January 2019

Oklahoma State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

2920 N Lincoln Blvd, Suite A • Oklahoma City, OK 73105-3488

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19.01 Reminder to Board-Licensed Pharmacists, Pharmacy Technicians, and Businesses

As a friendly reminder, it is **your** responsibility to renew your license or permit before it expires! The Oklahoma State Board of Pharmacy office sends out postcard renewals 60 days prior to expiration as a **courtesy.** Failure to receive a reminder does not exempt any licensee from renewal, late fees, and/or cancellation. Pharmacist licenses and technician permits expire the last day of the licensee's birth month. Pharmacy and facility licenses have their specific expiration dates on the licenses, which should be posted at all times in a conspicuous place.

19.02 From the Inspector's Desk

- As a reminder, please verify that the national drug code (NDC) of the product being dispensed to the patient matches the NDC of the product being billed to third parties!
- Oklahoma pharmacies: Please post your licenses for e-kits near the pharmacy license so that they are visible and easily noticeable to the compliance officers. If you have an abundance of e-kit licenses and do not have enough space to post them, please have them readily available for the compliance officers, and please put them in a format that is easy to view and read.

Senate Bill 1446: Immediate Release Opioids

The following language is adapted from an email sent to registrants on October 30, 2018, regarding Oklahoma Senate Bill (SB) 1446:

After meeting with the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) and several state agencies, here are some of the highlights of SB 1446 that may help pharmacists in applying this bill to their pharmacy practice.

SB 1446 applies only to immediate release opioids prescribed for acute pain and includes tramadol and codeine products. Buprenorphine is not included in this law. Diagnosis for "acute vs chronic" pain is not required on the prescription by OBNDD; however, insurance policies or company policies may require it. Pharmacists may ask the

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National Pharmacy Compliance News

January 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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patient, check the prescription monitoring program, check the patient profile, or contact the prescriber to verify if the prescription is for "acute vs chronic" pain. Pharmacists are not required to verify acute pain diagnosis and will need to utilize their professional judgment.

Prescribers must follow this timeline for acute pain events:

The initial prescription for an acute pain event can be issued for a seven-day supply to be determined by the prescriber. If a second prescription is needed, then the prescriber, after consultation with the patient, can issue another prescription for a seven-day supply. Consultation is **not** defined in the law. Individual licensing and regulatory boards can define what constitutes a consultation. The consultation could be by telephone, telemedicine, face to face, etc, but there **must** be a consultation between the prescriber and the patient. If a third prescription is needed, there must be a written agreement, pain management agreement, or pain management contract in place between the prescriber and the patient. Pharmacists are not required to make sure this contract is in place. However, this information may be requested during the counseling and verification process.

Any provider authorized to prescribe opioids shall adopt and maintain a written policy or policies that include the execution of a written agreement to engage in an informed consent process between the prescribing provider and the qualifying opioid therapy patient.

"Qualifying opioid therapy patient" means a patient requiring opioid treatment for more than three months, a patient who is prescribed benzodiazepines and opioids together, or a patient who is prescribed opioids that exceed 100 morphine milligram equivalents per day. **If the patient is on chronic pain medication and has an acute event, then the pharmacist will carefully evaluate the impact of adding an immediate release opioid to the patient's therapy.**

After the above information was distributed, the Board office was made aware that Governor Mary Fallin signed and adopted emergency rules regarding SB 1446. You are advised to refer to OBNDD 475:30-1-4(c)(2) for a complete version of these rules. A section of the rule is as follows (emphasis added):

475:30-1-4. Manner of issuance of prescriptions

(c) A practitioner must state on a written prescription for any controlled dangerous substance the name, address and Federal Drug Enforcement Administration registration number of the practitioner; the date of delivery of the prescription; the name, dosage and strength per dosage unit of the controlled dangerous substance; the name and address of the patient, or if it is a veterinary prescription, the species of the animal and the name and address of the owner; the directions for use and any cautionary statements required; and if allowable, the number of times to be refilled.

(1) The face of a prescription must not be materially altered; if an error is made in filling out the prescription, a new prescription must be written by the prescribing practitioner.

