



# Kentucky Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Outsourcers and Third-Party Logistics Providers Licensure**

Effective August 15, 2017, outsourcers and third-party logistics providers have been reclassified from wholesale distributors to their own classification of outsourcers and third-party logistics providers in the Commonwealth of Kentucky. Information and applications are located on the Kentucky Board of Pharmacy website at [www.pharmacy.ky.gov](http://www.pharmacy.ky.gov). If you have already renewed for 2018 as a wholesale distributor, please contact the Board office at 502/564-7910.

## **Drug Manufacturer and Wholesale Distributor Renewal Deadline Is September 30, 2017**

Drug manufacturer and wholesale distributor permits/licenses expire on September 30, 2017. Drug manufacturers or wholesale distributors may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Board's website at [www.pharmacy.ky.gov](http://www.pharmacy.ky.gov). If you have any questions concerning the renewal process, please contact the Board office. A drug manufacturer or wholesale distributor application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2017.

## **John F. Atkinson Service Award**

Katie Busroe, RPh, Board pharmacy inspections and investigations supervisor, received the 2017 John F. Atkinson Service Award from the National Association of Boards of Pharmacy® at the Association's 113<sup>th</sup> Annual Meeting in May 2017 for her dedication to protecting the public health through her work in pharmacy inspections and investigations, as well as sterile and nonsterile compounding training. She has been employed with the Board for 19 years and is active in many local, state, and national organizations and committees.

## **Immunizations**

This year's Kentucky General Assembly updated Kentucky Revised Statute (KRS) 315.010(22), giving pharmacists increased authority to administer Centers for Disease Control and Prevention (CDC)-recommended vaccinations via protocol beginning at age nine. Prior to this legislative change, Kentucky law allowed pharmacists to administer only the flu vaccine to children starting at age nine; this change brings all other age-appropriate vaccinations in line with the flu vaccine. The law went into effect on June 29, 2017.

## **Consolidation of Prescription Refills**

The General Assembly created KRS 315.202, allowing a pharmacist, in his or her professional judgment, to consolidate a prescription for a non-controlled maintenance medication written with refills into no more than a 90-day supply. This law went into effect on June 29, 2017.

## **2017 Legislative Changes to the Controlled Substances Act**

*By Kaitlyn Bartley, 2018 PharmD Candidate*

There were many legislative changes to the Kentucky Controlled Substances Act during the 2017 Legislative Session. The statutory changes are effective as of June 29, 2017. However, in some cases regulatory changes must be made to reflect the statutory changes. Notification will be given when the regulatory changes become effective. There were a number of changes to KRS 218A.010, including defining carfentanil and fentanyl derivatives, which allows law enforcement to charge individuals in the trafficking of these substances, as well as clarifying industrial hemp to be defined in the Controlled Substances Act as it is defined elsewhere in Kentucky law. Additional changes in the Controlled Substances Act include, but are not limited to, the following:

1. KRS 218A.020 changes include expanding the authority of the Kentucky Office of Drug Control Policy

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## **WHO Launches Global Patient Safety Challenge on Medication Safety**

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

## **Continuous Quality Improvement and Patient Safety Organizations**

 *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).*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

## **NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster**

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at [www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation\\_v1\\_4.pdf](http://www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf). Additional information for pharmacists about emergency preparedness is available on the NCPDP website at [www.ncdp.org/Resources/Emergency-Preparedness](http://www.ncdp.org/Resources/Emergency-Preparedness).

## **FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil**

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

News to a particular state or jurisdiction can only be ascertained  
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at [www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm](http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm).

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at [www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm](http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm).

### **FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding**

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at [www.fda.gov/Drugs/DrugSafety/ucm502075.htm](http://www.fda.gov/Drugs/DrugSafety/ucm502075.htm), FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf) and [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf).

### **APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services**

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at [www.pharmacist.com/immunization-center](http://www.pharmacist.com/immunization-center).

### **CPE Training on Older Adult Fall Prevention Available Online**

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at [www.cdc.gov/steadi/training.html](http://www.cdc.gov/steadi/training.html) for more information.

### **New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act**

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), 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 Presents Series of CE Webinars for Students and Clinicians**

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at [www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars).

(ODCP) to request the rescheduling of a substance. Other changes include authorizing the addition of a federally scheduled drug to the same schedule in Kentucky. This does not preclude permitting a more restrictive scheduling by the state, if deemed appropriate.

2. The repeal of the following statutes relating to the previous controlled substances (CS) scheduling system:

- ◆ KRS 218A.030
- ◆ KRS 218A.050
- ◆ KRS 218A.070
- ◆ KRS 218A.090
- ◆ KRS 218A.110
- ◆ KRS 218A.130

3. The following statutes have been added or modified to include the addition of fentanyl and carfentanil:

- ◆ KRS 218A.1410
- ◆ KRS 218A.1412
- ◆ KRS 218A.14141
- ◆ KRS 218A.142

4. Major changes to KRS 218A.202 include:

- ◆ Requires emergency departments to report dispensing of all CS (the prior statute only required reporting of Schedule II dispensing only for a quantity exceeding 48 hours).
- ◆ A new section requiring the reporting of all positive toxicology screens performed by hospital emergency departments to evaluate a patient suspected of drug overdose.
- ◆ Permits practitioners and pharmacists to obtain Kentucky All Schedule Prescription Electronic Reporting program reports on the birth mother of an infant who is currently being treated for neonatal abstinence syndrome or otherwise suspected by the practitioner of prenatal drug exposure.

5. Amend KRS 218A.205 to require state licensing boards to establish regulations on prescribing and dispensing of CS in accordance with the CDC's 2016 *Guidelines on Prescribing Opioids for Chronic Pain*, which limits the prescribing of Schedule II CS to a three-day supply to treat acute pain, with the following exceptions:

- ◆ In the professional judgment of the practitioner, the patient needs more than a three-day supply and this need is documented;
- ◆ Treating chronic pain;
- ◆ Treating cancer pain;
- ◆ Treating patient at end of life or in hospice;
- ◆ Part of a narcotic treatment program;
- ◆ Treatment of pain after a major surgery or significant trauma, as defined by the licensing boards in consultation with the ODCP;

- ◆ Dispensed or administered directly to the patient in an inpatient setting; and
- ◆ Any additional scenario authorized by the licensing boards.

Please note that KRS 218A.205 states: "For the purposes of pharmacy dispensing, the medical necessity for a Schedule II controlled substance as documented by the practitioner in the patient's medical record and the prescription for more than a three (3) day supply for that controlled substance are presumed to be valid."

6. KRS 218A.180 was amended to permit an oral prescription for a Schedule II CS only for immediate administration to a patient enrolled in a hospice program or a resident in a long-term care facility (LTCF). The Kentucky Cabinet for Health and Family Services (CHFS) is in the process of updating regulation 902 Kentucky Administrative Regulation (KAR) 55:095 to reflect this change. In addition, KRS 218A.180 was updated to clarify that an electronically prescribed CS must comply with federal law Title 21 Code of Federal Regulations Part 1311. A CS prescription that is computer-generated and printed or faxed must be manually signed by the prescriber; otherwise, it does not meet the definition of an electronic CS prescription.

7. An addition was made to 902 KAR 55:095 that permits the partial filling of a Schedule II CS for patients who are not terminally ill or a resident of an LTCF. The partial filling must be requested by the patient or the prescribing practitioner, and no additional dispensing may occur beyond 30 days from the date of issuance of the prescription. This would allow for partial dispensing of a Schedule II CS in two different scenarios in the community pharmacy setting: 1) the pharmacy is unable to fill the prescription and has 72 hours to complete the filling, or 2) the patient or prescribing practitioner request a partial fill and the pharmacist may do so for up to 30 days. CHFS is in the process of updating this part of the regulation.

Please contact the Drug Enforcement and Professional Practices branch of the Kentucky Office of Inspector General at 502/564-2815 for additional questions.

### **2017 National Rx Drug Abuse & Heroin Summit**

In April 2017, Board members and staff were able to attend the 2017 National Rx Drug Abuse & Heroin Summit in Atlanta, GA. The international conference, started in 2012 by Operation UNITE under the leadership of US Representative Harold "Hal" Rogers, brings together businesses, academia, government agencies, and community organizations to address the growing opioid crisis.

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According to the CDC, 91 Americans die every day from an opioid overdose (that includes prescription drugs and heroin). Deaths from prescription opioids have more than quadrupled since 1999. In 2014, almost 2 million Americans abused or were dependent on prescription opioids.

Pharmacists play a vital role in the fight against prescription drug abuse and heroin use. According to the CDC's March 17, 2017 *Morbidity and Mortality Weekly Report*, the transition between acute opioid use to long-term therapy can occur quickly. The possibility of chronic use begins to increase after a three-day supply and rises rapidly thereafter. When initiating opioids, prescribers should exercise caution when prescribing for more than one week of opioids or when authorizing a refill or a second opioid prescription, because these actions approximately double the chances of use one year later.

The Kentucky state legislature addressed prescribing for these acute pain situations by passing legislation that limits Schedule II CS opioids to a three-day supply, with some exceptions. The legislation does allow for some exemptions to this three-day limit. Pharmacists can counsel patients on the risks of prescription opioids and help patients make informed decisions about their care.

The misuse and abuse of prescription opioids often starts at home. Drug take-back programs provide patients and caretakers with the opportunity to dispose of unwanted prescriptions in their medicine cabinets. Pharmacies are able to establish drug disposal programs

within their facilities. Local law enforcement offices also often have a place for patients to dispose of medications.

More than 1,780 Kentucky pharmacists are certified to dispense naloxone via protocol. The ODCP maintains a website that directs patients and community members to pharmacies that have established protocols and have naloxone available.

## Resources

- ◆ Drug disposal locations in Kentucky: <http://odcp.ky.gov/Pages/Prescription-Drug-Disposal-Locations.aspx>
- ◆ Naloxone and needle exchange locations in Kentucky: <http://odcp.ky.gov/Stop-Overdoses/Pages/Locations.aspx>
- ◆ March 17, 2017 *Morbidity and Mortality Weekly Report*: [https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm?s\\_cid=mm6610a1\\_w](https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm?s_cid=mm6610a1_w)
- ◆ CDC overdose data: <https://www.cdc.gov/drugoverdose/index.html>

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