September 2020

West Virginia Board of Pharmacy News

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Current COVID-19 Updates and Guidance

The West Virginia Board of Pharmacy continues to monitor the coronavirus disease 2019 (COVID-19) state of emergency situation closely and provide updates and guidance as needed. The most recent information is located on the home page at *www.wvbop.com,* and the documents are emailed to all active pharmacists and pharmacies licensed in West Virginia. Please contact the Board at 304/558-0558 or boardofpharmacy@wv.gov if you have additional questions or would like to update your email address. The waivers provided during the COVID-19 state of emergency will cease to be in effect at the end of the state of emergency.

Opioid Antagonist Reporting to the CSMP – Reminder

Recently, the Board has identified that some pharmacies may not be transmitting all information to the West Virginia Controlled Substance Monitoring Program (CSMP) for opioid antagonists dispensed, as required by West Virginia Code of State Rules (WV CSR) §15-8-3 and §60A-9-4. When the law originally passed in 2016 it was promoted to increase availability of naloxone to the public. This was a portion of legislation permitting pharmacists and interns to dispense naloxone pursuant to a protocol developed in consultation with the West Virginia Department of Health and Human Services Bureau for Public Health in WV CSR §16-46-3a. While it seems that naloxone is consistently being reported to the CSMP, other opioid antagonists – like naltrexone – are not reported by pharmacies when dispensed, despite the requirement to report all dispensed opioid antagonists. The Board reminds pharmacists and pharmacies to confirm that all opioid antagonists dispensed from the pharmacy are configured to be reported to the West Virginia CSMP as required by WV CSR §15-8-3 and §60A-9-4.

WVDEP Rule Changes to Impact Health Care Facilities and Reverse Distributors

The Board was notified on July 15, 2020, by the West Virginia Department of Environmental Protection (WVDEP) that West Virginia adopted and incorporated by reference the requirements of 40 Code of Federal Regulations Part 266, Subpart P, also known as the "Pharmaceuticals Rule," into the West Virginia Hazardous Waste Management Rule (33 CSR 20). The Pharmaceuticals Rule became effective July 1, 2020, in all parts of the state.

WVDEP is developing educational materials for pharmacies and health care facilities to assist in the proper management of pharmaceutical waste under these new requirements. The Pharmaceuticals Rule will bring changes to the management of the following materials:

- potentially creditable hazardous waste pharmaceuticals in reverse distribution;
- non-creditable hazardous waste pharmaceuticals;
- nicotine reduction therapy and vaping product wastes;
- Drug Enforcement Administration controlled substances and household pharmaceuticals from drug take-back programs or events; and
- hazardous waste determinations for any over-the-counter pharmaceuticals, dietary supplements, and other retail items not eligible for reverse logistics.

To assist pharmacies and health care facilities with education and awareness of these new requirements, the WVDEP has developed a free online webinar. The webinar is available by selecting "Pharm Rule Guidance for HFs and RDs" on WVDEP's web page at *dep.wv.gov/WWE/ee/hw/Pages/Generator-Assistance.aspx.*

National Pharmacy Compliance News

September 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.

FDA Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

Immunization Updates – Related Statute Change, Emergency Rule, and COVID-19

We are heading into a busy immunization season with influenza vaccination time rapidly approaching. Make certain that you have renewed your immunization permit. The Board has provided a waiver for CPR cards. For any CPR cards that have expired since March 2020, the pharmacist is able to renew his or her immunization permit and will have up to 90 days after the end of the state of emergency to complete an approved CPR course and send in the updated, valid CPR card.

Changes in permitted immunizations by pharmacists and interns were approved during the 2020 West Virginia Legislative Session. Senate Bill 544 expanded 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 provided 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 COVID-19 pandemic. The emergency rule includes language ensuring that a COVID-19 vaccine (either approved or authorized), when recommended, will also be permitted to be administered to those aged 11-17 years with a physician prescription, parental consent, and screening, and for all patients age 18 and older.

CDC has recently updated the guidance for immunizations provided in pharmacies during the pandemic. These are available on the CDC's website, with helpful information including:

- **Vaccination Guidance During a Pandemic:** *https://www.cdc.gov/vaccines/pandemic-guidance/index.html*
- **Guidance for Pharmacies:** *https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html*
- **Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations:** *https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html*

Change in Enforcement Date of USP Chapter <800>

The June 2020 Board *Newsletter* confirmed that enforcement of US Pharmacopeia (USP) Chapter <800> Hazardous Drugs—Handling in Healthcare Settings was to begin on July 1, 2020. However, as with many regulations, COVID-19 has caused alterations. At the June 2020 meeting, the Board voted to delay enforcement of the USP Chapter <800> requirements in West Virginia until July 1, 2021. COVID-19 has resulted in construction project delays and significant personal protective equipment (PPE) shortages. The PPE shortages have made implementation of USP Chapter <800> standards extremely difficult. The Board will be providing additional information and guidance in spring 2021 to let pharmacies know expectations during an inspection as it relates to USP Chapter <800>.

Updates to the Board Website

The Board website at *www.wvbop.com* is currently undergoing some changes. All renewals were completed online during the most recent renewal season. There are also changes coming to add FAQs, continuing education, and protocols sections. These are in development and will continue to grow as material is created. The goal is to have an easier-to-use resource center for pharmacists, interns, technicians, and pharmacies. Continue to monitor the website and the Board's Facebook page for up-to-date information.

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West Virginia Board of Pharmacy

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