December 2018

West Virginia Board of Pharmacy News

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Immunization Rules Updates

The West Virginia 2018 legislative session brought several pharmacy rule updates. Included among these is the expansion of vaccinations for pharmacists and pharmacy interns in West Virginia. In addition to the influenza, pneumococcal, hepatitis A and B, herpes zoster, tetanus-diphtheria-pertussis (individual or combination), and meningococcal vaccines that pharmacists have been able to administer per the Centers for Disease Control and Prevention's (CDC) recommended immunization schedule for adults and children and adolescents, pharmacists can now provide the human papilloma virus (HPV) vaccine for patients 18 years and older. The CDC Advisory Committee on Immunization Practices' current HPV recommendations are for girls and women ages nine to 26 and boys and men ages nine to 21, with men qualifying up to the age of 26.

While Food and Drug Administration did approve a modification of the biologic license for 9-valent HPV vaccine in October 2018 for people 27 to 45 years old, CDC has not expanded recommendations for use of the vaccine beyond the recommended ages listed above. Pharmacists are reminded that West Virginia Code of State Rules (WV CSR) §15-12-6 authorizes pharmacists to administer the immunizations in accordance with the treatment guidelines for immunizations from CDC's latest publication.

The rules also now permit pharmacists to provide two vaccinations, influenza and HPV, to patients ages 11 to 18 with stipulations. They are the only vaccines that may be provided to this patient population in the pharmacy setting. The pharmacy must have a valid prescription from a physician for each immunization administered. Note: A standing order or protocol does not meet the prescription requirement for the 11- to 18-year-old population per statute and rule. The pharmacy must also have written, informed parental consent to administer the vaccination and ensure that there are no contraindications for the patient to receive it.

Technician Updates

Prior to the 2018 legislative session, pharmacy technician trainees were required to have graduated from a high school or obtained a certificate of general education development (GED). It was recognized that West Virginia high schools have students enrolled in high school competency-based pharmacy technician education and training programs as part of the curriculum. These high school students needed to be able to legally obtain a pharmacy technician trainee registration to be in the program and work in a pharmacy. The WV CSR was updated to allow an individual who meets all other requirements and remains enrolled in the training center to be eligible to obtain a pharmacy technician trainee registration. If the trainee leaves the program at the training center, he or she may no longer work as a trainee.

A pharmacy technician rules update that is not complete but is in process permits reciprocity for pharmacy technicians. The statute passed the 2018 legislative session. An individual who has obtained a national certification as a pharmacy technician and has practiced in another jurisdiction for a period of time as determined by the West Virginia Board of Pharmacy will be considered for registration reciprocity. This process is not finalized as the rules must be approved by the state legislature. A future update will keep you informed on this matter.

Central Fill Rules Updates

West Virginia had previously not allowed central filling of prescriptions. Central prescription filling means the filling of a new or refilled prescription at the request of the originating pharmacy for delivery to the patient when presented with a prescription. A given pharmacy can choose to outsource or use a central filling pharmacy for prescription filling as long as the pharmacies have the same owner, have an agreement that outlines specifically the responsibilities and services, and share a common electronic file system. There are specific requirements for the central fill pharmacy and originating pharmacy to ensure safety for patients. Details for the central fill rules can be found by viewing the WV CSR §15-14 Rules for Centralized Prescription Processing.

CSMP Updates

The Board has partnered with Appriss Health to integrate information from the West Virginia Controlled Substance

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National Pharmacy Compliance News

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NABPF
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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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Monitoring Program (CSMP) into the clinical workflow of prescribers and pharmacists via NarxCare. All practitioners who dispense to residents of West Virginia must report all Schedule II, III, IV, and V controlled substances (CS) and opioid antagonists to the West Virginia CSMP each 24-hour period. Currently, there is data sharing with multiple states including Arizona, Arkansas, Colorado, Connecticut, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, New Jersey, New Mexico, New York, Nevada, Ohio, Pennsylvania, South Carolina, Tennessee, and Virginia, along with the District of Columbia.

The NarxCare platform will be made available at no cost to all West Virginia health care providers via their electronic health record and pharmacy management system vendors providing vital data to clinicians. (It is important to note that not all vendors are currently integrated. Your integration process and duration time is dependent upon your vendor.) For more detailed information about the integration process, please visit *https://info.apprisshealth.com/wvehrintregrationrequest.*

West Virginia Senate Bill 273

The West Virginia 2018 Legislature passed Senate Bill (SB) 273 to tackle the chronic opioid crisis. There have been many questions surrounding this bill and its impact on pharmacists and pharmacies. SB 273 includes limitations primarily on opioids, but in some situations includes all Schedule II prescriptions. The bill does not apply to patients currently in active treatment for cancer, receiving hospice care from a licensed hospice provider or palliative care provider, or residents of a long-term care facility; to any medications that are being prescribed for use in the treatment of substance abuse or opioid dependence; or to an existing provider-patient relationship established before January 1, 2018, if there is an established and current opioid treatment plan in the patient's medical record. The bill includes limitations on initial and subsequent prescriptions, narcotics contracts, and exceptions.

The bill does not require the prescriber to include diagnosis information on the prescription in West Virginia as is common in other states. It was not the intent of the bill for pharmacists to enforce the limitations placed on initial and subsequent prescriptions. However, this does not absolve the pharmacist from the long-existing corresponding responsibility to ensure that the prescription is legitimate. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the Controlled Substances Act (21 United States Code §829). The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. A pharmacist who knowingly and intentionally distributes a CS not for a legitimate medical purpose may be prosecuted along with the issuing prescriber (WV CSR §15-2-8). There are anticipated changes coming this legislative session to clarify this statute and the role of the pharmacist.

Veterinary Prescriptions

Veterinarians are also required reporters to the West Virginia CSMP, and it is essential to ensure that all information submitted to the CSMP is being put into the system correctly. WV CSR §15-1-22.1.4(b) states that medications dispensed to outpatients should have a label affixed to the container that the drug is dispensed in, which includes if the patient is an animal, the last name of the owner, and the name and species of the animal. Prescriptions are being incorrectly processed in a variety of ways, including being filled under the owner's profile, causing it to appear that the owner is getting the CS instead of the animal when the prescription is reported to the CSMP as required by §15-8-3. This serves as a reminder of the correct way to label these prescriptions.

Hepatitis A Outbreaks and the Bureau of Public Health

The West Virginia Bureau of Public Health (BPH) is working to help address the hepatitis A outbreak in West Virginia and is requesting the assistance and partnership of pharmacists. As of November 2018, there were 1,725 cases of hepatitis A, and 57% of these have been in Kanawha and Cabell counties. However, 37 counties in West Virginia have been impacted. While a two-dose series of vaccinations (separated by six months) is recommended, in an outbreak situation **a single dose of hepatitis A vaccine has been shown to successfully control outbreaks of hepatitis A.** BPH is requesting pharmacy assistance with increasing vaccinations among the highest risk individuals, who include:

- Persons who use injection or non-injection illicit drugs
- Men who have sex with men
- Persons who are homeless or in transient living situations
- Persons who have been incarcerated
- Persons with acute or chronic liver disease, including those with hepatitis B and/or hepatitis C virus
- Persons with ongoing exposure to a group listed above

For the hepatitis A vaccine screening tool and additional information, pharmacists can visit *www.hepawarewv.org*. If the cost of the vaccine is prohibitive for the patient to receive the vaccine at the pharmacy, **please refer the patient to the local health department.**

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West Virginia Board of Pharmacy

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