



Role and Applicability of USP General Chapter <800> Related to Safe Handling of Hazardous Drugs

Summary

On December 1, 2019, USP's standard on the safe handling of hazardous drugs, General Chapter <800>, became official. General Chapter <800> is **informational** and not compendially applicable. USP General Chapter [<800> Hazardous Drugs – Handling in Healthcare Settings](#) describes practice and quality standards for handling hazardous drugs. USP is committed to maintaining patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs (hazardous drugs) in healthcare facilities.

Compendial Applicability

USP General Chapters, monographs, and related programs are intended to help protect and improve the health of people, in part by facilitating access to high quality, safe, and beneficial medicines.

A general chapter numbered below 1000 becomes compendially applicable and thus is considered a required standard only when:

1. the chapter is referenced in a monograph;
2. the chapter is referenced in another General Chapter below 1000; or
3. the chapter is referenced in General Notices.

General Chapter <800> is informational and not compendially applicable because it is not referenced in *General Notices*, a monograph, or another applicable general chapter numbered below <1000>.

Revisions to General Chapters [<795> Pharmaceutical Compounding—Nonsterile Preparations](#) and [<797> Pharmaceutical Compounding—Sterile Preparations](#), published on June 1, 2019, include cross-references to <800>. This would have made <800> compendially applicable for facilities that are required to implement <795> and <797>. Due to the appeals received on certain provisions in revised USP <795> and <797>, the chapters have been remanded to the Compounding Expert Committee with the recommendation for further engagement on the issues raised in the appeals (see [Compounding Appeals](#)). This means that the currently official chapters of [<795>](#) (last revised in 2014) and [<797>](#) (last revised in 2008) remain official. These currently official compounding chapters do not reference USP <800>.

In the future, if the revised USP <795> and <797> contain reference to USP <800>, <800> would be applicable and compendially required **only to the extent to which USP General Chapters <795> and <797> apply**. For hazardous drugs, this means only when a practitioner is “compounding” (as that term is defined in USP <795> and <797>) <800> would be applicable and compendially required. Since administration is out of scope of USP <795> and <797>, General Chapter <800> would not be applicable or compendially required in this context.



Enforcement

State agencies (e.g., State Boards of Pharmacy), other regulators (e.g., Occupational Safety and Health Administration), and oversight organizations (e.g., The Joint Commission) may make their own determinations regarding the applicability and enforceability of <800> for entities within their jurisdiction. USP continues to engage and inform regulators, accreditation organizations, and stakeholders about the compendial status of the chapter. USP plays no role in enforcement.

USP Standards for the Handling and Compounding of Hazardous Drugs

The known risks associated with hazardous drug exposure present a compelling public health challenge. General Chapter <800> was developed based on public health need and potential exposure of approximately [8 million U.S. healthcare workers to hazardous drugs each year](#). There were also published reports of adverse effects in healthcare personnel from occupational exposure to hazardous drugs. Although General Chapters <795> and <797> contained some information on handling of hazardous drugs, there was no public standard aimed to minimize the potential risk of exposure. To meet this need, the Compounding Expert Committee sought to expand on the principles of hazardous drug compounding established in USP <795> and <797> and to develop a general chapter specific to the handling of hazardous drugs through the development of USP <800>. USP is committed to maintaining patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs (hazardous drugs) in healthcare facilities.

Additional Resources

For additional information on General Chapter <800>, see:

- ▶ [USP <800> FAQs](#)
- ▶ [FAQs on the Compounding Appeals](#)