Director's Forum

USP <800>: Key Considerations and Changes for Health Systems

Priya Sahadeo, PharmD,* and Robert J. Weber, PharmD, MS, BCPS, FASHP†

On March 28, 2014, The United States Pharmacopeia and The National Formulary (USP-NF) published USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, as open for public comment in the USP Pharmacopeial Forum (PF) 40(3). Pharmacy directors must be proactive in understanding the impact that USP <800> will have on their processes for preparing sterile products. USP General Chapter <797> pertains to the compounding of both hazardous and non-hazardous drugs. USP <800> serves as a new standard to guide the handling of hazardous drugs in order to protect patients, health care personnel, and the environment. USP <800> describes hazardous drug handling related to the receipt, storage, compounding, dispensing, administration, and disposal of both sterile and nonsterile products and preparations. Regardless of all of the requirements listed in USP <800>, there is no substitute for disciplined, consistent work practices regarding proper sterile technique. This point should be emphasized with all compounding personnel. Even if one is compounding in the most compliant USP <800> cleanroom, improper technique can negate all the benefits of the physical structures. Pharmacy leaders at every level will play a key role in assisting an organization to achieve timely compliance with USP <800> standards. Until the standard becomes official, it is important for pharmacists to become familiarized with the latest draft to identify potential barriers to compliance and to strategize a plan to overcome barriers. Although complying with USP <800> may seem to be a daunting task, it can be manageable if approached in a systematic organized way.

INTRODUCTION

The 2012 New England Compounding Center tragedy is well known; 678 confirmed cases of contaminated intravenous preparations resulted in over 60 deaths.¹ As the analysis of the tragedy unfolded, it was obvious that many of the deaths and disabilities could have been prevented if the center had adhered to fundamental guidelines of preparing sterile intravenous preparations. A call to action was generated by many professional organizations and groups to take the recommendations for compounding as set forth by The United States Pharmacopeia (USP) seriously. The authority of the US Food and Drug Administration (FDA) in regulating sterile compounding was reviewed, and accrediting organizations took a firm stand on institutions implementing the standards of USP General Chapter <797>. As a result, a 2014 National Survey of <797> standards

in hospitals showed increases in compliance with both sterile preparation and hazardous drug requirements – but there was room for significant improvement.²

On March 28, 2014, The United States Pharmacopeia and The National Formulary (USP-NF) published USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Setting, as open for public comment in the USP Pharmacopeial Forum (PF) 40(3), the free online-only journal in which USP publishes revisions to USP-NF. The first round of public comments ended on July 31, 2014; these comments were incorporated by the USP Compounding Expert Committee into a revised chapter. The second round of public comments on the revised chapter opened on December 1, 2014 and closed on May 31, 2015. The official date of chapter publication has not been determined, but it is highly anticipated by

*PGY2 Pharmacy Administration Resident, †Administrator, Pharmacy Services, The Ohio State University Wexner Medical Center, Columbus, Ohio

stakeholders because this chapter requires key operational changes in the preparation of intravenous medications. Pharmacy directors must be proactive in understanding the impact that USP <800> will have on their processes for preparing sterile products.

The goal of this article is to provide a primer to pharmacy directors and others on new requirements and updates to hazardous drug handling as designated by USP <800>. This article will provide a brief overview of the USP, review the highlights of <800>, describe differences between USP <797> and USP <800>, and describe the impact that <800> will have on sterile compounding programs in health systems. Protecting the public by preventing harm from tainted sterile products is of paramount importance and is a fundamental step in providing patient-centered pharmacy services. Protecting personnel who are involved in the handling of hazardous drugs is just as important and should be given the attention it deserves.

THE UNITED STATES PHARMACOPEIAL CONVENTION

Overview

The United States Pharmacopeial Convention is a not-for-profit scientific organization that develops and publishes general chapters in order to provide the public with quality standards regarding drugs, excipients, and supplements.³ The standards include, but are not limited to, areas such as product identity, strength, quality, and purity. The value of these standards lies in the robust approval process for publication in the USP-NF. Although standards generally originate from sponsors, the supporting data that they provide is first reviewed by USP's scientific staff and volunteer experts; they then undergo rigorous public review and comment, followed by final approval from a USP Expert Committee. Six months after publication in the USP-NF, the standard becomes official and can be enforceable by the FDA and other agencies.

There are 5 USP-NF general chapters on compounding³: USP <795> Pharmaceutical Compounding–Nonsterile Preparations, USP <797> Pharmaceutical Compounding–Sterile Preparations, USP <1160> Pharmaceutical Calculations in Prescription Compounding, USP <1163> Quality Assurance in Pharmaceutical Compounding, and USP <1176> Prescription Balances & Volumetric Apparatus. As a general rule, chapters that are named with numbers under 1000 are enforceable and chapters named with numbers greater than 1000 are informational. Health system pharmacists are most likely familiar with USP <795> Pharmaceutical

Compounding–Nonsterile Preparations and USP <797> Pharmaceutical Compounding–Sterile Preparations. USP <797> is the standard by which to prevent harm and death to patients who are administered compounded sterile preparations (CSPs). USP <797> has undergone one revision that was published in 2008 and is currently undergoing a second revision, which was started in July 2010.⁴

USP <797> and USP <800>

The objective of USP <797> is “to prevent harm, including death to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins, variability in the intended strength of correct ingredients, unintended physical or chemical contaminants and ingredients of inappropriate quality in CSPs.”⁴ USP <797> therefore focuses on the minimum practice and quality standards to ensure safe preparation of CSPs for patient use and is divided into sections such as responsibility of compounding personnel, personnel training and evaluation in aseptic manipulation skills, hazardous drugs as CSPs, verification of compounding accuracy and sterility, environmental quality and control, suggested standard operating procedures (SOPs), elements of quality control, finished preparation release checks and tests, storage and beyond use dating, maintaining sterility, purity and stability of dispensed and distributed CSPs, patient monitoring and adverse event reporting, and quality assurance program. These standards are important and, when upheld, can mitigate serious patient harm. The New England Compounding Center fatal meningitis outbreak of October 2012 resulted from noncompliance with compounding standards and highlighted the importance of compliance to scientifically tested practices and techniques as outlined in USP <797>.

USP <797> applies to the compounding of both hazardous and nonhazardous drugs. It defines a hazardous drug as one which studies in animals or humans indicate that exposures have a potential for causing cancer, development of reproductive toxicity, or harm to organs. USP <797> also recommends referring to the most updated National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings to identify whether a drug is classified as hazardous.⁵ A section within USP <797> titled “Hazardous Drugs as CSPs” addresses the risk of adverse effects to health care workers, general storage conditions of hazardous drugs, general

handling of hazardous drugs, allowable preparation hoods, recommended personal protective equipment (PPE), use of closed-system transfer devices (CSTDs), training of personnel handling hazardous drugs, routine environmental sampling, and improvement actions. The recommendations in this section provide a broad scope of guidance and do not offer in-depth recommendations on the areas listed above.

Although USP <797> provides guidelines for preparing sterile compounds, there is a need for defined standards related to the handling of hazardous drugs. Annually, there are over 8 million US health care personnel who are potentially exposed to hazardous medications.⁶ There have been various reports in the literature regarding the harmful effects of hazardous medications to health care workers, such as compromised reproductive health, increased risk for cancers, and a range of adverse effects including rashes, ocular problems, and headaches.⁷ Within the last 25 years, agencies such as Occupational Safety and Health Administration (OSHA) and NIOSH, as well as organizations such as the American Society of Health-System Pharmacists (ASHP), have addressed issues and provided guidance about handling hazardous drugs.

USP <800> Hazardous Drugs—Handling in Healthcare Settings serves as a new standard to protect patients, health care personnel, and the environment. USP <800> describes hazardous drug handling related to the receipt, storage, compounding, dispensing, administration, and disposal of both sterile and nonsterile products and preparations.

Who Can Enforce USP Standards?

USP is not an enforcement agency. State boards of pharmacy usually regulate the compounding practices of the organizations within their jurisdiction. Although boards of pharmacy do not delineate every compounding standard within their laws and rules, most boards have one blanket law that specifically mandates compliance with the USP's compounding general chapters. The FDA also has oversight over compounding and may legally enforce USP's compounding standards,⁸ however the FDA is perhaps most concerned with USP standards from the perspective of ensuring that compounded products are not adulterated from the standards set forth in their monographs. The Joint Commission on Accreditation of Healthcare Organizations has standards that are congruent with USP <797> principles. Even though The Joint Commission does not survey for compliance

with the details of USP <797>, USP standards can assist organizations in complying with relevant and applicable Joint Commission standards.⁹ It can reasonably be anticipated that The Joint Commission may take a similar approach to USP <800>.

