



West Virginia Board of Pharmacy

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USP Chapter <800> Hazardous Drugs: Minimum Requirements for Retail Non- Compounding Pharmacies

Contributed by Tom Robinette, Chief Compliance Officer

The concern for the exposure of health care workers to hazardous substances, hazardous drugs in particular, started to appear in the 1970s. In 1985, the American Society of Health-System Pharmacists (ASHP) published the first *ASHP Technical Assistance Bulletin on Handling Cytotoxic Drugs in Hospitals* and in 2004, the National Institute for Occupational Safety and Health (NIOSH) published the first list of antineoplastic and other hazardous drugs, which was followed by four updated lists through 2016. In March 2014, United States Pharmacopeia (USP) published the first proposal for Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. Following public comment and revision, the final USP Chapter <800> was published in 2016 and becomes official and enforceable on December 1, 2019. The West Virginia Board of Pharmacy will enforce all enforceable USP chapters, per the West Virginia Code of State Rules.

§15-1-11.1.2. All standards set by the United States Pharmacopeial Convention (“USP”) are the minimum standards followed by all licensed pharmacists and pharmacies during the course of the professional practice of pharmacist care.

There are portions of this standard related to the use and handling of active pharmaceutical ingredients, eg, powders, liquids, and sterile compounding, that are quite complex and require specially designed rooms, equipment, and/or personal protective equipment (PPE). However, for the vast majority of pharmacists, the compounding of hazardous drugs is not part of their routine practice. The following is a summary of the minimum requirements that will need to be addressed for retail, non-compounding pharmacies.

- ◆ Each entity must have a designated person who is qualified and trained to be responsible for developing and implementing appropriate procedures, overseeing compliance with the chapter and other laws or regulations, ensuring competency of personnel, and environmental control of the storage areas. This person must be given responsibility and authority to accomplish his or her task.
 - ◇ This person does not need to be a pharmacist.
 - ◇ Training can be obtained by attendance of courses or online instruction.
 - ◇ The designated person does not need to be on staff; a consultant may be hired to meet this requirement.
- ◆ The entity must maintain a list of hazardous drugs that are included in the latest edition of the *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings*.
 - ◇ This document is available online, free of charge.
 - ◇ There must be documentation that the list is reviewed every 12 months.
- ◆ Hazardous drugs in final dosage forms that do not require any more manipulation other than counting, pouring, or repackaging can be exempted from the containment requirements of this chapter and can be stored with regular stock if the following conditions are met.
 - ◇ An assessment of risk must be performed, which addresses:
 - » Type of hazardous drug
 - » Dosage form
 - » Risk of exposure
 - » Packaging
 - » Manipulation (Note: cutting or crushing of solid dosage forms will require full containment requirements of this chapter)

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National Pharmacy Compliance News

September 2019



NABPF

National Association of Boards
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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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a [Drug Safety Communication](#), provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

“Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse,” the agency said in the communication. “Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.”

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the [News and Events section](#) of the FDA website.

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

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a [DEA press release](#), this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest,

prosecution, imprisonment, and revocation of their DEA numbers. 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 legitimate investigation or legal action is 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.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- ◆ maintaining quality manufacturing compliance,
- ◆ strengthening and refining regulations on compounding from bulk drug substances,
- ◆ finalizing the agency’s memorandum of understanding with the states, and
- ◆ issuing revised draft guidance for compounding by hospital and health systems.

“We’ve worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs,” then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a [statement](#) published on the FDA website. “We anticipate that 2019 will be an equally productive year for the FDA’s compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . .”

In addition, Gottlieb and Abram’s statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a [press release](#) from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

“Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis,” Senate Minority Leader Chuck Schumer said in the press release. “We must hold China accountable for their role in the fentanyl trade. China’s new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers.”

In a December meeting with President Donald Trump, China’s President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be “the largest source of illicit fentanyl and fentanyl-like substances” in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The

company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a [press release](#) posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy[®] (NABP[®]) Drug Disposal Locator Tool, available in the AWA[®] Rx[®] Prescription Drug Safety section of the NABP website, [www.nabp.pharmacy/initiatives/AWA[®]RxE](http://www.nabp.pharmacy/initiatives/AWA[®]RxE). With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at <https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine>.

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- ◇ Must be reviewed every 12 months
- ◇ Example of assessment of risk:

Drug (Type of hazardous drug)	Methotrexate (antineoplastic)
Dosage form	Tablet
Risk of exposure	Minimal: solid dosage form
Packaging	Manufacturer original package
Manipulation	Counting Repackaging Dedicated counting tray Approved chemotherapy gloves Stored with regular stock

◆ Receipt

- ◇ Must be unpacked from shipping containers in an area segregated from other staff and persons.
- ◇ Must be in neutral or normal air pressure; cannot be in an area where there are strong air drafts.
- ◇ Staff must, at a minimum, don protective chemotherapy gloves that meet the ASTM D6978 standard (this is noted on the packaging of the gloves).
- ◇ Evaluation must be made to determine if additional PPE is required.

