



New WV BOP Officers Elected at the June 2024 Board Meeting

The quarterly Board of Pharmacy meeting was held June 2-3, 2024 at Oglebay Resort, Wheeling, WV. New officers were elected including Dennis Lewis, RPh as President, David Bowyer, RPh as Vice President, and Jenna Misiti as Secretary for the 2024-2025 year. Their terms began the first of July.

Update on USP Chapter 800 Hazardous Drug Inspections

An update related to USP Chapter 800 Hazardous Drugs has been provided to this Chapter. The comprehensive Hazardous Drug Inspection will only apply to pharmacies that perform sterile and non-sterile compounding. It is important to recognize that while the Board will only complete the Hazardous Drug Inspection for these pharmacies, the pharmacist-in-charge should ensure that pharmacy staff understands how to handle these medications to minimize risk even when not manipulating them via compounding.

Immunization Updates:

The CDC Immunization Schedule is annually updated and the new schedules posted each fall. However, the Advisory Committee on Immunization Practices (ACIP) meets at least quarterly to review new evidence on currently available vaccines and revise the schedules. The authority for pharmacists in WV to order and administer vaccines in WV is based on the current CDC recommended vaccines. Therefore, WV pharmacists should always stay up-to-date on the current vaccine recommendations for each population. The current CDC recommendation for immunization schedules and recent meeting recommendations that have been adopted by the CDC Director can be found <https://www.cdc.gov/vaccines/acip/recommendations.html>. The most recent ACIP meeting occurred June 26-28, 2024 and included changes to vaccines for RSV, COVID-19, influenza, pneumococcal, and meningococcal among others. Make certain you stay up-to-date!

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Fiddleheads. Dolly Sods ~ Photo by Betsy Elswick, PharmD



Multiple Statute and Rule Changes from the 2024 Legislative Session



Effective - May 3, 2024

§15-1 General Rules of The Practice of Pharmacy

Two primary changes were made to W.V. 15 CSR 1.

1. The first change requires immediate notification to the WV Board of Pharmacy in two situations:
 - The separation of employment of any pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee for any confirmed drug-related reason, including but not limited to, adulteration, abuse, theft, or diversion, and notification shall include the reason for the termination.
 - If it is the employment of the Pharmacist-in-Charge that is terminated, the owner and/or pharmacy permit holder shall immediately notify the Board of Pharmacy.
2. Also, the definition of telepharmacy was expanded to permit the provision of direct patient-care activities when the patient is unable to be present in the pharmacy for a personal face-to-face interaction.

§15-3 Rules for Continuing Education for Pharmacists

During the 2023 legislative session the requirements for the Drug Diversion Continuing Education was changed, requiring a rule change update and clarifying the statute change. Beginning for renewal cycle 2024, if you have reported Drug Diversion CE to the WV BOP during a licensure renew before 2024 you DO NOT need to report the Drug Diversion CE requirement for 2024 or in the future. Licensees who are renewing for the first time and have never reported the 2-hour board-approved Drug Diversion CE requirement to the WVBOP are required to report it this year in 2024 at license renewal or at the next license renewal.

§15-12 Pharmacist, Pharmacy Intern, and Pharmacy Technician Administered Immunizations

The rules update for pharmacy-based immunizations are comprehensive and revised to encompass the permissions originally allowed during the COVID-19 pandemic. Changes are summarized here:

- Pharmacists may order and administer CDC recommended vaccines for individuals ages 3 years and up. Pharmacy Interns and pharmacy technicians may administer under pharmacist supervision. (NOT pharmacy technician trainees)
- Pharmacists, pharmacy interns, pharmacy technicians must complete a Board-approved training program AND have valid CPR certification.
- Pharmacists and pharmacy technicians must register with the Board prior to giving immunizations. Pharmacy interns must provide all documentation to the supervising pharmacist and it shall be stored at the pharmacy.
- Immunizations permitted include for age 3 years and up when a prescription order is provided **OR** pharmacist ordered immunizations for individuals age 3 years and up in accordance with CDC Immunization Schedule available here. If the individual is age 3-17 years the vaccine shall only be administered with parental, informed consent, provided there are no contraindications, and after informing the patient and the adult caregiver accompanying the patient of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and referral for patients as appropriate.
- The immunizations must be given according to training and the Vaccine Information Statement must be provided.
- The record-keeping, reporting, policies, preparation for immunization emergencies, remain the same.

