



## FAQs for NABP

(Updated 2017-10-26)

### **1. What is the status of the General Chapter <800> and when will General Chapter <800> become official?**

USP announced the intent to postpone the official date of General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*. The intent of this postponement is to align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797> *Pharmaceutical Compounding – Sterile Preparations*, to provide a unified approach to quality compounding. The next revision to General Chapter <797> is anticipated to be published in the *Pharmacopeial Forum* 44(5) September/October 2018 for a second round of public comment. Both USP General Chapter <797> and USP General Chapter <800> are anticipated to become official on December 1, 2019. Sections of the revised <797> may have longer implementation dates that will allow time for adoption of the standard.

### **2. What does ‘official date’ mean?**

The USP “official date” indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of regulators such as the FDA, states, and other government authorities. USP has no role in enforcement.

### **3. Other than the change to the official date, are there other expected substantive changes to USP General Chapter?**

No. The only part of USP General Chapter <800> that is expected to change is the official date, which is expected to be changed to December 1, 2019.

### **4. Is <800> currently enforceable in the United States?**

From a compendial standpoint, a USP general chapter numbered below <1000> becomes enforceable through reference in the General Notices, a monograph, or another applicable general chapter numbered below <1000>. At this time, <800> is not specifically referenced in the General Notices, a monograph, or another applicable general chapter numbered below <1000>.

However, states may make their own determinations regarding the applicability and enforceability of <800> to entities within their jurisdiction. USP has no role in enforcement. As a result, the specific enforceability of <800> depends on the legal framework that you are analyzing.



**5. Does the December 1, 2019 official date of <800> impact my current or early adoption of the general chapter?**

No. USP encourages adoption and implementation of General Chapter <800> to help ensure a quality environment and protection of healthcare workers and patients when hazardous drugs are handled.

**6. How do I adopt USP General Chapter <800> if sections are not harmonized with USP General Chapter <797>?**

Two sections that are not harmonized between the two chapters are: Segregated Compounding Area and 'Low volume' hazardous drug compounding. Below please find guidance on how to adopt USP <800> until the revised USP <797> is published.

**Segregated Compounding Area (SCA)**

- USP <797> only allows low-risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond-use date (BUD) to be prepared in an unclassified segregated compounding area (SCA).
- USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 30 ACPH and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.
- Note the differences in terminology and requirements in the SCA in USP <797> and C-SCA in <800>.
  - For early adoption of <800>, low- and medium- risk level HDs may be prepared in a C-SCA provided it meets the requirements in the chapter and the CSP is assigned a BUD of 12 hours or less.
  - For facilities that have not yet adopted <800>, the standards in USP <797> would apply. Only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA.

**"Low volume" hazardous drug compounding**

- USP <797> allows facilities that prepare a "low volume" of HDs to compound these drugs in a non-negative pressure room if "two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.
- USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- For early adoption of <800>, HDs must be prepared in a C-SEC meeting the requirements in the chapter.
- For facilities that have not yet adopted <800>, the standards in <797> would apply. Facilities preparing a low volume of HDs may continue to compound these CSPs outside a negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.