March 2019

Arkansas State Board of Pharmacy News

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Regulation Changes

Regulation 5 – Nursing Home Consulting

Changes that became effective on August 1, 2018, did the following:

1. Updated language regarding the destruction of unused drugs for long-term care facilities so as to remove outdated language.
2. Updated emergency kit guidelines for use in long-term care.
3. Established a list of emergency medications that can be used in crisis stabilization units.

Regulation 7 – General Regulations Regarding Prescriptions

Changes that became effective on January 1, 2019, did the following:

1. Reduced regulatory burdens when transferring prescriptions between pharmacies by allowing for transfers to be "communicated directly between two licensed or registered individuals where one of the two must be a pharmacist," meaning that interns and technicians can take part in the transfer of prescriptions under supervision. This change also states, "Pharmacies transferring prescriptions may utilize facsimile or other electronic means to communicate information for transfers," which will be a useful tool for non-controlled substances (CS). Drug Enforcement Administration (DEA) regulations state that the transfer of CS refills, "must be communicated directly between two licensed pharmacists."
2. Added language to specify that a pharmacist cannot dispense more of a Schedule II narcotic medication than a prescriber can prescribe as required by Act 820 of 2017.
3. Clarified partial filling of Schedule II prescriptions.

Regulation 8 – Wholesale Distribution

Changes that became effective on August 1, 2018, did the following:

1. Clarified language in Regulation 8 to match statutory language in Section 17-92-108 (Fees) of Arkansas Code.
2. Allowed an outsourcing facility to operate under a single permit if it does not provide medications directly to patients.

Regulation 9 – Pharmaceutical Care/Patient Counseling

Changes that became effective on December 1, 2017, did the following:

1. Matched updated statutes to delete language for the Medications Administration Advisory Committee.
2. Matched updated statutes to remove the limitations on the list of medications that can be administered by pharmacists.
3. Deleted a reference that CPR courses must be accredited by the American Heart Association, which does not accredit such courses.

Legislative Updates of 2019

Act 173 – This act removes obsolete language regarding the staggering of terms for a member of the Arkansas State Board of Pharmacy.

This act was sponsored by Representatives Marsh Davis and Justin Boyd and Senator Mathew Pitsch.

Acts 174 and 175 – These acts repeal advisory committees to the Board.

These two acts, sponsored by Representatives Davis and Boyd and Senator Pitsch, removed language regarding advisory committees for medical equipment and hospital pharmacies. Any interested party has the opportunity to make public comments to the Board under the current process.

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.*

Board Interpretations and Policy Updates

90-Day Drug Supply

The Board has had many questions over the years regarding whether or not a pharmacist can automatically fill a 90-day supply upon a patient's request when the patient has a prescription written for a shorter duration with sufficient refills to fill 90-days' worth for the patient's insurance plan or even for cash. The Board discussed this during the February Board meeting and came up with the following interpretation: A pharmacist may fill an advanced days' supply of a non-controlled maintenance medication for an amount not to exceed the total approved with the original supply, plus refills. In essence, if a prescription is written for a blood pressure medication for a 30-day supply with five refills, the pharmacist could change this to a 90-day supply and fill it for the patient, with the patient's consent. This would not require a call or notification to the prescriber.

In the instance of CS, the pharmacist may only fill more than indicated on the initial prescription after consultation with and approval by the prescriber, which should be noted on the prescription or in the pharmacy's software system for that prescription.

Multi-Dose Packaging

The Board recently voted to allow a **change to the memorandum of understanding (MOU) for multi-dose packaging** that includes up to a 93-day supply of medication to be packaged when requested and allows a patient or caregiver the ability to bring back packaged medications to the pharmacy for repackaging due to changes in the patient's medication regimen. In these instances, the pharmacy/pharmacist must have policies and procedures in place for documenting what is repackaged and exactly what was changed. The pharmacy/pharmacist must leave the original fill date on the package, and either allow the patient to take back any removed medication or destroy it. These issues must be covered by the policies and procedures of the pharmacist/pharmacy, which explain how this will be done.

The pharmacy will inform patients that any changes to existing medications should be reported immediately to the pharmacy, so that the pharmacy can instruct the patient on modifying the pill pouches already dispensed. The patients and/or caregivers will be responsible for ensuring that any modifications or discontinuations made to prescriptions already dispensed are accurate.

Pharmacies wishing to take advantage of this policy change must enter into an updated MOU with the Board. The updated MOU is available on the Board's website in the Forms & Instructions section.

Prescription Drug Take-Back Success Ongoing – *www.artakeback.org*

The April 2018 drug take-back event resulted in a total of 28,020 pounds of unused medications being gathered, which once again surpassed the Board's hopes for this event and also shows why Arkansas's take-back program is ranked third in the nation. The October 2018 drug take-back event collected 26,529 pounds of unwanted, potentially dangerous drugs. The cumulative efforts of Arkansas's take-back events have resulted in 318,203 pounds of unused medications, estimated at 442.6 million pills, being removed from homes and destroyed responsibly so that they can no longer be a danger to someone else. This fact is astounding when considering that without this service, millions of doses of medications might still be sitting around the state in closets, medicine cabinets, and bathrooms.

In partnership with DEA, Arkansas Drug Director Kirk Lane, and others, the *www.artakeback.org* website has up-to-date information surrounding drug disposal and destruction. Please remind your patients that these locations are available year round. Please note that as DEA registrants, all pharmacies must account for all controlled medications and must utilize a reverse distributor or their wholesaler for outdated or unusable drugs. Furthermore, pharmacies may not receive unwanted medications from patients unless they are registered with DEA as an authorized collector. The next DEA National Prescription Drug Take-Back Day will be held on Saturday, April 27, 2019.

Update Registrant Records

Please ensure that your pharmacy address, phone number, and employment records are up to date through the License Maintenance portal on the Board website. The pharmacy license and facility ID are on the reverse side of your pharmacy license. Pharmacists, interns, and pharmacy technicians should also ensure that their contact information is current. Failure to notify the Board of your current mailing address and employment are grounds for disciplinary action. If you prefer, you may alternately notify the Board by fax, mail, or email.

Nonsterile Compounding for Office Use

A recent letter from Food and Drug Administration (FDA) to the Oklahoma State Board of Pharmacy clarifies FDA's stance that nonsterile compounding for office use is not allowed by retail pharmacies. A patient-specific prescription is needed for sterile and nonsterile compounded products. Compounds for office use must be provided by a 503B facility (outsourcing facility).

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Controlled Substance Inventories

CS inventories must be conducted at least every two years. The biennial inventory may be taken on any date within two years of the previous biennial inventory date. All inventories and records of Schedule II substances must be maintained separately from all other records of the registrant. The pharmacist must make an exact count or measure of contents for any Schedule II substance. Substances in Schedules III, IV, or V may be estimated unless the container holds more than 1,000 tablets or capsules, in which case the pharmacist must make an exact count of the contents. The inventory shall be signed by the pharmacist, dated, and noted whether the inventory was taken at the opening of business or the close of business.

CS inventories must also be taken upon change of ownership of the pharmacy and/or change of the pharmacist-in-charge.

Special Notice About the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office (501/682-0190) if you have questions about any of the articles in this *Newsletter.*

Arkansas Pharmacy Support Group Help Line
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