(A) A pharmacist may add to the prescription the patient's address or age, the prescribing practitioner's federal DEA number, or the generic drug name if used.

(B) After confirming with the prescribing practitioner, the pharmacist may add information indicating the strength, whether tablet or capsule form, and whether it is compounded if such additions would not materially alter the prescription.

(C) If omitted, the directions (Sig) or the quantity, may be added by the pharmacist after confirming with the prescribing practitioner.

(D) Documentation of contacting the prescribing practitioner will be noted on the back of the prescription regarding (B) and (C) above.

(2) A written prescription for a controlled dangerous substance in Schedule II becomes invalid thirty (30) days after the date of issuance, with day one (1) of the thirty (30) day period being the first day after the date of issuance.

(A) After issuing an initial prescription pursuant to Section 2-309I of Title 63, an individual practitioner may issue one (1) subsequent prescription for an immediate-release opioid drug in Schedule II in a quantity not to exceed seven (7) days if:

(i) The subsequent prescription is due to a major surgical procedure and/or "confined to home" status as defined in 42 U.S.C. 1395n(a);

(ii) The practitioner provides the subsequent prescription on the same day as the initial prescription;

(iii) The practitioner provides written instruction on the subsequent prescription indicating the earliest date on which the prescription may be filled (i.e. "do not fill until" date); and

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(iv) The subsequent prescription is dispensed no more than five (5) days after the "do not fill until" date indicated on the prescription.

(3) Each scheduled drug shall be written on a single prescription form, and no other prescriptions (controlled or non-controlled) shall be written on the same prescription form.

19.03 Out-of-State Mid-Level Practitioners

Pharmacies can now fill non-controlled dangerous substance (CDS) prescriptions from out-of-state optometrists, physician assistants, and advanced practice registered nurses. For pharmacies to fill CDS prescriptions from out-of-state optometrists, the optometrist needs to be licensed in Oklahoma. For pharmacies to fill CDS prescriptions from out-of-state physician assistants and advanced practice registered nurses, they need to be licensed in Oklahoma and supervised by an Oklahoma-licensed physician. The law to allow this became effective on November 1, 2018.

19.04 Disciplinary Actions

Maria Epp, Technician #4246 – Case No. 1532: Admits guilt on all four counts including theft while working as a registrant. **Revoked.**

Barujah Sharrieff, Technician #23930 – Case No. 1539: Found guilty on all four counts including theft while working as a registrant. **Revoked.**

Britt Bowman, Technician #18351 – Case No. 1540: Found guilty on one count including failure to conduct oneself at all times in a manner that will entitle her to the respect and confidence of the community in which she practices. **Revoked.**

Sheila White, Technician #12722 – Case No. 1541: Admits guilt on all four counts including theft while working as a registrant. **Revoked.**

Stephenie Gillan, Technician #22986 – Case No. 1542: Found guilty on all counts including larceny of prescription drugs. **Revoked.**

ASPCares, #1-7722 – Case No. 1530: Respondent neither admits nor denies guilt on all five counts including that only a pharmacist is responsible for the control and distribution of all drugs. Respondent is on unsupervised probation for two years until September 26, 2020. **$10,000 fine.**

Walmart Pharmacy No. 10-0576, #2-3761 – Case No. 1535: Respondent neither admits nor denies guilt on all seven counts including that the pharmacy and pharmacist must establish and maintain effective controls against diversion.

Calendar Notes

The Board is scheduled to meet on January 16, 2019, and March 6, 2019. Both meetings will begin at 8:30 AM.

Change of Address or Employment?

Please be diligent in keeping your information up to date and, if possible, remind your coworkers and employees. **Failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns** must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. Oklahoma Pharmacists Helping Pharmacists (OPHP) is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574 ext 5773. All calls are confidential.

This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website. (74 O.S. §3105 and 65 O.S. §3-114)

The *Oklahoma State Board of Pharmacy News* is published by the Oklahoma State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Dorothy Gourley, DPh - Executive Director
Brittany Parrott - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager