



West Virginia Board of Pharmacy

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Pharmacy Rules Effective March 22, 2019 Reciprocity for Pharmacy Technicians

A pharmacy technician who has obtained a national certification and practiced in another jurisdiction for at least a year is eligible to apply for reciprocity in West Virginia. The individual must be in good standing in the original state of jurisdiction. He or she must still apply as a pharmacy technician trainee and complete the 20-hour, site-specific training program. The applicant will then apply to be a pharmacy technician by providing satisfactory proof to the West Virginia Board of Pharmacy of his or her licensure status with the board of pharmacy in the state in which the individual was licensed and proof of national certification. In states where there is no technician licensure, a notarized document with proof of satisfactory employment by the previous pharmacist-in-charge (PIC) is sufficient.

Pharmacy Technician Trainee Hours

Pharmacy technician trainees are now required to have a minimum of **500 hours** of employment within a **12-month** period under the direct supervision of a pharmacist to complete the on-the-job, competency-based pharmacy technician training program. This is a reduction in required hours from 960 hours in 15 months. The pharmacy technician trainee has 90 days to pass the national test and get registered as a pharmacy technician after obtaining the required hours. If an individual is currently registered as a pharmacy technician trainee and has 500 hours (including the 20-hour, site-specific training program), he or she may go ahead and apply to take a national pharmacy technician certification exam. Once the exam is passed, he or she may apply to be a West Virginia pharmacy technician through the usual process.

Cashiers in the Pharmacy

A person who handles prescription drugs only during the point of sale in order to provide the prescription drug to a

patient and accept a payment, is **not** subject to the licensure requirements of the [Pharmacy Laws and Legislative Rules of West Virginia §15-7](#) (Pharmacy Technicians). This handling process includes the cashier having access to the pharmacy's operating system to view unique information for each patient. A pharmacy may require an individual to complete a criminal background check before he or she is hired, but it is not a requirement of the Board.

Bills Passed in the 2019 Legislative Session

The West Virginia Legislature passed numerous bills related to pharmacy practice this session. While many of the laws become effective the first week of June 2019, some require rules or protocols to be written and will not be able to be implemented until a later date. Information on the actual initiation for these bills will be updated on the Board's website at www.wvbop.com.

HB 2524: Conversion of Prescriptions and Emergency Fills

House Bill (HB) 2524 is effective as of June 6, 2019, and has three parts: 30-day to 90-day conversions, dosage substitutions, and emergency prescriptions for life-sustaining medications. For a prescription that has been previously filled for a patient for a maintenance drug for a chronic condition, a drug taken on a regular basis to prevent disease, or a contraceptive, the pharmacist may consult with the patient and determine if he or she is stabilized and if conversion is desired. Regarding the first section of the bill, the pharmacist will be able to make certain changes without consulting the prescriber. For example, if the prescription is written for a 30-day supply with five refills, the pharmacist could change the prescription to a 90-day supply with one refill. This conversion authority excludes controlled substance (CS) prescriptions.

National Pharmacy Compliance News

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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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD[®] Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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The second section of this bill covers dosage substitutions. If the pharmacist is unable to dispense a drug in the prescribed dosage, the pharmacist may substitute the same drug in a different dosage, as long as the aggregate dosage of the prescription remains the same and the pharmacist counsels the patient on the differences and notifies the patient's prescriber of the drug product substitution within five business days of the substitution. This dosage substitution language does not require the health plan to provide coverage for the substitution. For example, if the pharmacist could not dispense amoxicillin suspension of one concentration (400mg/5mL versus 250mg/5mL), the pharmacist could dispense a covered concentration with the appropriate directions and quantity, notify the provider within five business days, and counsel the patient.

The final section in this bill is related to emergency prescriptions for life-sustaining medications. It allows a pharmacist to provide up to a 30-day supply or the standard unit of dispensing (eg, an inhaler or vial of insulin) if the following conditions are met:

1. The pharmacy has a record of a previous prescription for the medication with no valid refills for the patient requesting it.
2. It is not a CS.
3. The pharmacist is unable to obtain authorization to refill the prescription from a health care professional responsible for the patient's care.
4. In the pharmacist's professional judgment, the medication is essential for sustaining life or continuing therapy for a chronic condition, and failure to dispense the drug could result in harm to the patient.

This emergency supply may only be provided one time per drug per 12 months, and the pharmacist is required to maintain a list of specific records for one year. The pharmacist must notify the prescriber within 72 hours.

