General Chapter <797> Pharmaceutical Compounding–Sterile Compounding

Type of Posting: Notice of Intent to Revise
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Expert Committee: Compounding Expert Committee

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the Compounding Expert Committee intends to revise the General Chapter <797> *Pharmaceutical Compounding ? Sterile Preparations*.

Based on the number and significance of public comments received in response to the revision proposal published in *Pharmacopeial Forum (PF)* 41(6), the USP Compounding Expert Committee is proposing to revise this chapter. The Expert Committee seeks stakeholder feedback on the proposed revisions to the chapter, including the following major changes:

1. Reorganization of the chapter to include section and subsection numbers.
2. Placement of procedural information in boxes.
3. Definition of the scope of the chapter to include sterile compounding activities and exclude administration of medication (e.g., withdrawing doses for administration).
4. Simplified compounded sterile preparation (CSP) microbial risk levels from three (low, medium, and high) to two—Category 1 CSPs and Category 2 CSPs. Category 1 and 2 CSPs are distinguished primarily by the facility in which they are made and the time period within which they must be used, i.e., the beyond-use date (BUD).
    - Category 1 CSPs have a shorter BUD and may be prepared in an unclassified segregated compounding area (SCA).
    - Category 2 CSPs have a longer BUD and must be prepared in a cleanroom suite (buffer room with ante-room).
5. Addition of guidance on use and storage of opened or needle-punctured conventionally manufactured products and CSPs.
6. Addition of information on notification and recall of CSPs that have out-of-specification results.
7. Clarification of requirements for compounding allergenic extract prescription sets.
8. Removal of information related to handling of hazardous drugs and addition of references to *Hazardous Drugs—Handling in Healthcare Settings* ?800?.

9. Removal of the section on radiopharmaceuticals as CSPs and addition of a reference to *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging* ?825?. General chapter ?825? is also proposed for public comment in PF *44*(5).

Additionally, the Expert Committee is considering the development of new resource(s) to assist compounders in extending BUDs for Category 2 CSPs to include criteria for validated stability-indicating assays and testing for sterility, endotoxins, container-closure integrity, and particulate matter. The resource(s) are intended to guide correct interpretation and application of testing results.

The proposed revision will be published in *PF* 44(5) [Sept.–Oct. 2018] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on November 30, 2018. In the absence of any adverse comments the proposed revisions will become official on December 1, 2019. To allow additional time for public review and comment, the proposed revisions are included below in advance of their publication in *PF* 44(5):

- *<797> Pharmaceutical Compounding ? Sterile Preparations*

Please use the electronic form to submit your comments. Comments should include corresponding line number(s) to the proposed revisions to the General Chapter. Please see instructions for submitting public comments on <797>.

Should you have any questions, please contact Jeanne Sun, Manager to the Compounding Expert Committee (CompoundingSL@usp.org).

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