HIGHLIGHTS FROM USP <800>

This article is not meant to be a comprehensive review of USP <800>, but rather a review of the most important aspects of these regulations.¹⁰ Pharmacy directors should have a general knowledge of the contents of <800>, along with a general knowledge of the differences between <800> and <797>.

Section 2: List of Hazardous Drugs

Section 2 lists the requirements for entities that should maintain an internal list of hazardous drugs. USP <800> does not provide a comprehensive list of hazardous drugs, but it references the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. Entities can utilize NIOSH's criteria for identification of hazardous drugs when deciding to add drugs to their custom list, along with drugs already on the NIOSH list. Since 2012, NIOSH has updated their list biennially, with the next update anticipated in 2016. USP <800> requires that entities review their own lists at least annually, so this could provide a means by which to ensure that the NIOSH updates are considered each time. The finalized USP <800> may also require an update, as necessary, to the organization's list of hazardous drugs whenever a new agent or dosage form is used by the organization. However, this requirement may undergo wording changes based on the last round of feedback received. The intent of USP <800> seems to be to encourage entities to take a more conservative approach when there is uncertainty about the classification of a drug as hazardous.

The 2014 NIOSH update stratified drugs as antineoplastic, non-antineoplastic, and those that pose a reproductive risk. This stratification guides containment requirements as listed in Table 1.

Section 3 and 4: Types of Exposure and Responsibilities of Personnel Handling Hazardous Drugs

Sections 3 and 4 describe various routes of entry of hazardous drugs into the body, including exposure based on the type of activity being performed, such as dispensing, compounding, administration, patient care activities, spills, receipt, and transport. Section 4 has a unique requirement for entities to designate

Table 1. Containment requirements guide

Antineoplastic hazardous drugs		Non-antineoplastic hazardous drugs and drugs that pose a reproductive risk
Require manipulation	Do not require further manipulation other than counting dosage forms	
Must follow containment requirements outlined in USP <800>	Follow containment requirements per manufacturer or conduct an internal assessment of risk to determine if alternative containment strategies are necessary	Perform and document an internal assessment of risk to determine if alternative containment strategies are necessary

a Compounding Supervisor who is qualified and trained to be responsible for all aspects of hazardous drug handling, including, but not limited to, the development and implementation of procedures; compliance with laws, regulations, and standards; personnel competency; and environmental control. USP <800> provides no guidelines as to the credentials of the compounding supervisor nor whether the person has to be a pharmacy employee (pharmacist or pharmacy technician). However, it can be reasonably expected that both organizational leaders and hospital pharmacy leaders would prefer this position to be within the pharmacy department. Pharmacy leaders may choose to create a new position for this compounding supervisor or assign these responsibilities to an existing position within the department.

Section 5: Facilities

Section 5 is separated into 4 sections: receipt, storage, compounding, and containment supplemental engineering controls. *Receipt* refers to the unpacking of the drug from its original shipping containers; this must be done in a neutral/normal pressure or a negative pressure room to prevent the dispersal of any hazardous drug contamination on the packaging. Drugs cannot be unpacked in sterile compounding areas or positive pressure areas. The anteroom to a

negative pressure room is usually always a positive pressure room, so care must be taken to ensure no drugs are unpacked in this area. This requirement can present challenges, as a dedicated space for unpacking that meets these requirements has to be found.

USP <800> section on *storage* presents a change from the guidance of USP <797>. USP <797> states that hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.⁴ USP <800> recognizes the 2014 NIOSH stratification of hazardous drugs and reflects this in its storage requirements, as depicted in **Table 2**. Of note, USP <800> allows sterile and non-sterile hazardous drugs to be stored together, but only sterile hazardous drugs may be stored in a negative pressure buffer room. If the sterile drug is an antineoplastic that requires manipulation, it must be stored in a negative pressure buffer area anyway.

USP <800> section on *compounding* is subdivided into nonsterile compounding and sterile compounding. It describes the classification of engineering controls as primary (containment primary engineering control or C-PEC or the hood), secondary (containment secondary engineering control or C-SEC or the room in which the C-PEC is contained), and supplemental or adjunct controls that offer additional levels of protection (eg, CSTDs).

Table 2. Storage requirements guide

Hazardous drugs that can be stored with other nonhazardous drug inventory	Hazardous drugs that must be stored separately from other nonhazardous drugs
<ul style="list-style-type: none"> Non-antineoplastic hazardous drugs Reproductive risk-only hazardous drugs Final dosage forms of antineoplastic hazardous drugs 	Antineoplastic drugs or hazardous drugs API requiring manipulation other than counting final dosage forms: store in a negative pressure room with at least 12 air changes per hour (ACPH)
	Refrigerated antineoplastic hazardous drugs: store in a dedicated refrigerator in a negative pressure area with at least 12 ACPH

Note: API = active pharmaceutical ingredient.

For nonsterile hazardous drug compounding, the C-PEC should be externally vented or redundant HEPA filtered in series and must be placed in a C-SEC that has at least 12 ACPH. If a C-PEC is used solely for nonsterile compounding, unidirectional flow is unnecessary. Additionally, a C-PEC that is used for sterile compounding may be used for nonsterile compounding, but it must be properly decontaminated and disinfected before sterile compounding is resumed.

For sterile hazardous drug compounding, the C-PEC must provide a Class 5 or superior air quality and must be externally vented. By these requirements, a laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) should not be used for such compounding. USP <800> requires that the C-PEC be contained within a C-SEC that is an ISO Class 7 buffer room or an unclassified containment segregated compounding area (C-SCA). A C-SCA is a type of C-SEC with nominal requirements for airflow and room pressurization in that it is ISO unclassified but is a segregated room that maintains negative pressure and is externally vented with at least 12 ACPH. The only sterile hazardous drugs that may be prepared in a C-SCA are low-and medium-risk drugs. A C-SCA is a less expensive option to an ISO-classified, negative pressure cleanroom and provides allowance for compounding of hazardous drugs in clinics that do not have negative pressure cleanroom infrastructure, which is often the case for many outpatient settings. However, if a drug is compounded in a C-SCA, the beyond use date (BUD) will be limited to 12 hours to offer protection to the patients from microbial contamination. The requirement described above is a stricter requirement from USP <797>, which allowed a small volume of hazardous drugs to be compounded in a C-PEC located in a non-negative pressure room. Additionally, USP <800> outlines requirements for maintaining an ISO Class 7 buffer room, as well as requirements for a line of demarcation and transport procedures when the entrance to an ISO Class 7 buffer room is a positive pressure nonhazardous drug buffer room.

USP <800>'s requirements with respect to CSTDs are also different from USP <797>. Whereas USP <797> recommended the use of CSTDs, USP <800> mandates that they be used both for compounding and administering once the dosage form allows. Examples of dosage forms that may not allow the use of CSTDs include intrathecal, ophthalmics, and irrigations. This is a very significant change as it may affect entities that currently do not use CSTDs. These devices are more expensive than traditional

needle and syringe compounding equipment. There are currently no universal performance standards for CSTDs. USP <800> enforcement will favor the market for CSTDs, so more stringent device regulation will be necessary to ensure quality control from existing and potential manufacturers. Furthermore, when contracting the purchase of a CSTD product from a vendor, each entity should consider device effectiveness, nursing input, and pharmacy input.

Section 6: Environmental Quality and Control

Section 6 describes surface wipe sampling and states that it should be performed at least every 6 months. There are currently no certifying agencies for the vendors of wipe kits nor set standards for acceptable limits of surface contamination with hazardous drugs. This is an area for future improvement. If contamination is measured, the compounding supervisor must document and contain the contamination, then take specific actions to reassess areas for improvement such as personnel retraining and improvement of engineering controls.

Section 7: Personal Protective Equipment

Section 7 gives specific and thorough guidance on gloves, gowns, head, hair, shoe and sleeve covers, eye and face protection, respiratory protection, and disposal of used PPE. Certain requirements are specifically stated:

- Compounding sterile and nonsterile hazardous drugs: Use gloves, gowns, head, hair and shoe covers.
- Administering antineoplastic hazardous drugs: Use gloves.
- Administering injectable hazardous drugs: Use gloves and gowns.

When handling antineoplastic hazardous drugs, double gloves must be worn; these gloves must have been tested for permeability according to the American Society for Testing and Materials (ASTM) standard D6978. Similarly, a second set of shoe covers must be donned when an individual enters the hazardous drug compounding area or C-SEC, and then removed upon exiting; this can be a tedious task for personnel who move between the negative pressure room to the anteroom. For all other activities, the entity must state their PPE requirements based on exposure risk and type of handling of hazardous drugs, including receipt, storage, transport, compounding, administration, deactivation/decontamination, cleaning, disinfecting, and spill control.

Sections 8, 9, and 10

Sections 8, 9, and 10, Hazard Communication Program, Personnel Training, and Receiving, contain important information. Section 8 refers to the requirement of entities to establish policies and procedures to ensure worker safety during hazardous drug handling. Such policies should include training on labeling, transport, storage, and use of easily accessible Safety Data Sheets (SDS) for every hazardous chemical used. Section 9 lists minimum areas of training for all personnel who handle hazardous drugs and requires that these individuals be fully trained and demonstrate competency before they independently handle hazardous drugs. Reassessment of competency must be performed and documented at least every 12 months, with the introduction of a new hazardous drug or equipment, and when a significant change in process occurs. Section 10 specifies that hazardous drugs must be received from the supplier sealed in impervious plastic and delivered immediately to the hazardous drug storage area. This section also mandates that PPE be worn, including tested, power-free chemotherapy gloves. There are clear instructions on how to handle damaged shipping containers and product, including containment, return, disposal, retrieval of usable items from a container with damaged items, and reporting procedures.

Sections 11 through 14

These sections (Labeling, Packaging, and Transport; Dispensing Final Dosage Forms; Compounding; and Administering) address key considerations in the logistics of hazardous drug safety. When a hazardous drug is in transit, it must be clearly labeled so as to be easily identifiable as such, at all times. Packaging containers should be carefully chosen on the basis of physical integrity, stability, sterility, and protection from damage, leakage, contamination, and degradation. The section on transport encourages compliance with relevant federal, state, and local regulations. It also cautions firmly against the use of a pneumatic tube system to transport any liquid hazardous drug and any antineoplastic hazardous drug due to breakage and contamination risks. Furthermore, clean designated equipment should be used when dispensing final dosage forms that do not require further manipulation. In light of the increasing use of automation by many hospital pharmacies, the following guidance is also very pertinent: Tablet and capsule forms should not be placed in automated

counting or packaging machines, because stress on the dosage forms can introduce powdered contamination into the equipment. Compounding of hazardous drugs must follow the standards within USP <795> and <797>, and compounding equipment must be designated and not intermixed for compounding of nonhazardous drugs. Additionally, section 13 urges the utilization of commercially available products as starting ingredients instead of crushing tablets, opening capsules, and using active pharmaceutical ingredients (APIs). The section on administration guides the use of PPE for administering hazardous drugs and recommends the use of protective techniques and ancillary devices when applicable. This section also lists the Oncology Nursing Society Safe Handling of Hazardous Drugs publication as a valuable resource on hazardous drug administration.

Sections 15 through 18

Sections 15 through 18 (Deactivation/Decontamination, Cleaning and Disinfection; Spill Control; Disposal; Documentation and Standard Operating Procedures) provide very detailed and specific guidance for the use of PPE for such activities, as well as definitions of and agents to be used in each cleaning step, including the use of combination agents (cleaning steps: deactivation, decontamination, cleaning, and disinfection). This guidance directs when cleaning should occur, lists techniques for wiping, and gives guidance on when and how to clean areas under the work tray of a C-PEC. The section on spill control stresses the importance of quick and easy access to a spill kit, signs for restricting access to the area, documentation of the circumstances and management of the spill, and immediate medical evaluation of anyone who has had direct skin or eye contact with hazardous drugs. Only qualified personnel wearing PPE should be involved in spill containment. Section 16 mandates that SOPs be developed for spill prevention and containment, but it does not provide detailed guidance on the content of spill kits nor guidance on appropriate training of personnel for spill management. The disposal section urges compliance with applicable federal, state, and local laws pertaining to hazardous drug waste; it is important for pharmacy leaders to be up to date with such regulations. The documentation and standard operating procedures section provides guidance on which activities must be documented and the content that must be included in the SOPs for the safe handling of hazardous drugs.