HB 2849: Technician Classes and Scope

HB 2849, which technically is effective as of June 7, 2019, requires rules to be written for the implementation of this law. The rules will be submitted for passage during the next legislative session and should be implemented in 2020. It contains two sections: one on nuclear pharmacy technicians and one on pharmacy technician scope of practice. Nuclear pharmacy technicians have always had a separate designation, but they still had to pass one of the two national pharmacy technician certification exams. Nuclear pharmacy technicians now have a separate endorsement and will have requirements that are specific to their area, rather than a national pharmacy technician certification exam.

The bill also expanded the role of pharmacy technicians in West Virginia. The purpose of this is to permit the technician to do appropriate technician tasks, thus allowing pharmacists time for patient-centered care. The expanded tasks for pharmacy technicians who are under the direct supervision of a pharmacist include completing a list of a patient's current prescription and nonprescription medications to provide for medication reconciliation, supervising registered pharmacy technicians and pharmacy technician trainees, and screening medical records. Additionally, pharmacy technicians who have worked full-time for at least the previous two years may perform pharmacy technician product verification where no clinical judgment is necessary, and the pharmacist makes the final verification. The registered pharmacy technician must furnish the Board with an affidavit signed and dated by the supervising PIC of the facility that employs the applicant, attesting to the applicant's competency in the advanced areas of practice that he or she will work. There will be comprehensive rules written for this new law that must be passed to fully implement this program. Expect these technician scope expansion opportunities in 2020.

HB 2768: Opioid Reduction Act Update

The original Opioid Reduction Act passed in 2017, placing limits on initial CS prescriptions and documentation requirements for physicians. The updates to the bill work to clarify many of the uncertainties that providers have seen in the last 12 months with implementation. As of June 7, 2019, the law will only apply to Schedule II opioids. Therefore, pharmacies may return to filling a 90-day supply of non-opioid Schedule II medications. Other new language in the bill includes the following statement:

A pharmacist is not responsible for enforcing the provisions of this section [the initial prescription day supply limits] and the Board of Pharmacy may not discipline a licensee if he or she fills a prescription in violation of the provisions of this section.

The Board reminds pharmacists that nothing in this bill eliminates the pharmacist's state and federal corresponding responsibility to ensure that the prescription is for a legitimate medical purpose in the usual course of professional practice. Pharmacists who identify physicians routinely violating the law regarding initial prescription limits for Schedule II opioid prescriptions should contact the West Virginia Board of Medicine.

HB 2525: Tobacco Cessation Therapy Access Act and HB 2583: Family Planning Access Act

Both new laws will enable pharmacists to provide protocol-driven, direct patient care for tobacco cessation

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therapy and self-administered hormonal contraceptives. Both programs will utilize protocols that are currently in development and standing orders from the West Virginia State Health Officer. HB 2525 will enable a pharmacist to initiate non-controlled prescription and over-the-counter medications and other professional services for tobacco cessation with Board-approved training. The patient's primary care provider must be notified within two days of service initiation.

HB 2583 is similar, but for self-administered hormonal contraception for individuals 18 years and older. This contraceptive medication can be provided for 12 months, and the primary care provider must be notified if indicated. While the effective dates of this legislation are June 4, 2019, and June 7, 2019, respectively, neither of these laws may be implemented until the protocols are completed, training is approved and finished, and the standing order is issued. Monitor the Board website for the latest information.

SB 489: Pharmacy Audit Integrity Act

Senate Bill (SB) 489 provides additional amendments to a law passed last session to increase transparency and integrity in the pharmacy audit process. The law now requires pharmacy benefits managers (PBMs) to be licensed by the West Virginia Offices of the Insurance Commissioner and imposes reimbursement standards on 340B medications. The law will also impose quarterly reporting requirements

on the PBM regarding the amount paid to the pharmacy provider per claim for the West Virginia Public Employees Insurance Agency and limits allowable fees and adjustments during audits.

Miscellaneous Bills

Two final pharmacy-related bills from this West Virginia Legislative Session are SB 518: Sale of Dextromethorphan (effective May 31, 2019) and HB 2509: Felony for Prohibited Acts (effective June 4, 2019). SB 518 requires the purchaser of dextromethorphan to be 18 years old. The product does not need to be behind the counter. HB 2509 makes it a felony to acquire or obtain possession of any amount of a CS by misrepresentation, fraud, forgery, theft, deception, or subterfuge. While the possession will now be considered a felony versus a misdemeanor, it will still be at the discretion of the prosecutor to determine how to charge the individual.

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West Virginia Board of Pharmacy

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