March 2020

News

West Virginia Board of Pharmacy

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USP <800> Update

The West Virginia Board of Pharmacy voted at the December 2019 meeting to begin enforcing United States Pharmacopeia (USP) General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings on July 1, 2020. This chapter covers safe handling standards for drugs considered hazardous by the National Institute for Occupational Safety and Health. USP Chapter <800> is available at *https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.* The Board inspectors and director of professional and regulatory affairs are prepared to answer questions and assist as you finalize compliance. The September 2019 *Newsletter* provides additional guidance for non-compounding pharmacies that need to complete policies for USP Chapter <800>. You may call 304/558-0558 with questions.

Hormonal Contraception and Tobacco Cessation Protocols Update

With the passing of House Bills 2525 and 2583 during the 2019 West Virginia legislative session, the completion of the hormonal contraception and tobacco cessation protocols for pharmacists in West Virginia have been steadily underway. Both bills are essentially complete and the training programs for pharmacists are currently being finalized. The training for pharmacists will begin as soon as possible, targeting for March 2020.

The self-administered hormonal contraception protocol will consist of a four-hour, web-based training program. This program is self-paced and, once completed, the continuing education provider reports the completion to the Board. This makes the registration process easier for pharmacists. At this time, the Board does not anticipate a fee to register to participate in this protocol. There is a fee for the web-based training program. The training will be continually accessible to the pharmacist for review and reference, in addition to accessing updated information. The training and tools incorporated into the training have been customized to the West Virginia hormonal contraception protocol.

The tobacco cessation protocol will roll out shortly after the contraception program. There are two pathways for pharmacists to be able to participate. The first pathway is for the pharmacist to complete a three-hour training program. At this time, there are two programs in development: a live event and a web-based alternative. These consist of pharmacotherapy, smoking cessation motivational interviewing, and how the program operates. Completion of one of these Board-approved programs and registration with the Board enables the pharmacist to participate in the prescribing and provision of tobacco cessation products portion of the protocol. The protocol requires that patients receive both pharmacotherapy and behavioral coaching. The behavioral coaching must be completed by an individual who is a certified tobacco treatment specialist (CTTS). If the pharmacy does not have a CTTS available, the patient can be referred to the West Virginia Tobacco Quitline for the behavioral coaching.

The second pathway is for a pharmacist who is already a CTTS to complete a one-hour, web-based training on how the program works and then provide the Board with the CTTS and web-training documentation. This pharmacist would be able to complete both the prescribing via protocol and the behavioral coaching.

The information regarding the initiation of the protocol programs will be on the Board's website with links to the web-based training programs and information regarding the live training programs. Stakeholders are working diligently to make these available as soon as possible. Please call the office if you have additional questions at 304/558-0558.

National Pharmacy Compliance News

March 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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

Veterinary Controlled Substance Prescriptions

Recently, regulatory changes have resulted in veterinarians writing more prescriptions for dispensing at a pharmacy instead of self-dispensing at the veterinary clinic or animal hospital. Because of this, veterinarians are getting more questions from pharmacists about their controlled substance prescribing. Recognize that dosing for different species can be unique from usual human dosing and many homes have multiple pets. Work with the veterinarian to provide the best care possible.

Buprenorphine Dispensing

The Drug Addiction Treatment Act of 2000 required qualified practitioners to have waivers to prescribe or dispense buprenorphine. These practitioners will receive an "X" waiver number that pharmacists and pharmacies should make certain is on the prescription prior to filling. To ensure that the correct information is uploaded into the West Virginia Controlled Substance Monitoring Program, please select the physician listing with the "X" waiver number when filling the prescription, when possible.

Arlie Winters' Passing

It is with sadness, but fond memories, that the Board notifies you of the passing of longtime Board inspector and compliance coordinator, Arlie Arnold Winters, Jr. Mr Winters of Winchester, VA, formerly of Berkeley Springs, WV, passed away at age 87 from a brief illness on December 26, 2019. He received his bachelor of science degree in pharmacy from West Virginia University School of Pharmacy in 1954. Mr Winters worked as a community pharmacist, hospital pharmacist, nursing home consultant pharmacist, and Board inspector. He also served as a first lieutenant in the US Army as pharmacy officer and administrative officer. He worked tirelessly for the Board as a pharmacy inspector and then compliance coordinator from February 1986 until his retirement in 2015. He is survived by his wife, Gloria; two sons, Arlie III and his wife, Mary, and Chris; and daughter Cynthia Williams and her husband, David, along with numerous grandchildren and great-grandchildren. Mr Winters' impact on the practice of pharmacy in West Virginia remains ever present.

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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