



West Virginia Board of Pharmacy

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PIC Responsibilities Regarding Technician Trainees

There have been numerous pharmacy technician trainees requesting extensions in order to complete the requirements to apply to be a pharmacy technician. As a reminder, the pharmacist-in-charge (PIC) has specific responsibilities to make certain the pharmacy technician trainee is on track to successfully become a West Virginia-registered pharmacy technician. The responsibilities of the PIC to the pharmacy technician trainee are:

1. Maintain the pharmacy technician trainee manual for your pharmacy.
2. Supervise the training program for all trainees.
3. Maintain a record of all technicians who successfully complete the training program and attest to the West Virginia Board of Pharmacy those persons who have met the requirements necessary for registration with the Board.
4. Maintain a record of completed training hours if the technician trainee is doing the on-the-job, competency-based pharmacy technician trainee program, which requires 960 hours in 15 months per West Virginia Code of State Rules (WV CSR) §15-7-4.2.

The written record of the trainee's training must include the following:

1. The name of the pharmacy technician trainee
2. The dates of the training
3. A general description of the topics covered
4. A written statement confirming the technician trainee is competent to perform the tasks covered
5. The name of the person supervising the training
6. The signature of both the trainee and the PIC or another supervising pharmacist

When the pharmacy technician trainee first starts at the pharmacy, he or she should begin training by completing the Board-approved, 20-hour training program regarding the dispensing process in that pharmacy as required by WV CSR §15-7-3.2. In many pharmacies this may be a computer-based training program orienting the technician trainee to the pharmacy tasks in that specific pharmacy setting. The pharmacy technician trainee has 90 days from the completion of the required hours and training program to obtain the national certification and the state certification. This includes passing the test and submitting the application to the Board to be a pharmacy technician. Extension requests need to be completed fully with adequate information and explanation from the PIC. If the pharmacy technician trainee is deficient in a certain area, the PIC should indicate this on the extension request and indicate the plan for remediation to resolve the deficiency. Finally, if the pharmacy technician trainee fails to become a pharmacy technician and does not receive an extension, he or she must stop working in the pharmacy upon the expiration date of his or her pharmacy technician trainee registration.

Transfers for Controlled Substances

In October 2017, Drug Enforcement Administration (DEA) issued a letter clarifying its stance on transferring unfilled controlled substance (CS) prescriptions. The letter clarified that whether an unfilled prescription can be transferred to another pharmacy depends on how the prescription was received at the pharmacy. If the prescription was truly electronically prescribed, meaning it meets all requirements relating to electronic prescriptions and is a Schedule II-V CS, it can be transferred. This would only be if the information could be sent to another pharmacy electronically without being filled. Transferring the prescription via telephone or another method would not be permitted if it is unfilled.

National Pharmacy Compliance News

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NABPF
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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 Con-

trolled 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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If the prescription for a Schedule III-V CS is received via telephone, fax, or paper, according to 21 Code of Federal Regulations §1306.25(a):

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.

Therefore, a pharmacist may **not** transfer an **unfilled** prescription that has been received via phone, fax, or paper. However, a pharmacist may transfer the refills after the prescription has been filled the first time. Simply placing the prescription "on hold" in the pharmacy database does not constitute filling the prescription, and therefore the prescription may not be transferred. The original DEA letter can be found at https://cdn.ymaws.com/www.ascp.com/resource/resmgr/files/dea_redirection_issue.pdf.

CS Inventories

Complete inventories of CS are to be completed every two years according to WV CSR §15-2-7.5. Additionally, West Virginia requires that a perpetual inventory of all Schedule II medications be kept and reconciled monthly. These are only the inspector's checklists, so make sure you are keeping your inventories up to date and reconciled.

Annual Inspections

Starting January 1, 2019, the Board began annual inspections of the pharmacies and registered entities in West Virginia. This is a change from biennial inspections. If you are uncertain of your last inspection, call the Board at 304/558-0558, and its staff can let you know the date of your most recent inspection.

West Virginia Official Prescription Paper

West Virginia official prescription paper requirements have been in place for several years, but Board inspectors are still seeing prescriptions that are not written on paper

that satisfy the requirements. As a reminder, the requirements include that the paper must have features that will prevent unauthorized copying, erasure modification, and an ability to counterfeit the prescription pad. WV CSR §15-1-27 dictates that the prescription blank must have check boxes to indicate the quantity. If the prescription is electronically printed in both numerical and word format, then the check boxes are not required.

Renewal Time Is Approaching

You will receive a renewal notice in the mail with complete instructions. Renewals are now done online and will begin on May 1, 2019. You must complete all fields. If you are unsure of your retirement date, please estimate. It is fine if it changes. This is a requirement of the West Virginia Legislature and your renewal cannot be processed without this information. Your renewal form must be received by June 15, 2019, for your application to be processed on time and for your license to be valid on July 1, 2019. Renewals received after June 30, 2019, will be subject to late fees.

Legislative Session

There are several bills relating to pharmacy currently working their way through the West Virginia Legislature. As you hear about them, remember that they will not become final until after the entire legislative process is complete and the bill is signed by the governor. Also, there is often a waiting period for the effective date. Information will be available on the [Board website](#), via the *Newsletter*, and on the Board's forthcoming Facebook page as new laws and regulations become effective.

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