March 2019

Kentucky Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601

2019 Board Officers

The Kentucky Board of Pharmacy has elected Craig Martin as president and Ron Poole as vice president for 2019. This is Dr Martin's first term as president and his third full year on the Board. This is Mr Poole's first term as vice president and his third year as a Board member.

John Fuller

John Fuller has been appointed by Governor Matt Bevin to the Board for a four-year term expiring January 1, 2023. Mr Fuller has been employed by Kroger for 32 years. He resides in Versailles, KY, with his wife, Lynn.

2019 Board Calendar

The Board approved the following 2019 meeting dates at its December 12, 2018 meeting:

- ♦ January 30, 2019 (past)
- ♦ March 27, 2019
- ♦ May 29, 2019, at Sullivan University's College of Pharmacy and Health Sciences
- ♦ July 31, 2019
- ♦ September 25, 2019, at University of Kentucky's College of Pharmacy
- ♦ November 13, 2019
- ♦ December 11, 2019

Meetings are held at the Board office unless otherwise designated and begin at 9 AM. Pharmacists and the public are invited to attend.

DEA Policy on Transferring CS Prescriptions

Board staff continually fields questions on the Drug Enforcement Administration (DEA) policy of transferring controlled substance (CS) prescriptions that have been placed on hold and never dispensed by the original pharmacy. The way in which a pharmacist is to handle the transferring of a CS prescription on hold that has never been dispensed is dependent upon the format in which the CS prescription was issued: electronically prescribed versus written, faxed, or verbally authorized.

Electronically Prescribed Schedule II, III, IV, and V Prescriptions

DEA regulations do not allow for the transfer of Schedule II CS prescriptions but do allow for the transfer of Schedule III, IV, and V CS prescriptions for the purpose of refilling only. However, contrary to the regulations, DEA has a current policy allowing for the transfer of electronically prescribed Schedule II, III, IV, and V CS prescriptions that have been placed on hold and never dispensed as long as the prescriptions remain electronic. DEA does not provide any guidance on how this is to be done or the documentation required. In previous discussions, DEA has referred to this act as forwarding the electronically prescribed CS prescription. The current DEA policy is that the verbiage "forwarding" is interchangeable with "transferring" for the purpose of electronically prescribed CS prescriptions only.

Written, Faxed, and Verbal Schedule III, IV, and V Prescriptions

21 Code of Federal Regulations 1306.25(a) states:

> The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

It is DEA's policy that a written, faxed, or verbally authorized Schedule III, IV, or V CS prescription that has been placed on hold and never dispensed cannot be transferred. The pharmacist may contact the prescriber to cancel the CS prescription that is on hold and issue a new prescription;

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National Pharmacy Compliance News

March 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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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or, in the case of a written prescription, return the original to the patient, if feasible.

Summary

An electronically prescribed Schedule II, III, IV, or V CS prescription on hold that has never been dispensed may be transferred to another pharmacy as long as the prescription remains electronic. A written, faxed, or verbally authorized Schedule III, IV, or V CS prescription on hold that has never been dispensed may not be transferred to another pharmacy.

The original letter dated October 6, 2017, from James Arnold, chief, Liaison and Policy Section, Diversion Control Division, DEA, may be viewed at *https://pharmacy.ky.gov/documents/dea%20policy%20on%20transferring%20controlled%20substance%20prescriptions.pdf.*

Board Soliciting Comments on Hazardous Drug Regulation

At the December 20, 2017 Board meeting, the following pharmacists were appointed to the Hazardous Drug Committee (HDC): Matt Martin, chair, Professional Compounding Centers of America; John Carver, Baptist Health LaGrange Kresge Infusion Pharmacy; Paul Daniels, Board inspector; Jennifer Grove, owner of Bluegrass Drug Center; Chris Harlow, owner of St Matthews Community Pharmacy and past president of Kentucky Pharmacists Association; Barb Jolly, professor at Sullivan University College of Pharmacy and Health Sciences; Trenika Mitchell, professor at University of Kentucky College of Pharmacy; and Alyson Roby, owner of Medica Pharmacy and Wellness Center.

