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.