



Making a world of difference in cancer care

American Society of Clinical Oncology

Frequently Asked Questions:

The Regulation of Safe Handling Practices for Hazardous Drugs Used in the Treatment of Individuals with Cancer

The American Society of Clinical Oncology (ASCO) is committed to promoting and supporting research, guidance, and educational materials to help ensure the safety of professionals in the oncology workforce who handle or otherwise potentially come into contact with hazardous drugs. This document addresses frequently asked questions regarding the safe handling of hazardous drugs.

What is the USP and how are the USP's standards enforceable?

The United States Pharmacopeia (USP) is a private, non-profit, scientific organization that sets standards for the safe and proper use of medications. USP is not an enforcement agency, so the USP does not enforce adherence to any of its standards at the national or state level. Historically, USP has focused on developing standards that define the content and purity of drugs and other substances. Some of these standards are incorporated by reference into the laws and regulations that the U.S. Food and Drug Administration (FDA) actively enforces.

The USP has developed standards in the areas of drug compounding and, most recently, the safe handling of hazardous drugs. To date, we are not aware of any activity by the FDA to adopt or enforce these standards at the national level. In some instances, states have incorporated the USP's compounding standards in part or in whole within state requirements, most commonly within the regulation of pharmacies that are subject to the rules promulgated by state boards of pharmacy.

What is USP <800>?

USP released a final version of General Chapter <800> *Hazardous Drugs – Handling in Healthcare*

Settings in February 2016. USP <800> lays out requirements for receiving, storing, compounding, dispensing, administering, and disposing of sterile and non-sterile hazardous drug products and preparations. The chapter aims to promote patient safety, worker safety, and environmental protection by reducing unintended exposure to hazardous drugs.

When will USP <800> be effective?

The USP states that USP <800> will become effective on July 1, 2018.

How can USP standards be adopted?

State and local governments or private accreditation organizations could adopt USP standards in whole or in part at any time. At the state level, adoption could arise either by action through the state legislature or by action taken by a state agency, board of medicine, or board of pharmacy. Although the USP has set a specific implementation date, state or private entities could establish implementation dates that start before or after the USP's recommendation.

Are there any substantive problems with USP <800> from the perspective of community-based oncology practices?

The development of USP <800> remains controversial. USP failed to adequately consult with physician specialty organizations while crafting the standards, even though USP takes the position that USP <800> has applicability to physician practices and other community-based settings of care. We understand that USP is working to revamp its process for developing new general chapters like USP <800>, but unfortunately, we believe that the flawed process contributed to some counterproductive requirements in the final policy.

ASCO is committed to promoting safety in the oncology workplace. Concerns arise when burdensome requirements of uncertain value are recommended or required that may divert attention or resources away from more effective interventions. There are some very good recommendations within USP <800>; however, there are some areas in which there is insufficient scientific evidence to conclude that some of the mandates under USP <800> would result in material benefits in safety for patients or the health care workforce. ASCO has specific concerns about requirements for external ventilation, separate storage areas and refrigerators for antineoplastic drugs, closed system transfer devices, and the lack of consideration for the safety of pregnant workers. ASCO's comment letters on both drafts of USP <800> go into more detail on these and other concerns and can be found:

Here: [ASCO Comments July 2014](#)

And Here: [ASCO Comments May 2015](#)

How can I obtain a copy of USP <800>?

A subscription to the USP-NF or USP Compounding Compendium is required to view USP <800>. More information about those subscriptions can be found [here](#) and [here](#).

What is USP <797>?

The USP developed General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations* to prevent patient harm from contaminated compounded sterile preparations. The USP released a significantly revised version of USP <797> in September 2015 and public comments were accepted until February 1, 2016.

Are there any substantive problems with USP <797> from the perspective of community-based practices?

The current USP <797> is causing serious problems for physician practices in several states. The USP recently removed an exception within USP 797 for low volume compounding that could exacerbate the concerns already arising from USP <797> for physician practices in some states. Oncology drugs should be prepared with aseptic technique, but the requirements in USP <797> seem more applicable to bulk compounding and are overly burdensome for oncology practices. The recently proposed revisions to USP <797> may exempt certain activities that commonly occur in physician oncology practices, such as mixing and diluting activities, from the requirements of the chapter. ASCO's comments on the revised USP <797> can be found [here](#).

How can I obtain a copy of USP <797>?

A subscription to the USP-NF or USP Compounding Compendium is required to view USP <797>. More information about those subscriptions can be found [here](#) and [here](#). Proposed revisions to USP <797> are publicly available and can be viewed [here](#).

What is NIOSH and how are its standards enforceable?

The National Institute for Occupational Safety and Health (NIOSH) is part of the Centers for Disease Control and Prevention (CDC) and is responsible for conducting research and making recommendations for the prevention of work-related injury and illness. NIOSH is not an enforcement agency. A few states have incorporated NIOSH standards within state laws, and in these instances, enforcement is the responsibility of the state governments.

What is the NIOSH Alert?

The NIOSH Alert is a document entitled "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings" that NIOSH published in 2004. NIOSH officials are currently updating the Alert, and a new version is expected to be released in 2017. NIOSH also maintains a list of hazardous drugs, and the most recent version of that document ("NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings") was released in 2014. This document contains updated recommendations on personal protective equipment (PPE) use.

How can I obtain a copy of the NIOSH Alert?

The NIOSH Alert can be accessed [here](#).

What other materials has NIOSH developed on safe handling?

NIOSH maintains a list of recent scientific articles about occupational exposure to hazardous drugs on their website and has developed supplementary materials. NIOSH released a draft protocol for testing the efficacy of Closed System Transfer Devices (CSTDs) that function by vapor containment (“A Vapor Containment Performance Protocol for Closed System Transfer Devices Used During Pharmacy Compounding and Administration of Hazardous Drugs”) on September 8, 2015. On January 19, 2016, NIOSH issued a request for information for developing a similar protocol for CSTDs that use air filtering technology (“Request for Information on Development of a Performance Test Protocol for Closed System Transfer Devices That Incorporate Air-Cleaning Technology to Provide Worker Protection During Pharmacy Compounding and Administration of Hazardous Drugs”). In January 2015, NIOSH released a draft document “Current Intelligence Bulletin: Reproductive Risks Associated With Hazardous Drug Exposures in Healthcare Workers and Recommendations for Reducing Exposures.”

What is OSHA and how are its standards enforceable?

The Occupational Safety and Health Administration (OSHA) is part of the Department of Labor. OSHA assures safe and healthful working conditions for working men and women by setting and enforcing standards.

Does OSHA have regulations concerning the safe handling of hazardous drugs?

Section IV: Chapter 2 of the OSHA Technical Manual “Controlling Occupational Exposure to Hazardous Drugs” is an informational guidance first published in 1995. OSHA Technical Manuals assist OSHA compliance safety and health officers in hazard recognition, accident prevention, and establishing sound safety and health programs. Information in the technical manual is for informational purposes only and does not provide a substitute any federal or state laws or regulations.

How can I obtain a copy of the OSHA Technical Manual?

The OSHA Technical Manual can be accessed [here](#).