Multiple Statute and Rule Changes from the 2024 Legislative Session

§15-14 Central Fill Process

The change in §15-14 permits an employee of or under contract with a licensed pharmacy, or a licensed pharmacy technician or pharmacy intern, working under the supervision of the pharmacist, to access that pharmacy's electronic database from inside or outside the pharmacy and perform the prescription drug order processing functions permitted by the W.Va. Code 30-5-1 et seq., if the following conditions are met:

- The pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and
- No part of the database is duplicated, downloaded, or removed from the pharmacy's electronic database; and
- The pharmacy's electronic database shall only be accessed outside of the pharmacy via a virtual private network (VPN).

This aids with covering pharmacies that may need assistance with staffing and remote work.

§15-15 Regulations Governing Pharmacy Permits

Changes in §15-15 relate to notification when a pharmacy is closed or closing, either temporarily, permanently, or in case of an emergency. The requirements are specific and can be seen in their entirety [here](#).

Senate Bill (SB) 269 - Excluding test strips from definition of drug paraphernalia

SB 269 became effective on January 26, 2024, and states that drug test strips are not considered drug paraphernalia. This includes fentanyl test strips.

(cont.)

SB 668 - Increasing amount of certain controlled substances persons

may purchase annually

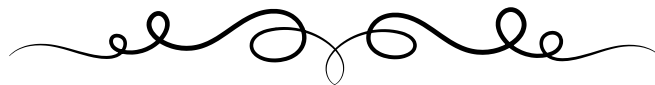
SB 668 became effective on May 23, 2024, and increases the amount of pseudoephedrine, ephedrine, phenylpropanolamine (all Schedule Vs in WV) that persons may purchase annually. This makes WV limits match the federal limits. The bill only changes the annual limit to 86.4 grams annually. The daily and monthly limits remain the same. This is updated in the multi-state real-time tracking system.

SB 325 - Relating to distribution of drugs to safety net providers and contract pharmacies

SB 325 became effective June 6, 2024, and is related to the covered entities in the 340B program. It prohibits the manufacturer from not delivering a 340B drug to a location authorized by a 340B entity to receive such 340B drug and prohibits the manufacturer from requiring a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services. Failure to comply may result in complaint, investigation, and possible fines.

SB 453 - Requiring pricing and payment transparency from pharmacy benefits managers contracting with PEIA

SB 453 became effective June 7, 2024, and relates to pharmacy benefit managers (PBM) and transparency with the state Public Employer Insurance Association (PEIA). The bill requires reimbursement at National Average Drug Acquisition Cost (NADAC) + dispensing fee equivalent to WV Medicaid.



Can pharmacists administer drugs other than immunizations?

This question is often asked of the Board. For the answer, we refer you to §30-5-10(a)(3) under Scope of practice for licensed pharmacist indicating that a licensed pharmacist may "provide drug administration." "Administer" is defined in §30-5-4 as the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Recognize that while pharmacists can administer medications, they are not authorized to prescribe or order them as permitted with immunizations. The authority is only covered in the scope of a pharmacist, not any other pharmacy personnel and may not be delegated.

Pharmacists must also ensure that appropriate training and education has been completed prior to providing additional medication administration. Questions can be addressed by emailing Krista Capehart at krista.d.capehart@wv.gov.

Helping Patients with Substance Use Disorder

by Lindsay Acree, PharmD

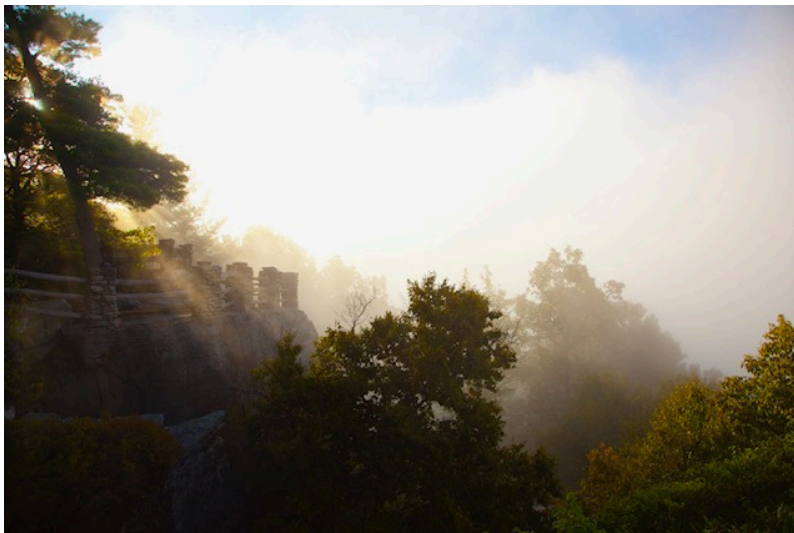
Pharmacists not only provide a vital resource to the community through provision of prescription medications, education, vaccines, and advice for over-the-counter medications, pharmacists are the most accessible providers and are trusted members of the community. Anyone in the community, regardless of whether they are a patient, can access healthcare advice by visiting a pharmacy. Many of our community members are struggling with health issues, but the ones with the most stigma are substance use disorders (SUD's) and mental health. When disease states are stigmatized, it may be difficult for individuals to ask for help or attempt to access treatment. West Virginia has the highest overdose death rate in the U.S. of 80.9 lives per 100,000 with the loss of over 1,300 lives in 2022 alone(1). West Virginia is not unique in that nationally illicit fentanyl among other synthetic opioids, are responsible for the majority of overdose deaths in 2022(2). There are many ways that pharmacists can help to reduce the number of lives lost in our state to overdose deaths including the provision of an opioid antagonist such as naloxone to anyone requesting, counseling every individual receiving an opioid regarding the risks, offering an opioid antagonist to every patient receiving an opioid or pharmacotherapy for SUD, and lastly building relationships with the community such that individuals feel comfortable coming to the pharmacy for help. Information regarding opioid antagonists, including links to brochures/education, state standing orders, and the Protocol for Pharmacists or Interns Furnishing Opioid Antagonist is available on the WV Board of Pharmacy website under the "FAQS" tab. A direct link to the page is available [here](#).

In order to be able to assist someone in locating treatment resources, the pharmacist or pharmacy staff also needs the tools to assist them. To facilitate this goal of preparing pharmacists to assist individuals with mental health concerns or SUD, beginning August 1, a new tab will be available under "FAQS" with resources available in the state including links for connection to treatment, suicide prevention, mental health services, and social services. By the fall, we plan to also have toolkits for each county to include local resources such as Quick Response Teams (QRT's), access to food or hot meals, clothing resources, naloxone access, etc. We also plan to partner with the West Virginia Office of Drug Control Policy to locate pharmacies and healthcare providers that are interested in participating in the HALO Initiative, which provides connection to treatment, access to transportation to treatment, and disposal kits for safe destruction of illegal substances. More information on the HALO initiative is located [here](#).

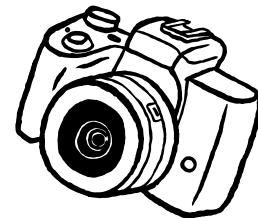
1. Drug Overdose Mortality by State. Centers for Disease Control and Prevention; National Center for Health Statistics. Updated Mar 1 2022. Atlanta GA. Accessed 6/27/24. Available from:

https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm#print

2. Kariisa M, O'Donnell J, Kumar S, Mattson CL, Goldberger BA. Illicitly Manufactured Fentanyl-Involved Overdose Deaths with Detected Xylazine — United States, January 2019–June 2022. MMWR Morb Mortal Wkly Rep 2023;72:721–727. DOI: <http://dx.doi.org/10.15585/mmwr.mm7226a4>.



Coopers Rock ~ Photo by Betsy Elswick, PharmD



Do you love taking
photos of our
beautiful state?

Submit them @
krista.d.capehart@wv.gov and yours
could be featured in the next
WV BOP Newsletter!

FDA Grants Exceptions from Some DSCSA Requirements for Small Dispensers

The FDA had granted a one-year stabilization period for all trading partners to enhance drug distribution security requirements lasting until November 27, 2024. In July 2024 the FDA additionally has granted small dispensers (pharmacies), and where applicable their trading partners, until November 27, 2026. This provides small dispensers additional time to stabilize their operations to fully implement the enhanced drug distribution security requirements of the Drug Supply Chain Security Act (DSCSA).

The FDA defines a small dispenser as, “a dispenser is considered a small dispenser, for the purposes of these exemptions, if, as of November 27, 2024, the company that owns the dispenser has 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians.” FDA states that, “Trading partners that do not qualify for the small dispenser exemptions and are unable to meet the enhanced drug distribution security requirements of section 582 of the FD&C Act by November 27, 2024, may request a waiver or exemption from those requirements.” The FDA recommends this be completed by August 1, 2024.

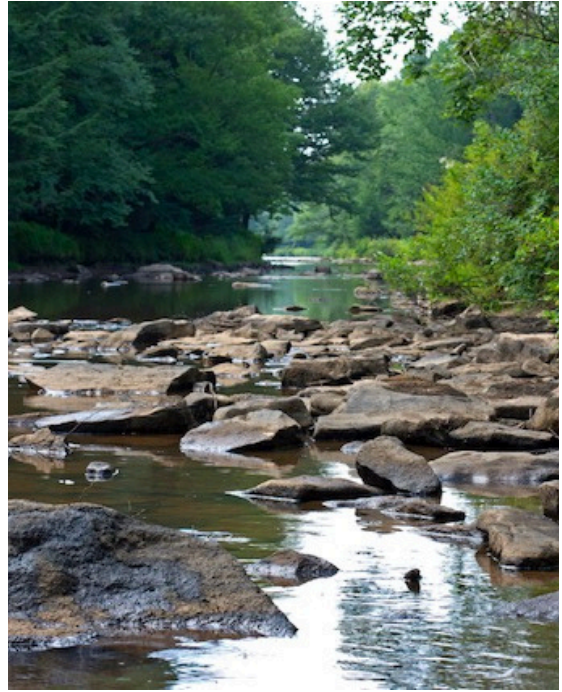
Additional information about the extension for small dispensers and waiver requests can be reviewed at the FDA website [here](#).

NEW Drug Shortages Portal

The FDA has created a new portal for patients, healthcare providers, and organizations to report. The portal is available [here](#). The instructions below are for the use of the portal.

To use the public portal:

1. First check the [Drug Shortages Database](#) for current shortages to see if FDA is already aware of this shortage. Search by your product's generic name or active ingredient.
2. If the drug is already in the Drug Shortages Database, talk with your health care provider or pharmacist for other treatment options during the shortage. FDA is actively working on resolving that shortage.
3. If the drug is NOT in the Drug Shortages database, send a report to FDA through our new public portal.



Blackwater River ~ Photo by Betsy Elswick, PharmD



Recent Board Action

Additional information as required by law on Board finalized discipline can be seen on the Board's website at www.wvbop.com under Public/Recent Board Action

Michael Miller 02/15/2024 - Revoked	Akina Pharmacy 2/16/2024 - Reprimand
Fletcher Panacea 2/15/2024 - Revoked	Michelle Wudyka 03/01/2024 - Revoked
CVS Pharmacy #6280 2/5/2024 - Reprimand	CVS Pharmacy #1308 04/15/2024 - Reprimand
CVS Pharmacy #3391 02/16/2024 - Reprimand	Molli Fitzwater 07/23/2024 - Revoked
CVS Pharmacy #4419 02/16/2024 - Reprimand	

Thank you for reading!

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Questions regarding the content of the July 2024 Newsletter can be sent to Krista Capehart, PharmD, Director of Professional and Regulatory Affairs at krista.d.capehart@wv.gov	

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