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WEST VIRGINIA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

West Virginia Pharmacy Regulatory Update

The West Virginia 2021 Legislative session was not extremely active on the pharmacy front. However, there are several new laws and rules to be aware of, which are summarized below.

- House Bill (HB) 2262 amends §60A-9-5 by adding pharmacists to the list of health care providers who must check the Controlled Substance Monitoring Program (CSMP). A pharmacist licensed by the West Virginia Board of Pharmacy shall access the West Virginia CSMP database for information regarding specific patients upon initially prescribing or dispensing any Schedule II controlled substance (CS), opioid, or benzodiazepine to a patient who is not suffering from a terminal illness, and at least annually thereafter should the practitioner or dispenser continue to treat the patient with a CS. This bill is effective May 31, 2021. The regulatory rules will be written over the next year.
- HB 2263 increases regulation of pharmacy benefit managers. It also demands increased choice of in-network pharmacies for patients. The requirements are varied and are regulated by the West Virginia insurance commissioner. This bill amends §33-51, effective June 28, 2021.
- Senate Bill 714 allows physician assistants (PAs) and advanced practice registered nurses (APRNs) to prescribe no more than a three-day supply, without a refill, of a Schedule II medication. This bill amends §30-3, effective July 8, 2021. PAs and APRNs must contact Drug Enforcement Administration (DEA) to add Schedule II medications to their DEA registration for prescribing prior to writing for the medication.

Several pharmacy rule changes were made by the West Virginia Legislature, and all became effective June 11, 2021.

§15-1 General Rules of Practice of Pharmacy

Defining what does **not** fall under compounding so that these items can continue to be prepared in pharmacies and patient access is ensured.

The following are not defined as "compounding" and are exempt from [United States Pharmacopeia (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 [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, non-allergenic 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;
- products combined are FDA approved;
- combining is not done in anticipation of medication orders;
- USP 795 beyond use dating (BUDs) 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;
- 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 CSR §15-1-18.

The definition of "electronic supervision" was added and defined as "a licensed pharmacist [who] provides supervision of the pharmacy through the utilization of audio and visual technology, which may be used with both direct and indirect supervision tasks of a pharmacy technician or pharmacy technician trainee." The Board wants to clarify the appropriate use of electronic supervision in West Virginia. The addition of this definition **does not** permit remote dispensing by a technician **nor** the operation of a pharmacy by a technician. The "electronic supervision" is to permit pharmacy technicians to complete tasks primarily in the same building or facility, such as collecting a medication list to assist with medication reconciliation (for example, the patient may be in another room or on another floor of a hospital, a pharmacy technician can go to the patient and collect the

information, and the registered pharmacist is available via iPad, etc). The statute provides a finite list of tasks that a pharmacy technician may perform under direct or indirect supervision, and those which a technician may not perform in any circumstance. Finally, the ratio of no more than four pharmacy technicians and/or pharmacy technician trainees per on-duty pharmacist operating in any pharmacy shall be maintained regardless of the use of electronic supervision.

A few additional changes in Chapter 15-1 include: pharmacies of any type may not sell, purchase, or trade, or offer to sell, purchase, or trade, any prescription drug sample and drug product selection; and substitution includes "authorized generics" in the acceptable products list for West Virginia. The sanitary regulations were simplified, and, if a pharmacy is closing, there is now a requirement that the location of all records must be provided to the Board upon closure.

§15-02 Controlled Substance Rules and §15-08 Controlled Substance Monitoring Program Rules

The changes made here were for consistency across the West Virginia statute and rule. It adds Schedule V medications to lists that include Schedule III and V. Schedule V prescriptions are valid for six months with five refills and must be reported to the CSMP.

§15-03 Continuing Education

The rule changes updated language to Accreditation Council for Pharmacy Education standards. The drug diversion continuing education requirement decreases from three hours to two hours per reporting period and provides flexibility on the content for this requirement. The two-hour requirement will start in renewal year 2022.

§15-05 Licensure of Wholesale Drug Distributors, Third-Party Logistics Providers, and Manufacturers

The changes to §15-05 place a requirement on wholesale distributors to report discipline within 30 days. Wholesale drug distributors shall also establish and maintain a list of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling – including a description of their duties and a summary of their qualifications – and provide the Board with such list upon licensure and renewal.

§15-12 Pharmacist and Intern Immunizations

Applicable after the coronavirus disease 2019 (COVID-19) state of emergency, this rule change significantly expands the immunizations that pharmacists and pharmacy interns can provide. It removes a "specific list" of immunizations that may be given by pharmacists/interns, and instead states that pharmacists and interns may administer vaccines that are Food and Drug Administration authorized or approved and recommended by Centers for Disease Control and Prevention and Advisory Committee on Immunization Practices for ages 18 years and up. For 11-17 years, a prescription and parental consent are required.

§15-12-3. Immunizations.

3.1 A licensed pharmacist or pharmacy intern may administer immunizations in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the US Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), including, but not limited to, the CDC's recommended immunization schedule for adults, children, and adolescents.

3.2. A licensed pharmacist or pharmacy intern may administer immunizations in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the CDC, including, but not limited to, the CDC's recommended immunization schedule for adults, children, and adolescents to a person age 11 through 17, with written informed parental consent when presented with a prescription from a physician and there are no contraindications to that patient receiving that vaccine.

USP Chapter <800> Hazardous Drugs Update

In summer 2020, the Board voted to postpone enforcement of USP Chapter <800> provisions until July 1, 2021, due to COVID-19. With this unprecedented year behind the Board, many West Virginia pharmacies are complying; however, some are still finding implementation to be difficult with product and worker shortages. The Board determined at its June 2021 Board meeting to allow enforcement to begin; however, there will be USP Chapter <800> inspection resources available on the website including checklists (by September 2021), and the first six months of inspections will be consultative with the inspectors providing feedback for correction. Questions regarding USP <800> compliance can be directed to the director of professional and regulatory affairs or the chief compliance officer at 304/558-0558.

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