



Kentucky Board of Pharmacy

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NTSB Recommendations for Prescribing CS

The National Transportation Safety Board (NTSB), an independent federal agency, is charged by Congress with investigating every civil aviation accident in the United States and significant accidents in other modes of transportation, including railroad, highway, marine, and pipeline accidents. The probable cause of accidents is determined, and safety recommendations are issued that are aimed at preventing future accidents.

As a result of conducting the safety study, “Drug Use Trends in Aviation: Assessing the Risk of Pilot Impairment” (SS 14/01), recommendations were made by NTSB and an inquiry was communicated to former Kentucky Governor Steve Beshear to determine how the following recommendations are met by health care providers in Kentucky.

Safety Recommendation I-14-001

Include in all state guidelines regarding prescribing controlled substances for pain a recommendation that health care providers discuss with patients the effect their medical condition and medication use may have on their ability to safely operate a vehicle in any mode of transportation.

Safety Recommendation I-14-002

Use existing newsletters or other routine forms of communication with licensed health care providers and pharmacists to highlight the importance of routinely discussing with patients the effect their diagnosed medical conditions or recommended drugs may have on their ability to safely operate a vehicle in any mode of transportation.

Pharmacists, when dispensing controlled substances (CS), should routinely address and implement NTSB recommendations by discussing and documenting their discussions with patients on the effect their medical

conditions and medication use may have on their ability to safely operate vehicles in any mode of transportation.

Anthony Gray Hired as General Counsel for the Board

The Kentucky Board of Pharmacy is pleased to announce Mr Anthony Gray as the Board’s general counsel. Mr Gray was hired on February 16, 2019, and he joins the Board with over 12 years of legal experience. Mr Gray previously worked as a partner in a national law firm, practicing in the areas of health care law and medical malpractice defense. Prior to entering private practice, he worked as an assistant commonwealth attorney in Fayette County, KY. Mr Gray is from Richmond, KY, and attended the University of Kentucky for his undergraduate degree and for law school. He lives in Lexington, KY, with his wife and two sons.

Regulation Changes

The Board is in the process of reviewing all regulations scheduled to sunset. These are regulations that have not been updated in the past seven years. The Board can decide to let the regulation expire, keep the regulation as is, or update the regulation. The following actions were taken at the March 27, 2019 Board meeting.

Allow to Expire

- ◆ **201 Kentucky Administrative Regulations (KAR) 2:080 Prescription Substitution.** This regulation is covered elsewhere in pharmacy law.
- ◆ **201 KAR 2:115 Controlled Release Tablets, Capsules and Injectables.** This regulation was combined and updated with 201 KAR 2:116.

Keep as Is

- ◆ **201 KAR 2:070 Prescription Intermediary Services Restricted**
- ◆ **201 KAR 2:160 Licensees; Inactive Status**
- ◆ **201 KAR 2:180 Pharmacies Sanitation**

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National Pharmacy Compliance News

June 2019



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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD[®] Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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- ◆ **201 KAR 2:185 Noncontrolled Substances Prescription Drug Refills**
- ◆ **201 KAR 2:190 Return of Prescription Drugs Prohibited**
- ◆ **201 KAR 2:210 Patient Records and Patient Counseling**
- ◆ **201 KAR 2:215 Nuclear Pharmacy Services**
- ◆ **201 KAR 2:250 Pharmacist Recovery Network Committee**
- ◆ **201 KAR 2:260 Automated Pharmacy System in Residential Hospice Facilities**
- ◆ **201 KAR 2:280 Prescription Dispensing for Formulary Compliance**
- ◆ **201 KAR 2:300 Common Database**

Proposed Amendments

- ◆ **201 KAR 2:010 Schools Approved by the Board.** The proposed amendment updates the regulation's language to use the current accreditation standards.
- ◆ **201 KAR 2:090 Reference Material and Prescription Equipment.** The proposed amendment allows pharmacies to decide the appropriate reference material and prescription equipment needed for its practice setting.
- ◆ **201 KAR 2:095 Dispensing Responsibilities.** The proposed amendment changes the title of this regulation to "Pharmacist Interns," allows a supervising pharmacist to decide what an intern may or may not do, and clarifies that the supervising pharmacist is responsible for all actions of the intern.
- ◆ **201 KAR 2:100 Security and Control of Drugs and Prescriptions.** The proposed amendment clarifies the type of barrier needed in a pharmacy.
- ◆ **201 KAR 2:116 Drug Products with Therapeutic Problems.** The proposed amendment changes the title of this regulation to "Substitution of Drugs, Biologics, and Biosimilar Products" and combines 201 KAR 2:115 and 201 KAR 2:116. It clarifies that pharmacists will follow the Food and Drug Administration (FDA) "Orange Book" and "Purple Book" when substituting.
- ◆ **201 KAR 2:165 Transfer of Prescription Information.** The proposed amendment allows pharmacists and interns to transfer non-controlled prescriptions that have been placed on hold but never dispensed.
- ◆ **201 KAR 2:225 Special Pharmacy Permit.** The proposed amendment changes the title of this regulation to "Special Limited Pharmacy Permit – Medical Gas" and includes all prescription medical gases not limited to oxygen and nitrous oxide.
- ◆ **201 KAR 2:230 Special Limited Pharmacy – Central Refill Pharmacy.** The proposed amendment changes the

title of this regulation to "Special Limited Pharmacy Permit – Central Fill," allows for original dispensing from a central fill pharmacy, removes limitation of refill dispensing, allows for out-of-state pharmacies to participate, and allows for a common ownership or contractual relationship.