◆ Storage

- ◇ If an assessment of risk has been performed, final dosage forms may be designated for storage with regular stock.
- ◇ Consideration should be given to segregation, storage containers, and hazardous drug alert labels.

◆ Handling

- ◇ Recommend designated counting trays and spatulas
- ◇ Recommend the use of chemotherapy gloves
- ◇ Assessment of risk to staff, eg, reproductive risks
- ◇ Comply with the Occupational Safety and Health Administration Hazard Communication Standard

◆ Disposal

- ◇ Must meet all state and federal regulations

◆ Spill control

- ◇ Must have detailed policy and procedure

◆ Documentation and standard operating procedures

- ◇ Must have written policies and procedures addressing:
 - » List of hazardous drugs
 - » Facility and engineering controls

- » Training and competency of personnel; documentation of training and competency assessment in all aspects of hazardous drug handling and policies and procedures; initially and every 12 months thereafter
- » Safe work practices
- » Training in the use of PPE
- » Receiving
- » Storage
- » Handling
- » Deactivating, decontaminating, cleaning, and disinfection (if applicable)
- » Spill control
- » Hazard communication program with personnel documentation
- » Labeling, packaging, transport, and disposal
- » Dispensing final dosage forms
- ◇ Policies and procedures must be reviewed annually

Beginning December 1, 2019, the Board inspectors will begin surveying for compliance with USP Chapter <800>. The key to compliance and a successful inspection will be attention to detail and will require complete written standard operating procedures for at least the above elements, documentation of training and competency assessment of personnel, and the appointment of a designated person.

The above guidelines represent the minimal requirements for a non-compounding dispensing pharmacy. There is no substitute for the careful reading of the full USP Chapter <800>, and pharmacists-in-charge (PICs) are strongly encouraged to read and process this information. The PIC is ultimately responsible for compliance. The Board inspectors will be available to consult or help with the interpretation of compliance requirements for this standard.

Compounding Standards for USP Chapters <795> and <797>

By Krista Capehart, Director of Professional and Regulatory Affairs

In addition to USP Chapter <800> Hazardous Drugs, the Board will also consider USP Chapters <795>, <797>, and <825> to be enforceable after December 1, 2019. USP Chapters <795> and <797> include revisions to the recommended beyond-use dates for compounded preparations. It is necessary for any pharmacists who are compounding to examine these sections in particular to ensure the proper labeling of the medications.

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USP Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations identifies what is and is not considered compounding and what needs to comply with this chapter. Some examples of activities that are not considered compounding include: reconstitution, repackaging, and tablet splitting. A notable change for USP Chapter <795> is that carpet is not permitted in the compounding area.

USP Chapter <797> Pharmaceutical Compounding – Sterile Preparations includes significant changes to the chapter from the previous version. The new Chapter <797> covers personnel training, garbing, facility requirements, and certifications. Many sterile compounding institutions will need to closely examine this chapter for potentially necessary facility and policy modifications.

USP Chapters <795>, <797>, <800>, and <825> are all available at <https://www.usp.org/news/new-revised-compounding-standards>. The Board inspectors are available for assistance regarding compliance with these chapters by calling the Board office.

Update on the Self-Administered Hormonal Contraceptive Protocol and the Tobacco Cessation Protocol

The West Virginia Board of Pharmacy, West Virginia Board of Medicine, West Virginia Bureau for Medical Services, and West Virginia Board of Osteopathic Medicine have been meeting regularly to complete the hormonal contraception protocol and the tobacco cessation protocol.

The groups are working diligently to complete the protocols as timely as possible, while creating the best program for patients and pharmacy, and have examined many states that have had successful programs for many years in an attempt to not recreate the wheel. Issues including training, workflow, and patient safety, among many others are being considered. It is anticipated that the contraceptive program will be operational in January 2020 and the tobacco cessation program soon after. Questions can be addressed by calling Krista Capehart at the Board office.

Pharmacy Laws and Legislative Rules of West Virginia – Update 2019

The 2019 edition of the *Pharmacy Laws and Legislative Rules of West Virginia* has been updated and is available for download on the Board's website at https://www.wvbop.com/download_resource.asp?id=265. For inspection purposes and compliance with §15-1-11.2.8, access to a downloaded copy of the published pdf satisfies this rule.

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