The HDC met seven times in 2018 and presented the Board with two options regarding a Kentucky-specific hazardous drug regulation at the October 17, 2018 Board meeting. The Board is taking comments on the options until March 31, 2019. The options are:

Option One:

1. Incorporate United States Pharmacopeia (USP) General Chapter <800> into a Kentucky Pharmacy Practice Act regulation with changes as outlined below.
2. Delay the implementation date of USP General Chapter <800> to one year from the filing of the Kentucky Pharmacy Practice Act regulation, incorporating USP General Chapter <800> with changes instead of the USP federal implementation date of December 1, 2019.
3. Allow the Board to consider and grant requested waivers from compliance with parts of USP General Chapter <800> if the pharmacy is a low-volume chemotherapy generator. Currently, the Board defines a low-volume chemotherapy generator as a pharmacy that does no more than five compounded sterile chemotherapy preparations in a two-week period (see July 9, 2008 Board meeting minutes).
4. Allow the Board to consider and grant requested waivers to resolve the discrepancies between USP General Chapter <800> and the June 1, 2008 version of USP General Chapter <797>, with which compliance is required per 201 KAR 2:076.
5. Change USP General Chapter <800>, Section 2 LIST OF HAZARDOUS DRUGS, Box 1, Containment Requirements, to read (added language in *italics*):

   BOX 1: CONTAINMENT REQUIREMENTS

Drugs on the [National Institute for Occupational Safety and Health (NIOSH)] List that must follow the requirements of this Chapter include: • Any hazardous drug (HD) active pharmaceutical ingredient (API), *except Section 5.3.1* • Any antineoplastic requiring HD manipulation

   USP General Chapter <800> Section 5.3.1 is NONSTERILE COMPOUNDING. It requires manipulation of any HD API, including Table 1, antineoplastic HDs; Table 2, non-antineoplastic HDs; and Table 3, HDs with reproductive effects, to be performed in a containment primary engineering control (C-PEC) such as a biological safety cabinet, compounding aseptic containment isolator, or containment ventilated enclosure and in a containment secondary engineering control (C-SEC) such as a negative pressure, externally vented separated room. This change to Section 2 Box 1 would allow pharmacists to compound with NIOSH List Table 2 and Table 3 APIs and not require the use of a C-PEC or a C-SEC.
6. Change USP General Chapter <800> Section 5.3.1 NONSTERILE COMPOUNDING, paragraph 3, to read (added language in *italics*):

   The C-PEC must be placed in a C-SEC that has at least 12 [Air Changes Per Hour] *for all NIOSH Table 1 APIs. An assessment of risk can be conducted for NIOSH Tables 2 and 3 APIs and manipulated dosage forms.*
7. Change USP General Chapter <800>, Section 15.2 Decontamination, second paragraph, to read (added language in *italics*):

   The amount of HD contamination introduced into the C-PEC may be reduced by wiping down HD containers. The solution used for wiping HD packaging must not alter the product label. The work surface of the C-PEC must be decontaminated between compounding of different HDs *unless a closed system transfer device (CSTD) is used. When a CSTD is utilized a standard*

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operating procedure (SOP) must be established by the facility to outline the decontamination process during compounding.

Option Two:

1. Incorporate USP General Chapter <800> into a Kentucky Pharmacy Practice Act regulation.
2. Delay the implementation date of USP General Chapter <800> to one year from the filing of the Kentucky Pharmacy Practice Act regulation, incorporating USP General Chapter <800> instead of the USP Federal implementation date of December 1, 2019.
3. Allow the Board to consider and grant requested waivers from compliance with USP General Chapter <800> to:
   a. Allow pharmacists to perform an assessment of risk to determine the need for a C-SEC for manipulation of any HD dosage form, including APIs on the NIOSH List Table 2, non-antineoplastic HDs; and Table 3, HDs with reproductive effects.
   b. Allow pharmacists to decontaminate the work surface of the C-PEC based on pharmacy SOPs if CSTDs are being used, rather than requiring the work surface to be decontaminated between compounding of different HDs as required by USP General Chapter <800>.
   c. Allow low-volume chemotherapy generating pharmacies to not comply fully with USP General Chapter <800>. Currently, the Board defines a low-volume chemotherapy generator as a pharmacy that generates up to five compounded and sterile chemotherapy preparations in a two-week period (see the July 9, 2008 Board meeting minutes).
   d. Allow resolution between USP General Chapter <800> and the June 1, 2008 version of USP General Chapter <797>, with which compliance is required per 201 KAR 2:076.
   e. Any other reason may be considered.

The deadline for submitting comments is March 31, 2019. Please submit comments by mail, email, or fax to:

Kentucky Board of Pharmacy
125 Holmes Street, Suite 300
Frankfort, KY 40601
Email: pharmacy.board@ky.gov
Fax: 502/696-3806

The comments will go to the HDC for review. All meetings of the Board and its committees are open to the public, and pharmacists and technicians are welcome to attend. Meeting schedules are posted on the Board website, *www.pharmacy.ky.gov,* in the Board Information section, under Calendar.

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.

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