



# WEST VIRGINIA BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

## ***New Inspector – Alyssa Starcher, RPh***

The West Virginia Board of Pharmacy is happy to introduce a new pharmacy inspector for the West Virginia Board of Pharmacy, Ms Alyssa Starcher. Alyssa graduated from the West Virginia University School of Pharmacy in 1998. She has spent the last 18 years as a consultant pharmacist but also has experience in hospital and retail pharmacy settings. Alyssa became a Board inspector in late March 2023.

## ***Rules and Statutory Updates From the 2023 West Virginia Legislative Session***

### ***Workload Task Force Recommendations Incorporated Into Rules***

#### **West Virginia Code of State Rules (WV CSR) §15-1-16.2.2**

The pharmacist-in-charge (PIC) is responsible for ensuring that all state and federal laws are followed. If an issue exists, the PIC is to notify the registrant and, in the old rule, the Board. This created a situation where the PIC felt that they were “tattling” on their employer just to ensure that they themselves were protected from discipline. The new process adds an additional step to promote PIC and employer communications to resolve issues, including documenting and notifying the permit holder of a violation verbally or via email and keeping a record of this notification in the pharmacy. If the violation is not resolved, then the PIC can provide

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written notification to the permit holder and the Board. At any point, nothing precludes the PIC from notifying the Board immediately.

### **WV CSR §15-7-5.3 et seq, Change in Technician-to-Pharmacist Ratio**

The pharmacy technician-to-pharmacist ratio is changed to six pharmacy technicians to one pharmacist **only** at the discretion of the PIC. Any decisions overriding such control of the PIC may be grounds for disciplinary action against the pharmacy permit holder.

### **WV CSR §15-15-7 Professional Work Environment**

A pharmacist, pharmacy intern, and pharmacy technician shall have a 30-minute uninterrupted meal break in an eight-hour shift; can have another 20-minute break if working a 12-hour shift, shall not be required by a pharmacy to work longer than 12 continuous hours per 24-hour period, inclusive of the required breaks, and must keep a record of the required breaks.

**7.4** In the case of an emergency, **as deemed by the professional judgement of the pharmacist**, a pharmacist, pharmacy intern, or pharmacy technician **may work longer than twelve continuous hours, work without taking meal breaks, or have a break interrupted in order to minimize immediate health risks for patients.**

The pharmacist must document and date the amount of time worked beyond the twelve hours limit or breaks missed along with the reason and make it available to the Board.

**7.5** The pharmacist-in-charge or designee shall determine the work schedule for pharmacy technicians based upon prior dispensing records. The pharmacist shall ensure adequate staffing levels based on prior dispensing records and patient care tasks. The pharmacist-in-charge shall have final approval of the work schedule. Any decision overriding such control of the PIC may be grounds for disciplinary action against the pharmacy permit.

**7.6** The pharmacist on duty or the pharmacy registrant shall notify the pharmacist-in-charge via telephone, e-mail, or text message whenever a prescription error, loss of drugs, or a violation of any statute or rule occurs and the pharmacist-in-charge is not present.

**7.7** A pharmacy shall not use advertisements or make solicitations that may jeopardize the health, safety, or welfare of patients, including, but not limited to, the use of advertisements or solicitations that:

**7.7.1** Are false, fraudulent, deceptive, or misleading;

**7.7.2** Include any claim regarding a professional service or product or the cost or price thereof that cannot be substantiated by the licensee.

**7.8** A pharmacy shall not require a pharmacist to participate in the use or distribution of advertisements.

**7.9** A pharmacy shall provide a working environment for all pharmacy personnel that protects the health, safety, and welfare of a patient, which includes, but is not limited to:

**7.9.1** employing sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with competency and safety or creates an environment that jeopardizes patient care as determined by the pharmacist-in-charge or pharmacists based on prior dispensing records and current patient care responsibilities;

**7.9.2** Providing appropriate opportunities for uninterrupted rest periods and meal breaks;

**7.9.3** Providing adequate time for a pharmacist to complete professional duties and responsibilities, including but not limited to:

**7.9.3.a.** drug utilization review;

**7.9.3.b.** immunization;

**7.9.3.c.** counseling;

**7.9.3.d.** verification of the accuracy of a prescription;

**7.9.3.e.** all other duties and responsibilities of a pharmacist as listed in the rules of the Board. **(emphasis added)**

### **WV CSR §15-15-9 Whistleblower Protection**

**9.1** A permit or license holder of the Board who is found to be in violation of 11 (c) CFR 1977.3 or §6C-1 known as the "Whistle-blower law" may be subject to disciplinary action by the Board.

**9.2** Nothing in this Section shall be deemed to diminish the rights, privileges, or remedies of an employee of a pharmacy under any other federal or State law, rule, or regulation or under any employment contract.

### **WV CSR §15-1-19 Clarification of When Facility Does and Does Not Need a Pharmacy Consultant**

This is separate from what facilities need a controlled substance permit.

