# USP GENERAL CHAPTER <797> REVISION: WHERE ARE WE NOW?

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On September 25, 2015, the United State Pharmacopeial (USP) General Chapter <797> Pharmaceutical Compounding – Sterile Preparations was posted to the Pharmacopeial Forum (PF) with notice for the intent to revise. The revision of this general chapter had been eagerly awaited by all those involved, both directly and indirectly, with compounded sterile preparations (CSPs). But before this revision could go into effect, it needed to be circulated for public review and comment. The chapter remained out for public comment until January 31, 2016.

To understand how vital this chapter is to the sterile compounding community, over 8,000 comments from more than 2,500 stakeholders were received by the USP Compounding Expert Committee. The Expert Committee has been reviewing the comments since receipt, and the committee is expected to continue the review process through the summer of 2016. All submitted comments are reviewed and considered. Comments related to allergen extracts and radiopharmaceuticals have prompted the need for the USP Healthcare Quality Standards Head of Science to host two roundtables to seek clarity in order to better understand the needs of these specific pharmaceuticals and determine the best way to proceed with the revision process.

Despite the progress on the chapter to this point, the effective date of this long-awaited chapter revision may be further delayed. Once all comments have been reviewed and the significance of further revisions has been evaluated, the Expert Committee's evaluation may result in USP General Chapter <797> being put forth for another public comment period. As per its statement released on May 16, 2016, USP does not yet have an anticipated date for publication. If another public comment period is needed once the chapter is ready again, it will be published in PF for another 90-day public comment period. PF is the free online journal in which USP publishes proposed revisions to USP–NF for public review and comment. For more information or to register for PF, visit www.usp.org/usp-nf/pharmacopeial-forum.

Although the released revision is only a proposal and the original current text found in USP-NF 38 is to be followed until the proposed chapter is approved and published, it is critical that compounding facilities start planning and preparing for the release of the new chapter. Additionally, all major changes in the chapter must be taken into consideration as to how they directly affect each compounding facility. By registering at www.usp.org/HQS-Signup-Form, stakeholders can receive free updates about the revision process and the status of USP General Chapter <797>.

The revision process for USP chapters and monographs takes an extended period of time, but there is good reason. All stakeholders' opinions matter, and all received comments are considered. Although the chapter's new official date is not yet set, each facility can better prepare for the final version by taking the general concepts of the proposed revision and comparing them to their current policies and procedures. The Food and Drug Administration (FDA) and other regulatory agencies, such as the State Board of Pharmacy, will expect all facilities to be in compliance with the new chapter once it is made official. By registering for USP updates and PF, facilities can stay up to date on the latest regarding USP General Chapter <797> and be prepared.

## References

**United States Pharmacopeial Convention:** www.usp.org/about-usp
**United States Pharmacopeial Convention:** www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision