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West Virginia Board of Pharmacy News

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Pharmacy Rules Effective March 6, 2020

Licensure and Practice of Pharmacy

Within licensure and practice of pharmacy rules, there were several minor changes made that should be noted for future practice. The first change relates to transfers of prescriptions from one pharmacy to another. This can now be legally done for non-controlled prescriptions by pharmacy interns. Controlled medication prescription transfers must still be completed between two pharmacists, as required by Drug Enforcement Administration.

All records in West Virginia pharmacies are required to be kept on site for one year, then may be kept off site in a Health Insurance Portability and Accountability Act-compliant manner for years two through five. Depending on the type of records, the pharmacy would have had a varying time frame to produce the necessary records. These time frames have all been standardized to 72 hours for record production, regardless of the record type.

The West Virginia Pharmacy Law Book is available only as a pdf file. The West Virginia Board of Pharmacy is no longer printing a paper book. This enables the Board to provide a new, current version every year. Pharmacies no longer need to keep an up-to-date print copy of the law book. Access to the most recent electronic version can be found by visiting *www.wvbop.com.*

Pharmacists and interns have been required to wear a white lab coat for years in West Virginia, while pharmacy technicians were required to wear a lab coat of a different color. Although, the white lab coat is no longer a legal requirement. Wearing a name tag identifying the individual and showing his or her job designation remains a requirement for all pharmacy employees. The only individuals who may wear a white coat in the pharmacy are the pharmacists or pharmacy interns.

A detailed explanation of the emergency dispensing of prescription medications when a pharmacist is unable to obtain a refill authorization has been updated. If a pharmacist is unable to obtain a refill authorization from a health care professional who issued the prescription and the pharmacy at which the pharmacist works has a record of the prescription for the drug in the name of the patient who is requesting it, a pharmacist may dispense an emergency supply of a prescription drug of life-sustaining medication or continue therapy for a chronic condition of the patient, when, in the professional judgment of the pharmacist, failure to dispense could result in harm to the health of the patient. An amount not to exceed a 30-day supply or the standard unit of dispensing of a non-controlled substance may be provided to the patient as demonstrated by records maintained by the pharmacy. An amount not to exceed a 72-hour supply of a Schedule III, IV, or V prescription may be provided to the patient as demonstrated by records maintained by the pharmacy. A pharmacist shall not dispense a particular drug to a patient as an emergency supply more than once in any 12-month period.

Lastly, the daily required "printout" of all refills completed and signed within 72 hours has been deleted from the regulations. Now, a verified record must be retrievable within 72 hours of when the refill was dispensed when it was requested.

§15-7 Regulation of Pharmacy Technicians

The scope of practice for pharmacy technicians has been modified. The following have been added to the list of tasks that pharmacy technicians may and may not complete.

May not:

- Perform any act within the practice of pharmacist care that involves discretion or independent professional judgment

continued on page 4

National Pharmacy Compliance News

June 2020

NABPF
National Association of Boards of Pharmacy Foundation

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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations*® (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy®'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain:*

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

continued from page 1

- Perform all pharmacy-related functions that the registrant has not been trained and the function has not been specified in a written protocol with competency established

May:

- File Schedule II prescriptions
- Perform pharmacy technician product verification where no clinical judgment is necessary, and the pharmacist provides the final verification
- Complete a list of the patient's current prescription and nonprescription medications to provide for medication reconciliation
- Supervise registered pharmacy technicians and pharmacy technician trainees
- Screen medical records

§15-14 Centralized Prescription Processing

Since 2018, West Virginia has permitted use of central fill pharmacies. The only modification this year is that a pharmacy may outsource a prescription drug order filling to another pharmacy via central prescription filling according to section 15-7 **except** for prescription drug orders for Schedule II medications. All other central fill pharmacy regulations remain the same.