**19.1.** Locations **requiring** a pharmacist to serve as a pharmacy consultant:

**19.1.1.** Hospital or medical clinic without a pharmacy;

**19.1.2.** Humane society;

- 19.1.3. Weight loss clinic (registered as a facility);
- 19.1.4. Urgent care clinic;
- 19.1.5. Long Term Care Facility, including but not limited to, skilled nursing facilities, intermediate nursing facilities, nursing homes, extended care facilities, assisted living facilities, rest homes, and personal care centers;
- 19.1.6. Opioid Treatment Facility or Medication Assisted Treatment Facility;
- 19.1.7. Jails and correctional facilities.

**19.2** Locations **not required** to have a pharmacist consultant;

- 19.2.1 Teaching institutions/researcher;
- 19.2.2 Emergency services;
- 19.2.3 Law enforcement;
- 19.2.4 Veterinary hospital/clinic (**emphasis added**)

### **WV CSR §15-20 et seq, Donated Drug Repository**

The Donated Drug Repository rules create a donated drug repository where drugs can be donated to be dispensed to eligible patients. Eligible recipients who may receive drugs to be dispensed to patients include: “[a] pharmacy, hospital, wholesaler, reverse distributor, federally qualified health center, nonprofit clinic, healthcare facility, an entity participating in a drug donation or repository program pursuant to another state’s law, or healthcare professional that is otherwise legally authorized to possess prescription drugs may become an eligible recipient for a period of one year by giving written notice to the board.” Eligible patients who may be dispensed the donated medication include indigent patients, which is defined as “a patient whose income is at or below the income eligibility requirements of the West Virginia Medicaid program, or who is uninsured, underinsured, or enrolled in a public assistance health benefits program.”

There are some limitations on the medications that can be donated into the program. The requirements for eligible drugs are as follows:

- (1) For prescription drugs, they do not expire before the completion of the medication by the eligible patient based on the prescribing health care professional’s directions for use and, for over-the-counter drugs, they do not expire before use by the eligible patient based on the directions for use on the manufacturer’s label; and
- (2) The drugs were donated in unopened tamper-evident packaging as defined by United States Pharmacopeia General Chapter 659, Packaging and Storage Requirements, including, but not limited to, unopened unit-dose and multiple-dose packaging.

(b) The following drugs may not be donated to the program:

- (1) Controlled substances;
- (2) Drugs subject to a federal Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to 21 U.S.C. §355-1 if inventory transfer is prohibited by such strategy; or
- (3) Drugs that there is reason to believe are adulterated.

These medications cannot be resold to patients, and an eligible recipient is responsible for the destruction of medications it has received that cannot be used in the program.

### **WV CSR §11-8 et seq, Collaborative Pharmacy Practice Agreements**

The entire process for entering into a collaborative pharmacy practice agreement (CPA) has been simplified and streamlined. The CPAs themselves no longer need to be approved by all three boards. The process is discussed below, and additional details can be found at <https://www.wvbop.com/practitioners/pharmacists/CollaborativePractice.asp>.

#### **Steps to Enter Into a CPA**

**Step 1.** Fill out the initial eligibility request form and submit it online to the Board ([wvbop.com](http://www.wvbop.com)) with satisfactory documentation of eligibility requirements (found in Section 3.4.3 a, b, or c [here](#)). This eligibility form shall be accompanied by a \$50 fee paid to the Board online.

- After initial verification is received and the Board verifies the pharmacist to be eligible, the Board will send the pharmacist a confirmation letter.

**Step 2.** After receipt of the confirmation letter, the pharmacist is to complete the collaborative pharmacy practice notification form with the physician(s).

**Step 3.** The collaborative pharmacy practice notification form must be submitted online to the Board ([wvbop.com](http://www.wvbop.com)) **with** the pharmacist's initial verification confirmation letter and shall be accompanied by a \$50 fee paid to the Board online.

**Step 4.** Once the Board receives and verifies a complete practice notification, it is effective and remains valid until the CPA terminates and is not subject to renewal or renewal fees.

### ***Pharmacy Immunizations – Update to WV CSR §15-12 et seq, Is Coming***

House Bill 2754 adds pharmacy technicians to the list of pharmacy personnel who can provide immunizations under the supervision of an immunizing pharmacist and lowers the age for pharmacist-, pharmacy intern-, and pharmacy technician-provided immunizations to ages three years and up without a physician prescription with a pharmacist's order and parental consent. The rules are being written at this time and will be implemented as quickly as possible.

## **DSCSA Resources**

Dispensers must be compliant with the Drug Supply Chain Security Act (DSCSA) by November 27, 2023. The National Association of Boards of Pharmacy® has put together a great free home study webinar, *Understanding New DSCSA Requirements and Common Diversion Schemes*, which is available at <https://nabp.pharmacy/resource/understanding-new-dscsa-requirements-and-common-diversion-schemes-home-study>. The website <https://dscsa.pharmacy/resources> is also a valuable resource for answering many questions.

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