December 2019

West Virginia Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board of Pharmacy Meeting Date

The next full West Virginia Board of Pharmacy meeting will be December 15-16, 2019, at the Board office, 2310 Kanawha Blvd East, Charleston, WV. The agenda and meeting minutes are accessible at *www.wvbop.com*. The meetings are open to the public, and the Board welcomes your attendance.

Immunization Law Requirements

With flu vaccination season well upon us, the inspectors have asked for a reminder of the legal requirements for immunizations in West Virginia. In order to provide immunizations, the pharmacist must have completed a Board-approved immunization training program, maintain current certification in basic life support from an approved course, complete two hours of continuing pharmacy education related to immunization each licensing year for a total of four hours each renewal period, and be registered with the Board. A pharmacy intern may immunize under the personal supervision of a pharmacist who is a registered immunizing pharmacist and has completed all of the training and certification required above. The intern does not register with the Board as an immunizing intern; the supervising pharmacist maintains the intern's proof of training.

Pharmacists in West Virginia may provide influenza, pneumococcal, hepatitis A, hepatitis B, herpes zoster, tetanus, tetanus-diphtheria, tetanus-diphtheria-pertussis, meningococcal, and human papillomavirus immunizations to individuals 18 years and over according to the Centers for Disease Control and Prevention (CDC) recommended schedule available at *www.cdc.gov/vaccines/schedules/index.html* or in accordance with an order from a properly authorized practitioner. For minors 11 to 17 years of age, the order must be from a physician. A pharmacist may not delegate his or her administration authority to any other person except a properly trained pharmacy intern under the personal supervision of the pharmacist. The administration must be per the CDC recommendations.

An immunization questionnaire must be completed for each person receiving an immunization, and if the patient is 11 to 17 years of age, there must be written informed parental consent and the physician prescription. Record of the immunization must be sent to the primary care physician or other licensed provider within 30 days of administration. The pharmacist shall report the administration to the West Virginia Statewide Immunization Information System (WVSIIS) database not more than 30 days from administration. If you are uncertain if this is happening, **check with your management.** This reporting must be done by the pharmacist/pharmacy, **not** the physician. Information on WVSIIS can be obtained at *www.wvimm.org/wvsiis,* under "New User enrollment form." All administration records must be maintained where the immunization is administered or the primary practice site of the pharmacist if it is an off-site event.

The pharmacist or pharmacy intern must have a readily retrievable response plan and maintain an emergency kit to manage an acute allergic reaction with epinephrine and diphenhydramine.

To remain compliant with Occupational Safety and Health Administration (OSHA) requirements, everyone with potential exposure must have completed blood-borne pathogen training annually. Additionally, make certain the safety syringes are reviewed and that the reviews are documented in the policy and procedure manual as required annually by OSHA.

DEA Form 106

It is generally well known that Drug Enforcement Administration (DEA) registrants are required to report theft or significant loss of controlled substances (CS) via DEA Form 106 according to Title 21 Code of Federal

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National Pharmacy Compliance News

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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.

USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and

Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey

The National Association of Boards of Pharmacy® (NABP®) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination® (NAPLEX®) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination "blueprint," are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.

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Regulations Part 1301. DEA has provided guidance for determination of "significant loss," stating:

> Individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether unexplained losses of controlled substances are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances.

This guidance is available at *www.deadiversion.usdoj.gov/fed_regs/rules/2005/fr0812.htm.*

Once Form 106 is submitted to DEA, this form must also be provided to the Board. According to West Virginia Code §15-2-9.3, in the event of lost or stolen CS, the registrant shall immediately submit DEA Form 106 to the Board. This can be sent via fax to 304/558-0572 or email to boardofpharmacy@wv.gov.

Naloxone

Dispensing of naloxone from the pharmacy can be done through one of the following:

1. a valid prescription from a prescriber
2. the naloxone standing order from the West Virginia state medical officer available at *https://www.wvbop.com/article.asp?ty=CTTS&action2=showArticle&id=14* as authorized in §16-46-7
3. the Board protocol for pharmacists or interns furnishing opioid antagonist naloxone hydrochloride developed in consultation with the West Virginia Department of Health and Human Resources (DHHR), Bureau for Public Health available at *www.wvbop.com/article.asp?ty=CTTS&action2=showArticle&id=14* as authorized in §16-46-3a

The educational handouts that must be provided to the naloxone recipient are created and maintained by the West Virginia DHHR, Bureau for Public Health, Office of Emergency Medical Services (OEMS). New handouts and training videos have been created and will be posted on the OEMS website at *www.wvoems.org/medical-direction/naloxone-information* in December 2019. The link to the new brochures and information will be available on the Board's website at *www.wvbop.com.*

USP Chapters <795>, <797>, and <800>

On September 23, 2019, the United States Pharmacopeial Convention (USP) issued a statement that USP Chapter <795> Pharmaceutical Compounding–Nonsterile Preparations and USP Chapter <797> Pharmaceutical Compounding–Sterile Preparations are currently being appealed. Therefore, they did not become effective on December 1, 2019, as anticipated, and the effective date has been postponed. The current official USP Chapters <795> (last updated 2014) and <797> (last updated 2008) will remain official until the appeals process is complete. USP Chapter <800> is informational and not applicable without the revised Chapters <795> and <797>. While USP Chapter <800> still became effective December 1, 2019, and the Board encourages pharmacies to become compliant for the protection of public health, the Board will not enforce USP Chapter <800> at this time. The inspectors remain ready to assist you with questions and concerns related to USP Chapter <800> compliance, and the Board will provide additional information at the resolution of the aforementioned appeal.

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.

West Virginia Board of Pharmacy

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