



Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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2021 Board Officers

The Kentucky Board of Pharmacy has elected Jill Rhodes as president and Peter Cohron as vice president for 2021. This is Jill Rhodes' first term as president and her fourth year on the Board. This is Peter Cohron's first term as vice president and his fourth year as a Board member.

New Board Members

Jonathan Van Lahr, RPh, has been appointed by Governor Andy Beshear to the Board for a four-year term expiring January 1, 2024. Mr Van Lahr has served as a consultant pharmacist to Breckinridge Memorial Hospital and has owned Save-Rite Drugs in Irvington, KY, since 1981. He has two children, Gabe Van Lahr, PharmD, and Andrew Van Lahr, JD, and has three grandchildren. He resides in Webster, KY, with his wife of 46 years, Marinetta Van Lahr, APRN.

Christopher Harlow, PharmD, RPh, BCGP, has been appointed by Governor Beshear to the Board for a four-year term expiring January 1, 2024. Dr Harlow is a community pharmacist and board certified geriatric pharmacist (BCGP). He is the director of pharmacy services and co-founder of St Matthews Community and Specialty Pharmacy in Louisville, KY. Additionally, Dr Harlow serves as adjunct faculty at the University of Kentucky and Sullivan University Colleges of Pharmacy. Dr Harlow is a 2010 graduate of the University of Kentucky, and completed a community pharmacy practice residency through the University of Kentucky College of Pharmacy and the American Pharmacy Services Corporation. Dr Harlow served on the board of directors of the Kentucky Pharmacists Association from 2014-2020, most recently having served as past president. He is currently a member of the American Pharmacists Association Policy Committee and chair of Kentucky's Substance Use Committee. Dr Harlow is also the Team Kentucky project lead and administrator for the CPESN Flip the Pharmacy practice transformation effort.

Dr Harlow has a passion for offering enhanced patient services. In his current role, he has developed and implemented patient care programs that meet the needs of his community. Under his leadership at St Matthews Community and Specialty Pharmacy, he has initiated several services including immunizations, a home-based medication therapy management program, a substance use disorder program, nonsterile compounding, integrative pharmacy services, and specialty pharmacy.

2021 Board Calendar

- ◆ March 30, 2021
- ◆ May 25, 2021
- ◆ July 27, 2021
- ◆ August 31, 2021
- ◆ September 28, 2021

- ◆ October 26, 2021

- ◆ November 30, 2021

Meetings are held virtually until pandemic restrictions are lifted and begin at 9 AM. Pharmacists and the public are invited to attend.

Child Fatalities and Near Fatalities From Accidental Ingestion of Prescription Medications

In 1970, to reduce the unintentional or accidental poisonings of children, Congress passed the Poison Prevention and Packaging Act (PPPA), which required the use of child-resistant packaging on different household substances, including medications. The overall incidence of unintentional poisonings decreased after passage of the PPPA. Starting in the early 2000s, accidental poisonings from medications have accounted for the majority of pediatric poisonings.¹ From 2001 to 2008, there was an increase in emergency room visits, injuries, and hospital admissions resulting from pediatric self-ingestion of medications, with the greatest increase in self-ingestion of prescription medications.²

CDC reports almost 50,000 young children a year are taken to the emergency room after unsupervised access to medications.³ Opioids, benzodiazepines, sulfonylureas, beta blockers, centrally acting antiadrenergics, and calcium channel blockers are the drug classes most associated with hospitalization of children under six years following accidental poisonings.⁴ Twelve active ingredients were involved in 45% of hospitalizations following accidental ingestions. Buprenorphine and clonidine accounted for 15% of hospitalizations.⁴ In comparing hospitalization after unsupervised opioid ingestion, one child was hospitalized per 500 unique buprenorphine patients, versus one child per 48,500 oxycodone patients, and one child per 119,000 hydrocodone patients.⁴

