a Kansas Statute or Regulation for Pharmacy Practice

On the inspection reports, the citation is placed in the area heading or at the end of each item. Licensees can access all Kansas statutes and regulations on the Board website under the Legal tab. The document is searchable. The FAQs on the website will also give the citation. Please use the citations to help understand and remain compliant with the Pharmacy Practice Act. "K.S.A." stands for Kansas Statutes Annotated and "K.A.R." stands for Kansas Administrative Regulations. If the citation is 21 CFR, it references a federal regulation.

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# National Pharmacy Compliance News

**March 2021**

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.


## DEA Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

## Time to End VinCRIStine Syringe Administration

*This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.*

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

**References**


1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*


## What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

*This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.*

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

## Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

## Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

## What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

## Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

## Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

## Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

# *Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA*

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

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### Self-Inspections

This has been a fantastic learning adventure for pharmacists and pharmacies. Many pharmacists-in-charge (PICs) have found areas they need to improve, which is why the forms were changed. Before, the pharmacy was either compliant or noncompliant. Now, there is an option to cite movement toward compliance – Needs Improvement (NI). The following are examples of areas of improvement:

- Access to current Kansas Pharmacy Laws/Regulations – Kansas Statutes Annotated (K.S.A.) 65-1642 and Kansas Administrative Regulations (K.A.R.) 68-2-12a.
- Central record keeping – 21 Code of Federal Regulations (CFR). Most marked Compliant (C) but keep records on site. Not Applicable (NA) would be more appropriate if records are not stored outside the pharmacy building.
- Electronic Data Storage Systems – K.A.R. 68-9-1 and 21 CFR 1306.22(f)(3). Type of Automation. This requests the type of pharmacy computer system (eg, Keycentrix, Pioneer, QS1, Rx30, Speed Script).
- Appropriate ID used/obtained/accepted for sale of Schedule V over-the-counter (OTC) products – K.S.A. 65-1643(j)(1)(B) and K.A.R. 68-20-22(d). Many marked NA. To sell OTC pseudoephedrine (PSE) (a Schedule V drug in Kansas), a consumer **must** present an appropriate ID to purchase. This ID query covers both OTC PSE and the Schedule V cough syrup purchases.
- Vaccination: Record reported – K.S.A. 65-1635a(b). Some pharmacies left this blank. Please make sure to report to the Kansas WebIZ program and the primary care physician or protocol physician.
- List newsletters reviewed – K.A.R. 68-7-12b(c). This is required to be documented on the continuous quality improvement report.
- Drug Enforcement Administration (DEA) Form 222 for Schedule II transfers – K.A.R. 68-20-17. Many marked NA. How do you dispose of outdated Schedule II controlled substances (CS)? Do you receive a DEA Form 222 before you send drugs to the reverse distributor? You must maintain this DEA Form 222 in your files.
- Ratio of pharmacy technicians to pharmacists – K.A.R. 68-5-16. A ratio should be technician: pharmacists. The Board was surprised to see 1:0 or 1.5:1. In one pharmacy there was no pharmacist working and in the other the pharmacy had a half of a person. If the pharmacy has three technicians and two pharmacists, the ratio is 3:2.
- Drug distribution to long-term care facilities (LTCFs) – K.A.R. 68-7-10. Specifically read subsection (b) of this regulation. Drug distribution includes the dispensing of patient-specific medications pursuant to a prescription. If the pharmacy dispenses medications to an LTCF (nursing home) and is in compliance with the regulation on how those medications are dispensed, then the appropriate answer would be either C or NI, hopefully.
- Prepackaging/Repackaging – K.A.R. 68-7-15 and Prepackaging/Repackaging Labels – K.A.R. 68-7-16. If the pharmacy does not pre- or repackage and the items are all marked NA, the next section should also be NA, as without pre- or repackaging there would be no need for labels for those items.

## *Vaccinations*

Kansas law does not authorize pharmacy technicians to administer vaccinations. Therefore, pharmacy technicians administering vaccines based on authorization granted by the federal Public Readiness and Emergency Preparedness Act (PREP Act) or other emergency authority need to ensure that they are not violating state law by vaccinating outside of the scope of the emergency authority. For example, influenza and shingles vaccinations are not authorized by the federal PREP Act. Pharmacy technicians (and the pharmacists supervising them) face disciplinary action by the Board for vaccinating outside the scope of emergency authority. A federal guidance document is available at *www.hhs.gov* for those seeking information on vaccinations by pharmacy technicians. Additional information is also available in the Board's COVID-19 guidance document found on the Board website.