§15-15 Regulations Governing Pharmacy Permits

There have been numerous changes related to pharmacy permits and the regulation of the pharmacies themselves. The Board has moved to a biennial renewal for all pharmacy permits. Fees are doubled for the new two-year time period. References that a pharmacy is required to have on hand are no longer listed in the regulations, but rather should be the "applicable current references readily available according to practice setting . . . "

Prior to this legislative session, the process for notification of a change of pharmacist-in-charge (PIC) was based on whether the individual was the employer or the employee, and each had a different time frame during which to comply. The new rule states that when a PIC changes at a pharmacy, both the PIC and the pharmacy must notify the Board in writing within 14 days. The original permit should be copied and the change in the PIC written on the original and the 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 $10 fee for the new registration reflecting the new PIC. Upon receipt of the notification, the Board shall provide the new registration to the pharmacy. An interim PIC may be designated for a period of time, not to exceed 60 days. If an interim PIC is designated who is not the permanent PIC, the fee shall not be charged, and a new permit shall not be issued until a permanent PIC is designated.

§15-16 Regulations Governing Pharmacists

In 2019, the West Virginia Legislature passed a law to permit many regulated professionals the opportunity to be eligible for licensure with a history of a felony. The legislature has stated that the individual cannot have been convicted of a crime bearing a rational nexus to practice duties of a pharmacy technician or pharmacist, unless all three of the following conditions are met:

1. more than five years have passed;
2. no other crime was committed during that period; **and**
3. the conviction was not for an offense of a violent or sexual nature.

Immunizations

Senate Bill (SB) 544 expands the pharmacist's and pharmacy intern's ability to provide immunizations in West Virginia. Prior to this statute change, West Virginia pharmacists were limited to a short list of immunizations. Now, pharmacists and pharmacy interns are permitted to administer immunizations in accordance with definitive treatment guidelines for immunizations promulgated by the latest notice from the United States 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. Additionally, for individuals aged 11-17 years, all CDC-recommended immunizations may be administered with a physician's prescription, parental consent, and screening that there are no contraindications to that patient receiving the immunization. An emergency rule was filed to make this immediately effective to ensure optimal provision of immunization services during and after the coronavirus disease 2019 pandemic.

Naloxone Dispensing

Pharmacists have been able to dispense naloxone to individuals without a prescription since 2017. House Bill (HB) 4102 establishes a community distribution model for naloxone after it has been dispensed to a governmental or non-governmental organization by the pharmacist, including a local health department, a law enforcement agency, or organization that promotes scientifically proven ways to mitigate health risks associated with substance

continued on page 5

continued from page 4

use disorders and other high-risk behaviors, which may, through its trained agents, distribute an opioid antagonist obtained pursuant to a prescription issued by a local physician. The pharmacy must keep a copy of the standing order as the record of dispensing to the organization and an invoice/record of the transaction. The pharmacy does not report this transaction to the West Virginia Controlled Substance Monitoring Program because it is a transaction to an organization, not an individual. It is the responsibility of the organization to report information to the Office of Drug Control Policy regarding the distribution to individuals.

Insurance Coverage for Diabetics

HB 4543 received a great deal of media attention this session. It requires health plans to cover at least one type of insulin from each class: rapid-acting, short-acting, intermediate-acting, long-acting, pre-mixed insulin products, pre-mixed insulin/GLP-1 RA products, and concentrated human regular insulin with a cost sharing maximum of $100 per 30 days. It provides for coverage of supplies and self-management education. A pharmacy benefits manager, a health plan, or any other third party that reimburses a pharmacy for drugs or services shall not reimburse a pharmacy at a lower rate and shall not assess any fee, charge-back, or adjustment upon a pharmacy on the basis that a covered person's cost sharing is being impacted.

Benefits for Pharmacist Rendered Care

SB 787 provides for pharmacists to receive benefits for care rendered within the pharmacist's scope of practice if such benefits would ordinarily be paid if the service was performed by another health care provider. Pharmacists can begin to enroll with plans on July 1, 2020. The bill permits billing for services that would be paid for if performed by another health care professional, as long as the service is within the pharmacist's scope of practice on January 1, 2021.

USP Chapter <800> Hazardous Drugs

On July 1, 2020, the Board will begin enforcing United States Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. If you have any questions, please contact the Board office at 304/558-0558, and the Board inspectors or director of professional and regulatory affairs will be happy to provide guidance.

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West Virginia Board of Pharmacy

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