The 2019 Annual Report of the Kentucky Child Fatality and Near Fatality External Review Panel listed overdose or ingestion cases as one of the top three categories for child fatality or near fatality in Kentucky for the last four years.⁵ In 2018, buprenorphine-containing products and clonidine accounted for 17 of the 31 overdoses or ingestions that the panel reviewed. In 2018, the Kentucky Poison Control Center received almost 5,000 inquiries about pharmaceutical exposures in young children, and 897 children under the age of 12 were treated in Kentucky emergency rooms for drug overdose.⁵

Unsafe medication storage and removal of prescription medication from original child-resistant packaging are common findings in unsupervised ingestions of medication.^{6,7}

CDC recommends storing all medications, including over-the-counter and dietary supplements, in a location that is out of children's reach and out of sight.³ Medications should be put away after every

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 vinCRISTine sulfate injection. Importantly, they have removed wording from the vinCRISTine package insert that described direct intravenous (IV) injection of vinCRISTine 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, vinCRISTine 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 vinCRISTine 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 vinCRISTine. 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 vinCRISTine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vinCRISTine 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 2014¹. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vinCRISTine labeling.²

ISMP has frequently referred to wrong route administration of vinCRISTine 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 vinCRISTine 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 vinCRISTine 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 vinCRISTine 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](https://www.fda.gov/biosimilars)
- ◆ purplebooksearch.fda.gov
- ◆ [fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act](https://www.fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act)
- ◆ [fda.gov/media/135340/download](https://www.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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use, with the safety cap locked after each use. Visitors should store any purses, bags, or coats with medication inside in secure locations out of children's reach and sight. In the majority of unsupervised ingestions of prescription medications by young children, the medication was removed from the original dispensing container, placed in an alternative container such as a weekly pill container or a plastic sealed bag, or the prescription medication was not in a container.⁷ Alternative containers are often used as reminders for patients to take medication and do not meet the PPPA's requirements for child-resistant packaging. Young children most often accessed medications prescribed to parents, grandparents, and siblings.

When counseling on proper medication storage, pharmacists should encourage parents and grandparents to follow the recommendations in CDC's Up and Away campaign³ and counsel on how to model safe medication behavior. Pharmacists should counsel patients receiving medication in non-child-resistant packaging, or who use alternative containers such as pillboxes, on the risks of unintentional pediatric ingestion of medications. Pharmacists should consider ordering and dispensing medication, specifically those medications at a high risk of pediatric poisoning, in child-resistant unit-dose packaging. The availability of manufacturer unit-dose packaged buprenorphine-naloxone strips in 2010 and tablets in 2013 resulted in a decrease in the incidences of accidental pediatric poisonings from buprenorphine.^{8,9}

The pharmacy and drug inspectors will be providing an information sheet regarding child fatalities and near fatalities with the inspection report following routine inspections.

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1. Budnitz DS, Lovegrove MC. The Last Mile: Taking the Final Steps in Preventing Pediatric Pharmaceutical Poisonings. *J Pediatr*. 2012 Feb;160(2):190-192.
2. Bond GR, Woodward RW, Ho M. The growing impact of pediatric pharmaceutical poisoning. *J Pediatr*. 2012 Feb;160(2):265-270.
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5. 2019 Annual Report Child Fatality and Near Fatality External Review Panel <https://justice.ky.gov/Boards-Commissions/cfnferp/Documents/Old Site/annual reports/2020 Annual Report Final.pdf>
6. Salzman M, Cruz L, Nairn S, et al. The Prevalence of Modifiable Parental Behaviors Associated with Inadvertent Pediatric Medication Ingestions. *West J Emerg Med*. 2019 Mar;20(2):269-277.
7. Agarwal M, Lovegrove MC, Geller RJ, et al. Circumstances Involved in Unsupervised Solid Dose Medication Exposures among Young Children. *J Pediatr*. 2020 Apr;219:188-195.
8. Wang GS, Severtson SG, Bau GE, et al. Unit-Dose Packaging and Unintentional Buprenorphine-Naloxone Exposures. *Pediatrics*. 2018 Jun;141(6):e20174232.
9. Hampp C, Lovegrove MC, Budnitz DS, et al. The Role of Unit-Dose Child-Resistant Packaging in Unintentional Childhood Exposures to Buprenorphine-Naloxone Tablets. *Drug Safety*. 2020 Feb;43(2):189-191.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