## *Email Addresses*

Are the facility's email addresses current? These email addresses are used by the Board as a means of official communication with a facility. The Board requests two email addresses from a facility.

- License contact email – should be the point of contact for registration issues, such as renewal reminders, application questions, or payments.
- Physical address contact email – should provide a way for the Board to reach someone located at the registered premises of the facility, such as the PIC.

These email addresses are available for review and update during the facility's annual registration renewal. At other times of the year, you may send email updates to pharmacy@ks.gov. Please be sure to include your facility registration number and indicate which email address(es) you are updating.

## *Treatment of Opioid Use Disorder*

In January 2021, the federal government announced that it will publish new guidelines in the treatment of opioid use disorder that exempts certain physicians from the certification

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requirement to prescribe buprenorphine for medication-assisted treatment. For more information on this topic and how it will affect dispensing at your pharmacy, please review the news release and document *Practice Guidelines for the Administration of Buprenorphine for Treating Opioid Use Disorder* by visiting *www.hhs.gov.*

## Board Receives Three-Year Grant for K-TRACS Program Enhancements

The Board received a 2020 Harold Rogers Prescription Drug Monitoring Program (PDMP) grant to enhance the K-TRACS program. The three-year grant in the amount of $975,489 began upon acceptance of the award late last year. Specific projects included in the grant funding are:

- development of a software tool to identify outlier opioid and stimulant prescribing and dispensing patterns;
- one-on-one peer review with pharmacists through the evidence-based practice of academic detailing;
- continued data quality and pharmacy compliance initiatives; and
- continued expansion of education and outreach programs.

K-TRACS will build upon previous initiatives awarded through the 2018 Harold Rogers PDMP grant that seek to optimize the use of K-TRACS as a clinical decision-making and prevention tool to reduce prescription drug misuse, abuse, and diversion.

The Harold Rogers PDMP grant is made available by the Bureau of Justice Assistance, a division of the United States Department of Justice.

## Kansas Electronic Prescribing Requirements

Effective July 1, 2021, every prescription order issued for a CS in Schedules II-V that contains an opiate shall be transmitted electronically. See K.S.A. 65-16, 128. The Board was tasked with issuing waivers to prescribers who qualify for one or more of the exceptions outlined in the statute and providing a verification method for pharmacists. The Board recently launched a web page dedicated to this topic.

- Prescribers can submit a request for waiver at any time and can later apply for six-month extensions.
- Pharmacists may (but are not required to) verify a prescriber waiver using the list generated by the Board and posted on the website. The list contains the prescriber name, license number, effective date, expiration date, and practice location for the waiver issued.

To keep it simple, waivers will always expire June 30 and December 31 each year (no more than six months). Please note, these are waivers of state requirements **not** federal requirements (see Centers for Medicare & Medicaid Services rules on CS prescribing). Initial waivers will take effect July 1, 2021, and will expire December 31, 2021.

If a prescriber prescribes a CS by non-electronic prescription, the prescriber must indicate the prescription is made pursuant to a Board waiver. **The pharmacist/pharmacy is not required to verify the validity of any waiver, either with the prescriber or the Board, but may do so in accordance with K.S.A. 65-1637.**

## Revoked Licenses and Registrations

In an effort to provide greater transparency to pharmacists, the Board will publish a list of revocations against Kansas pharmacists, interns, and technicians in its quarterly *Newsletter.* The Board encourages the PIC to verify the registration status of all employed technicians at least twice a year (June and November are recommended). The Board's license verification website is a secure and primary source of credential verification information, and is as authentic as a direct inquiry to the Board: *https://ksbop.elicensesoftware.com/portal.aspx.*

Please take notice of the Board's revocation action taken on these licenses, permits, and registrations:

- Hunt, Hailey Katherine 24-111467, Case 20-237
- Major, Megan Ann 24-111851, Case 21-315
- Nunn, Krista Lynn 24-109245, Case 20-299
- Peraza, Alexis Nicole 24-110040, Case 20-297
- Rehmer, Tamara Leigh 24-110947, Case 21-313
- Sears, Natasha Lynn 24-110932, Case 20-298
- Whitaker, Misty 14-15989, Case 20-220



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