American Hospital Association™
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Regulatory Advisory

February 7, 2020

USP Chapters <797> and <800> New and Revised Compounding Standards

At A Glance

At Issue

The United States Pharmacopeia (USP) in June 2019 released several new and revised pharmacy compounding standards. Specifically, USP published the final revised version of general chapter <797> (Pharmaceutical Compounding of Sterile Preparations) to accompany the previous released general chapter <800> (Hazardous Drugs Handling in Healthcare Settings). Due to pending appeals, the effective date of USP <797> remains postponed until further notice and USP <800> remains "informational" until <797> is finalized. While federal regulatory agencies and accrediting organizations likely will not begin enforcement of both chapters until after the appeals process is complete, several state boards of pharmacy already have begun enforcement of <800>, which may affect your hospital or health system's timeline for compliance.

AHA Take

While these standards provide an important reminder of the potential hazards of the chemical compounds used in medications, implementation of these standards will be complicated, and likely costly and time-consuming. In addition, while the effective date of USP <797> remains delayed and USP <800> remains informational until further notice, the AHA anticipates required compliance once final. We recommend organizations take immediate steps to assess their specific organizational readiness for compliance and develop a plan to make all necessary changes. Protecting health care personnel from harm resulting from occupational exposure to environmental hazards is a top priority for hospitals and health systems, and implementation of these standards will play a critical role in keeping providers and the patients they treat safe.

What You Can Do

- ✓ Share this advisory with your leaders in human resources, nursing, operations, risk management, pharmacy and information technology.
- ✓ Organize your internal team with responsibility for different components of implementation. (see checklist)
- ✓ Have staff develop an implementation plan and identify opportunities for early progress to demonstrate efforts to move toward full compliance. Use the resources included below as a starting point for your organization's work, as appropriate.

Key Takeaways

- Significant investment and cross-organization coordination will be necessary to comply with these standards.
- Consult your state board of pharmacy to determine if compliance with USP <800> is required in your state.
- If you have not done so already, begin assessing what changes your organization will need to make to comply with the new standards.
- USP <800>, while only informational for the time being, provides important standards around employee and environmental safety that all hospitals and health systems should consider.
- We anticipate required compliance with USP <800> at some point in the near future.

Further Questions

Contact Mark Howell, senior associate director of policy, at 202-626-2317 or mhowell@aha.org.

Background

In June 2019, the United States Pharmacopeia (USP) released several new and revised pharmacy compounding standards. Specifically, USP published revisions to general chapter <797> (Pharmaceutical Compounding and Sterile Preparations) and published a new general chapter <800> (Hazardous Drugs Handling in Healthcare Settings). Due to pending appeals, <797> remains postponed until further notice, and <800> remains "informational" until <797> is finalized. Hearing dates for the appeals were Jan. 21-22, 2020, and the AHA will update members as more information regarding the outcome of the appeals hearings becomes available.

Having an organizational plan for implementation should include:

- attention to needed changes in human resource policies;
- personnel training and protection requirements;
- the construction and ventilation of drug handling areas;
- changes to certain compounding requirements, such as beyond use dates and immediate use; and
- other steps needed to mitigate the risks of handling, administering and disposing of these medications.

Planning for these changes will be necessary if these standards are adopted as written by either the Centers for Medicare & Medicaid Services (CMS), the Joint Commission or your state board of pharmacy.

While <797> and <800> compliance will not be enforced on a federal level until finalized, several state boards of pharmacy currently require compliance with <800>, even as it remains "informational." Hospitals and health systems should consult with their state board of pharmacy to determine when compliance with <800> is required. Given the high priority of protecting health care personnel, <800> establishes important standards to implement necessary practices and ensure safety for all individuals involved in the receipt, compounding, administration and disposal of certain hazardous drugs. While compliance with these new standards may require significant capital investment, changes to employee training policies and adaptation of certain human resources protocols, the benefit of implementing these standards should not be underestimated.

Due to the broad impact of these standards, the AHA has separated resources into various sections below, with more in-depth information available in links attached to each of the categories. In addition, the AHA remains in contact with CMS and accrediting organizations and is advocating for a thoughtful and comprehensive plan to ensure compliance while acknowledging the large-scale changes required by these new standards.

Resources

Due to the wide-reaching impact of both chapters, leadership teams for hospitals and health systems will need to discuss the implications for meeting these new requirements. For example, those facilities with in-house compounding services may benefit from having their facility revisit the financial viability of in-house compounding services, which could require large-scale physical environment changes as a result of the new standards. For those facilities intending to continue in-house compounding, ensuring the development of a comprehensive approach for implementation and compliance is critical. In addition to the resources below, this advisory also includes a high-level checklist for hospital leadership to reference.

