JANUARY 2024

WEST VIRGINIA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Carveouts for Compounding Allow Pharmacists to Prepare What Patients Need

During the 2021 legislative session, the West Virginia Legislature removed a few limited items from the definition of compounding to ensure continued patient access to simple preparations given the recent changes to United States Pharmacopeia (USP) Chapter <795> Pharmaceutical Compounding – Nonsterile Compounding. 2.1.7.c. states that the following acts are not "compounding" and are exempt from USP <795> Compounding Standards. The following are not considered "compounding" and are exempt from USP <795> compounding standards:

- the reconstitution of a drug pursuant to a manufacturer's directions;
- the act of tablet splitting, crushing, or capsule opening, including those hazardous medications listed in the National Institute for Occupational Safety and Health (NIOSH) List Tables 2 and 3;
- upon the request of the prescribing practitioner and/or the patient for whom the prescription is ordered or such patient's agent, the addition of therapeutically inert, nonallergenic flavoring agents to a commercially manufactured product, not in excess of five percent (5%) of the preparation's total volume;
- the combining of commercially manufactured ready-to-use products under the following conditions:
    - no more than four (4) commercially manufactured ready-to-use products are combined;

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- products combined are FDA approved;
- combining is not done in anticipation of medication orders;
- USP <795> beyond-use dating is followed;
- combining with hazardous drugs from final dosage forms, listed in NIOSH List Tables 2 and 3, requires assessment of risk, the pharmacist or pharmacy technician should wear personal protective equipment as described in USP Chapter <800>, and must use compounding equipment dedicated solely for hazardous drugs; and
- a valid prescription shall serve as the combining record, including the name and amount or concentration, lot number, and expiration date of each ingredient; and
- the prescription label shall comply with the labeling requirements as set forth in West Virginia Code of State Rules (WV CSR) §15-1-18.

Buprenorphine Product Availability

The West Virginia Board of Pharmacy will be expanding a frequently asked questions (FAQs) section on the website at *www.wvbop.com* to include more information on medications for opioid use disorder. There have been questions regarding formerly incarcerated persons who are released and have a prescription for a buprenorphine product. Staff reached out to the West Virginia Department of Corrections and received a letter further explaining the program for treatment of incarcerated persons. These individuals will receive an ID that can be used to pick up the controlled substance. Also, these individuals should have Medicaid, but it may not be activated yet. A call to Medicaid can resolve this issue at the pharmacy level and the patient can receive medication without delay. The letter from the West Virgina Department of Corrections can be read here.

Reminder: PIC Changes at a Pharmacy

According to WV 15 CSR 16.1, a pharmacy may not operate without a designated pharmacist-in-charge (PIC). Therefore, if a pharmacy has a PIC leave, a new PIC must be designated immediately. An interim PIC can be designated for a period of no more than 60 days. The departing PIC and the pharmacy permit holder shall notify the Board within 14 days. According to WV 15 CSR 15-5:

> 5.1. When a pharmacist-in-charge changes at a pharmacy, both the pharmacist-in-charge and pharmacy must notify the Board in writing within fourteen (14) days. The original permit should be copied and the change in pharmacist-in-charge written on the original and copy of the permit. The copy of the modified permit shall be posted in the pharmacy. The original modified permit should be surrendered to the Board along with a ten-dollar ($10.00) fee for the new registration reflecting the new pharmacist-in-charge. Upon receipt of the notification, the Board shall provide for the

new registration to the pharmacy. An Interim pharmacist-in-charge may be designated for a period not to exceed sixty (60) days. If an interim pharmacist-in-charge is designated who is not the permanent pharmacist-in-charge, the fee shall not be charged, and a new permit shall not be issued until a permanent pharmacist-in-charge is designated.

COVID-19 Therapeutics

COVID-19 therapeutics Lagevrio™ (molnupiravir) and Paxlovid™ (nirmatrelvir/ritonavir) became commercially available on November 1, 2023, and as of December 1 are no longer available for free through the United States government patient assistance program (USG PAP). There are two programs that will enable patients to access the medication at the pharmacy with assistance. Pharmacies will need to purchase the medication from their wholesaler, and then the patient can utilize the PAP via the information contained here from the Administration for Strategic Preparedness and Response (ASPR).

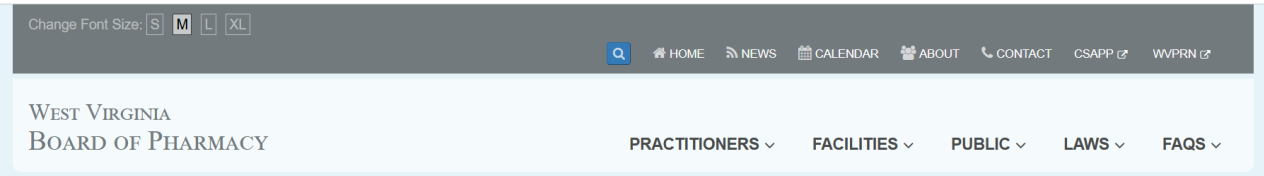
a. The Merck Patient Assistance Program (a 501c3 nonprofit organization) is now available to provide Lagevrio free of charge to patients who meet its eligibility criteria and who, without assistance, could not otherwise afford the product. Program information and applications are available at *MerckHelps.com/Lagevrio.*

b. The Paxlovid co-pay assistance program is available now for patients with commercial insurance. Patients can find information and download co-pay savings cards at *Paxlovid.com.* Providers can find information and download co-pay cards for patients using *Paxlovid.pfizerpro.com.*

c. With a start date of December 1, 2023, through December 31, 2024, individuals covered under federal programs, such as Medicare or Medicaid, and uninsured patients are eligible for the USG PAP and can receive Paxlovid at no cost. Health care providers and dispensing locations can provide information to patients regarding eligibility and how eligible patients can enroll in the PAP to obtain free products. Through this program, participating PAP dispensing sites will be reimbursed for any product dispensed, along with a dispensing fee. Retail pharmacies that would like to learn more about participating in the USG PAP can contact the program vendor at PharmacyNetworkContract102101@assistrx.com.

d. To assist in the transition from government-managed to commercial distribution, ASPR has FAQs posted on the COVID-19 therapeutics website and an updated therapeutics transition guide, *Sunsetting the U.S. Government COVID-19 Therapeutics Distribution Program.*

FAQs Section of the Board Website



The FAQs tab on the top right-hand corner of the Board's website is a treasure trove of information. This is where licensees can find the answers to many of the questions that come up in day-to-day practice that they are unable to find in a quick search of the current edition of the law book. All inspection forms, special programs, fraudulent prescriptions, and unique situational information can be found here. Staff compiles common questions asked to add to this section regularly. Take a few minutes to browse and see what is available here!

Finalized Discipline

Beginning with the April 2024 issue, finalized discipline will be appearing in the Board's quarterly *Newsletter.* This will enable individuals to view discipline through a link on the Board's website as is available on other Chapter 30 boards' websites and as required by law.

The West Virginia Board of Pharmacy News is published by the West Virginia 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.

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