- ◆ **201 KAR 2:240 Special Limited Pharmacy – Charitable Pharmacy.** The proposed amendment changes the title of this regulation to "Special Limited Pharmacy Permit – Charitable Pharmacy."
- ◆ **201 KAR 2:270 Expungement.** The proposed amendment redefines minor violations so that failure to timely renew means failure to timely renew within seven days of expiration and removes failing to complete HIV/AIDS continuing education (CE) as a minor violation, since HIV/AIDS CE is no longer required.
- ◆ **201 KAR 2:310 Compounding for a Practitioner's Office or Institutional Administration.** The proposed amendment changes the title of this regulation to "Compounding for a Veterinarian's Office or Institutional Administration for Veterinarian Use" and clarifies that non-patient-specific compounding by pharmacies is only for veterinarian use, not human use. FDA does not allow non-patient-specific compounding for human use by pharmacies.
- ◆ **201 KAR 2:340 Special Pharmacy Permit for Clinical Practice.** The proposed amendment changes the title of this regulation to "Special Limited Pharmacy Permit – Clinical Practice."

Proposed to Amend, but Still Under Review

- ◆ **201 KAR 2:105 Licensing and Drug Distribution Requirements for Wholesale Distributors**
- ◆ **201 KAR 2:106 Pharmacy, Manufacturer, or Distributor Closures**
- ◆ **201 KAR 2:170 Computerized Recordkeeping**
- ◆ **201 KAR 2:175 Emergency 72 Hour Prescription Refills** (See statutory change to Kentucky Revised Statute (KRS) 217.215(3).)
- ◆ **201 KAR 2:320 Permit Requirements for Manufacturers**
- ◆ **201 KAR 2:330 Emergency Pharmacy Powers**

Please refer to the Board website, www.pharmacy.ky.gov, to review the proposed regulation changes in their entirety and the timeline for the proposed regulation changes to take effect.

201 KAR 2:370 Pharmacy Services in Long-Term Care Facility (LTCF) went into effect on March 13, 2019. Among other changes, this allows a pharmacy to use automated dispensing machines for emergency stock

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and pharmacy stock in LTCFs. Please refer to the Board website, www.pharmacy.ky.gov, to review the regulation in its entirety.

2019 Kentucky Legislative Highlights

All bills passed during the 2019 legislative session and signed by Governor Matt Bevin will go into effect on June 27, 2019, unless otherwise stated.

Pharmacist emergency dispensing: House Bill (HB) 64, sponsored by representative and pharmacist Danny Bentley (R – Russell, KY), amends KRS 217.215(3) to allow a pharmacist to dispense more than a 72-hour supply of certain medications in emergency situations when the authorization for a refill may not be readily or easily obtained from the prescriber. The law allows a pharmacist to dispense up to a 72-hour supply of most medications if the prescriber cannot be reached for a refill authorization. This bill allows a pharmacist to dispense more than a 72-hour supply of insulin or medications used for the treatment of chronic respiratory diseases (eg, inhalers) if the standard unit of dispensing exceeds a 72-hour supply. The pharmacist can dispense an amount equal to the standard unit of dispensing, eg, one bottle of insulin or one inhaler.

Electronic prescribing of CS: HB 342, sponsored by representative and pharmacist Steve Sheldon (R – Bowling Green, KY), creates a new section of KRS 218A that requires all CS prescriptions to be electronically prescribed, with some exceptions, by January 1, 2021. The exceptions are:

- ◆ CS prescriptions issued by veterinarians;
- ◆ CS prescriptions for individuals in hospice care;
- ◆ CS prescriptions for residents of nursing facilities;
- ◆ CS prescriptions being filled by an out-of-state pharmacy;
- ◆ CS prescriptions issued by a practitioner under a research protocol;
- ◆ when the prescriber and dispenser are the same entity;
- ◆ when e-prescribing is unavailable due to temporary technology or electronic failure;
- ◆ when CS prescriptions include elements that are not supported by the most recent version of e-prescribing standards;

- ◆ when CS prescriptions are for compounded preparations, if the elements of the prescription cannot be incorporated with e-prescribing;
- ◆ standing CS orders due to a public health emergency; and
- ◆ in situations determined to be impractical for the patient to receive the e-prescription in a timely manner, and a delay would negatively impact the patient.

A practitioner may be granted a waiver on a year-to-year basis by the Kentucky Cabinet for Health and Family Services (CHFS) to comply. CHFS will promulgate administrative regulations about e-prescribing of CS.

Pharmacists dispensing naloxone as part of a harm reduction program: HB 470 amends KRS 217.186(7) to allow pharmacists utilizing the naloxone protocol to dispense naloxone to any person or agency that provides training as part of a harm reduction program, regardless of who the ultimate user may be. The documentation of the dispensing of the naloxone as part of the harm reduction program shall satisfy the documentation required by administrative regulations.

Allowance for expedited partner therapy for a sexually transmitted gonorrhea or chlamydia infection: HB 237, sponsored by representatives and pharmacists Danny Bentley and Steve Sheldon, creates a new section of KRS 214 to allow a practitioner to provide expedited partner therapy for a sexually transmitted gonorrhea or chlamydia infection to a patient's sexual partner(s). Therefore, if a patient is diagnosed with gonorrhea or chlamydia, the patient's sexual partner(s) may receive an antibiotic for treatment without being examined.

Please refer to the statutes for a full reading.

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Larry A. Hadley, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor &
Executive Editor

Amy Suhajda - Communications Manager