American Society for Healthcare Engineering (ASHE) Resources
Engineering personnel are primarily responsible for the physical environment provisions. This includes engineering controls used to protect the sterility of compounded preparations and the safety of staff working with hazardous drugs. These responsibilities include the construction, maintenance and operation of the spaces. Common physical spaces found in a working pharmacy include the general pharmacy, anteroom and buffer room(s); compounding area and sometimes a storage room or hazardous-drug storage room and the engineering controls; Containment Primary Engineering Control (C-PEC) or hood; and the ventilation system and its interaction with the various spaces. ASHE has developed two monographs that provide in-depth information regarding these issues. These can be accessed at ASHE USP 797 or ASHE USP 800 Resources

If you have questions concerning engineering requirements, contact Chad Beebe, deputy executive director of ASHE, at cbeebe@aha.org.

American Society for Healthcare Human Resource Administration (ASHHRA) Workforce Considerations
With the potential implementation of USP <800> in 2020, it is imperative that human resource leaders familiarize themselves with the health care worker protection requirements associated with exposure to hazardous drugs, and partner with their leadership teams to prepare their organization for the changes that will result from these new requirements. It is likely that the requirements contained in USP <800> and USP <797> will effect human resource leader functions in a number of ways, with the most significant effect on facilities that currently have in-house compounding services.

USP <800> and <797> have the potential to disrupt the workforce, necessitating a reduction or reallocation of full time employees. Human resource leaders from virtually all types of health care facilities will have to prepare for new training and retraining requirements, including attestation and documentation, additional regulatory scrutiny, and a potential increase in workers compensation claims that may result from increased awareness of harmful effects of occupational exposure to hazardous drugs.

If you have questions concerning human resource requirements, contact Catherine Carruth, executive director of ASHHRA at ccarruth@aha.org.

American Society for Health System Pharmacists (ASHP) Resources and Modules
Pharmacy executives should be aware that compliance with Chapter <800> standards may require facility renovations and new equipment. Installing negative-pressure, externally exhausted cleanrooms and hoods can be costly and may take several months. As the medication experts, pharmacy should take the lead on compliance with chapter <800>, but an interprofessional approach will be necessary to ensure all health care practitioners are kept safe. Pharmacists should consider leveraging the assessment-of-risk provision described in Chapter <800> to reduce the burden of standard implementation for non-antineoplastic hazardous drugs.

The revisions to Chapter <797> are the first changes to the chapter since 2008. While there are no significant changes to engineering control requirements, pharmacy executives should be aware of new personnel competencies, environmental monitoring and beyond-use dates. The chapter updates will require changes to departmental policies and procedures as well as periodic competency assessments.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians.

Additional Resources:

- ASHP Guidelines on Compounding Sterile Preparations
- ASHP Guidelines on Handling Hazardous Drugs
- USP <795>, <797> & <825> postponement FAQ
- ASHP Chapters <797> and <800> Consulting Services

e-Learning modules (free for members and non-members):

- Pharmacy Quick Reference Guide: Hazardous Drug Safety and Compliance with USP Chapter <800> in the Health System
- USP Chapter <800>: Focus on Approaches to Addressing Surface Contamination in Healthcare Settings
- Update on USP Chapter <797>: Strategies for Ensuring Compliance by the December 2019 Deadline

If you have questions concerning pharmacy requirements, contact Michael Ganio, ASHP director of pharmacy practice and quality, at mganio@ashp.org.

American Society for Healthcare Risk Management (ASHRM) Considerations for Compliance

It is essential that health care risk professionals have knowledge of USP <800> and its requirements for the protection of the health care worker from harm associated with exposure to hazardous drugs. USP <800> and USP <797> have many requirements that

reach beyond compounding and impact the entire health care organization. ASHRM has created a *USP <800> Monograph and Risk Readiness Checklist* to assist your organization in establishing what is required and where the organization currently stands in being compliant with USP <800>.

If you have questions concerning risk management requirements, contact Matthew Hornberger, executive director of ASHRM at mhornberger@aha.org.

Next Steps

Contact Mark Howell, senior associate director of policy, at 202-626-2317 or mhowell@aha.org. This advisory does not contain information pertaining to general chapter <795> (Pharmaceutical Compounding of Nonsterile Preparations) or general chapter <825> (Radiopharmaceuticals – Preparation, Compounding, Dispensing and Repackaging). Should your organization have questions about either of those chapters, please contact Mark directly.