Emergency Authorization for Pharmacists to Prescribe and to Administer COVID-19 Vaccines and Routine Childhood Vaccines

Kentucky Regulatory Requirements	Pharmacist Interns	Pharmacy Technicians
Registered with the Kentucky Board of Pharmacy	✓	✓
Administers vaccinations under the general supervision of a pharmacist	✓	✓
Possesses a current CPR certificate	✓	✓
Completes, or has completed as part of pharmacy school curriculum, an Accreditation Council for Pharmacy Education (ACPE)-accredited practical training program that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines	✓	
Has completed an ACPE-accredited practical training program that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines		✓
Completes a minimum of two hours of ACPE-accredited immunization-related continuing pharmacy education per each state registration period		✓

These are the regulatory requirements by which pharmacist interns and pharmacy technicians are authorized to administer vaccines under 201 Kentucky Administrative Regulations (KAR) 002:410E, effective February 22, 2021. Registrants should consult <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf> for Public Readiness and Emergency Preparedness Act (PREP Act) immunity requirements and <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html> for the CDC coronavirus disease 2019 (COVID-19) provider requirements. Pharmacies may need to meet additional requirements to meet conditions for participation in federal COVID-19 vaccine distribution programs.

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Vaccine Administration by a Pharmacist			
Kentucky Regulatory Requirement	Prescription written by licensed-prescriber per Kentucky Revised Statutes (KRS) 315.010(22)	Prescriber-approved protocol per KRS 315.010(22)	Prescriber-approved protocol per 201 KAR 2:410e*
Registered With the Kentucky Board of Pharmacy	✓	✓	✓
Age of Patient	Any age	♦ Adult ♦ Children nine to 17 years	♦ Children ages three through eight
Type of Vaccine	Any Food and Drug Administration (FDA)-approved vaccine or FDA-licensed COVID-19 vaccine		
Possesses a Current CPR Certificate	No CPR requirements per KRS 315.010(22)	No CPR requirement <i>Pharmacists may be required to possess a current CPR certificate according to their prescriber-approved protocol</i>	
Required Training	No training requirements	No training requirements <i>Pharmacists may be subject to required training according to their prescriber-approved protocol</i>	
Continuing Education (CE)	No CE requirements No CE requirements per 201 KAR 2:410E		

*Only authorized during state of emergency

Prescribing and Administration of Pharmacist-Prescribed Vaccine		
Kentucky Regulatory Requirements	Pharmacist Prescribes and Administers Routine Childhood Vaccine Pursuant to 201 KAR 2:410e*	Pharmacist Prescribes and Administers COVID-19 Vaccine Pursuant to 201 KAR 2:410e*
Registered With the Kentucky Board of Pharmacy	✓	✓
Age of Patient	Any individual 18 and under pursuant to the Advisory Committee on Immunization Practices standard immunization schedule	Any individual, so long as the vaccine is FDA-approved or licensed for that individual's age
Possesses a Current CPR Certificate	✓	✓
Required Training	Completes, or has completed, training on administering vaccinations. This may include: 1) Completion of a practical training program accredited by ACPE that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; 2) Graduation from an ACPE-approved pharmacy school in which hands-on immunization training was part of the curriculum; OR 3) Training via hands-on experience immunizing in current or previous pharmacy practice Note: No specific number of training hours are required.	
CE	No specific CE requirements for pharmacists Note: Pharmacy technicians must complete a minimum of two hours of immunization-related CE – see intern/technician table on page 4.	

*Only authorized during state of emergency

The above tables are limited to the legal requirements of the Kentucky Board of Pharmacy under KRS Chapter 315 and 201 KAR, Chapter 2. All licensees should consult <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf> for specific PREP Act immunity requirements and <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html> for the CDC COVID-19 provider requirements. Pharmacies and pharmacists may need to meet additional requirements to meet conditions for participation in federal COVID-19 vaccine distribution programs or specific prescriber-approved protocols.

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