Section 19: Medical Surveillance

Section 19 addresses the medical surveillance program, the purpose of which is to minimize adverse health effects in persons potentially exposed to hazardous drugs. The concept of medical surveillance is based on a proactive approach for early detection of health problems that compares trends over time with an employee's baseline health status. This involves tracking of personnel via assessments and documentation of symptom complaints, physical findings, and laboratory values in order to assess deviations from norms and changes over time. It can also provide a means by which to determine population health trends among exposed personnel compared to unexposed personnel; this can be very helpful in determining the significance of findings. Section 19 discusses elements that should be contained in the entity's medical surveillance program, such as creating an organized approach for identifying potentially exposed workers, the importance of confidentiality and maintenance of health records, and follow-up plans for workers who have shown health changes related to toxicity. Although this section provides criteria that can be used to assess exposure history, it does not provide guidance for determining what a high exposure is nor how this information should be interpreted. For example, it suggests using an estimate of the number of hazardous drug preparations/administrations a health care worker performs in a week; however, there is no "acceptable" number for comparison and evaluation. The mandates within this section present significant changes from <797>, especially concerning confidentiality of health records and continuous monitoring. Employees may not feel comfortable with their health information being managed by someone working within their department, so this sensitive information may have to be interpreted by a separate party such as employee health personnel or a separate contracted agency.

IMPACT OF USP <800> ON HEALTH SYSTEM PHARMACY

Executive leadership support from the organizational entity, as well as the pharmacy department, will be instrumental to ensure timely compliance with USP <800>. This standard is broad and all-encompassing and can be legally enforced at both the federal and state levels. Other agencies, such as The Joint Commission and Centers for Medicare and Medicaid Services (CMS), may also request compliance with USP <800> standards. As such,

the impact of these standards on the organization is large and deserves the attention of all necessary stakeholders.

Most pharmacy leaders will agree that they have an unspoken duty to reasonably ensure the safety and protection of their employees. Leaders are looked to for guidance in times of change. As such, they have a responsibility to know the contents of the standard, be able to decipher and analyze it, and lead strategies to uphold it.

Leaders should be proactive in strategizing their organization's compliance with the standards. This will help eliminate unexpected barriers. A team of pharmacy experts in supply chain management, compounding, hazardous drugs (such as oncology pharmacists), and pharmacy administration should perform a gap analysis to identify areas that need special attention. For example, the entity's list of hazardous drugs should be updated, and its facilities should be evaluated for necessary modifications. It is important to make modifications in such a way as to minimize interruptions to ongoing pharmacy operations, as it is important to continue to provide care to patients.

Some other areas that will need to be analyzed include the adequacy of PPE used by individuals who manipulate hazardous drugs, retraining of personnel with documentation of competencies, and the creation or updating of SOPs. Education will be a big project; not only will pharmacy personnel need to be updated, but also nurses, physicians, risk management, legal, and drug delivery personnel from contracted suppliers. The process by which a hazardous drug is delivered to an institution until that drug is safely administered to a patient consists of many steps. It is important that there is tight control at each step in this pathway, along with safeguards to prevent unintended consequences. USP <800> is intended to provide exactly this standardized guidance. If an organization upholds standards throughout the entire process except for one step, then that entity can be considered noncompliant. It is advisable for organizations to provide feedback to USP, even after the standard has been finalized and enforcement has begun. It would also be helpful for separate entities to network and share information on strategies that have worked or not worked and to publish scientific research in this area where possible. There are areas where scientific evidence is lacking and research would greatly assist to streamline recommendations and even redefine standards within USP <800>.

Implementing USP <800> will increase the safety of preparing hazardous drugs, but there will be challenges to compliance. Table 3 lists some challenges along with some recommended strategies.

Regardless of all of the requirements listed in USP <800>, there is no substitute for disciplined, consistent work practices regarding proper sterile technique. This point should be emphasized with all compounding personnel. Even if one is compounding in the most compliant USP <800> cleanroom, improper technique can negate all the benefits of the physical structures.

