General Chapter <797> Pharmaceutical Compounding—Sterile Preparations

Type of Posting: Notice of Intent to Revise

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Expert Committee: Compounding

In accordance with section 7.05(c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the Compounding Expert Committee intends to propose several revisions to General Chapter <797> Pharmaceutical Compounding—Sterile Preparations. The General Chapter has been under review since 2010 and has been significantly revised to clarify requirements, and reflect stakeholder feedback and learnings since the last revision became official in 2008.

Major revisions of the General Chapter include:

1. Reorganization of existing sections and placement of procedural information in boxes
2. Collapsing of the three compounded sterile preparation (CSP) microbial risk categories (e.g. low-, medium-, and high-risk) into two categories (Category 1 and 2) distinguished primarily by the conditions under which they are made and the time within which they are used.
3. Removal of information on handling hazardous drugs and added cross-references to <800> Hazardous Drugs—Handling in Healthcare Settings
4. Introduction of the terminology “in-use time” to refer to the time before which a conventionally manufactured product used to make a CSP must be used after it has been opened or punctured, or a CSP must be used after it has been opened or punctured.

The proposed revisions to General Chapter <797> will be published for public comment in Pharmacopeial Forum (PF) 41(6) [Nov.–Dec. 2015] on November 2, 2015, pursuant to section 7.02 of the Rules and Procedures. To allow additional time for public review and comment, the proposed revisions are included below with line numbers in advance of their publication in PF 41(6).

- *<797> Pharmaceutical Compounding—Sterile Preparations*

Please use the submission template when sending your comments to CompoundingSL@usp.org. Comments should include corresponding line number to the proposed revisions to the General Chapter. Comments will be accepted until January 31, 2016, the end of the comment period for PF 41(6).

Should you have any questions, please contact the Healthcare Quality Standards team at CompoundingSL@usp.org.