Additionally, not all changes have to be implemented at once. Having a defined strategy that addresses the parts of USP <800> that are easily implemented is key to achieving success with USP <800> compliance. Many entities are still attempting to achieve compliance with the standards set forth in USP <797>,² so this impending guidance can make it even more difficult for them to keep abreast of changes. However, health systems should view it as an opportunity to target compliance with both standards in one combined effort. For example, if

facilities need to make changes to comply with USP <800>, then it would be wise for them to make any additional necessary updates that would also ensure compliance with USP <797>.

CONCLUSION

USP <800> is a standard that consolidates existing recommendations for handling hazardous drugs into one universally recognized reference. This standard will require many key operational changes for health systems and will have a far-reaching impact for maintaining patient care standards and health care employee safety and protection. Pharmacy leaders at every level will play a key role in helping organizations achieve timely compliance with USP <800> standards. Until the standard becomes official, it is important for pharmacists to become familiar with the latest draft, identify potential barriers to compliance, and strategize a plan to overcome barriers. Although complying with USP <800> may seem to be a daunting task, it can be manageable if approached in a systematic organized way.

Table 3. USP <800> compliance challenges and corresponding readiness strategies

Potential compliance challenges ¹¹	Strategies for USP <800> readiness
Financial and budgetary restrictions	<ul style="list-style-type: none"> • Conduct a gap analysis • Prioritize projects according to feasibility, ease of execution, and resource sharing amongst departments
Physical plant limitations	<ul style="list-style-type: none"> • Involve facilities engineering in plan for redesigning clean rooms
Training and competency	<ul style="list-style-type: none"> • Identify areas where retraining is needed • Rewrite policies and procedures
Resource availability	<ul style="list-style-type: none"> • Form partnerships among departments within the health system • Form partnerships among nearby hospitals • Consider the possibility of outsourcing
Time	<ul style="list-style-type: none"> • Strategize from early on, not when the standard has been published • Focus on areas in which a change in the final guideline will not require a serious overhaul
Resistance to change	<ul style="list-style-type: none"> • Prepare for change management • Maintain staff morale • Manage expectations • Foster teamwork
Lack of support and awareness from executive leadership	<ul style="list-style-type: none"> • Educate on USP <800> especially on risks of noncompliance • Seek buy-in from an early stage • Leverage “culture of safety” principles

REFERENCES

1. Centers for Disease Control and Prevention. Multistate outbreak of fungal infection associated with injection of methylprednisolone acetate solution from a single compounding pharmacy—United States, 2012. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6141a4.htm>. Accessed September 12, 2015.
2. Douglass K, Kastango E, Cantor P. The 2014 USP Chapter <797> compliance survey. *Pharm Purchas Prod*. 2014;11(10suppl):S6-24.
3. The United States Pharmacopeial Convention. About USP. <http://www.usp.org/about-usp>. Accessed September 12, 2015.
4. The United States Pharmacopeial Convention. General Chapter <797> Pharmaceutical compounding—sterile preparations. <http://www.usp.org/usp-nf/official-text/revision-bulletins/general-chapter-pharmaceutical-compounding-sterile-preparations>. Accessed September 12, 2015.
5. National Institute for Occupational Safety and Health. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings 2014. <http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138.pdf>. Accessed September 12, 2015.
6. Centers for Disease Control and Prevention. Hazardous drug exposures in health care. <http://www.cdc.gov/niosh/topics/hazdrug/>. Accessed September 14, 2015.
7. Tocco A. The future impact of USP 800 in the health care setting. <https://oldsite.michiganpharmacists.org/education/online/continuingeducation012015.pdf>. Accessed September 14, 2015.
8. The United States Pharmacopeial Convention. Working with US FDA. <http://www.usp.org/about-usp/legal-recognition/working-us-fda>. Accessed September 14, 2015.
9. American Society for Healthcare Engineering. Regulatory Advisory: JCAHO clarifies their expectations related to USP <797> in perspectives. March 28, 2006. http://www.ashe.org/advocacy/organizations/USP/pdfs/usp_jcahoperspectives.pdf. Accessed September 15 2015.
10. The United States Pharmacopeial Convention. Briefing: <800> Hazardous drugs—handling in healthcare settings. http://www.usp.org/sites/default/files/usp_pdf/EN/m7808_pre-post.pdf. Accessed September 6, 2015.
11. ASHP Advantage. Discussion guide: An update on protecting health care practitioners and patients from hazardous drugs. www.ashpadvantage.com/usp800. Accessed September 18, 2015. ■