



# Compounding Expert Committee Update on USP <795> and <797>

May 14, 2022

## Background

On November 1, 2021, USP published proposed revisions to the USP Compounding General Chapters; <795> Pharmaceutical Compounding — Nonsterile Preparations and <797> Pharmaceutical Compounding — Sterile Preparations in the Pharmacopoeial Forum (PF 47(6)) for public comment. Both chapter revisions had been pre-posted on the USP website on September 1, 2021, to allow for an extended public comment period until January 31, 2022. Recognizing stakeholders' numerous challenges with maintaining normal operations during and responding to the COVID-19 global pandemic, USP extended the deadline from January 31, 2022, to March 17, 2022, in response to stakeholder requests, bringing the total public comment period to over 6 months.

## Stakeholder Engagement and CMP EC Update

Prior to the release of the proposed revisions, the Compounding Expert Committee (CMP EC) had engaged healthcare practitioners, regulators, academicians, and other key stakeholders in various sessions, including semi-structured interviews, a small roundtable discussion with invited participants, and a broader open forum discussion to collect feedback from a broad range of stakeholders. These engagements helped the CMP EC consider a wide range of perspectives to inform the revisions while maintaining scientific rigor and accounting for today's public health and practice needs. In conjunction with the release of the proposed revisions, the CMP EC released [informational documents](#) intended to supplement the proposed chapters and explain the CMP EC's rationale behind the revisions.

Between September 1, 2021, and March 17, 2022, the CMP EC held four Open Forum sessions to assist stakeholders in understanding the rationale for the proposed revisions. Recordings of the sessions are available [here](#). Over the comment period from September 1, 2021 to March 17, 2022, the CMP EC received and continuously reviewed more than 1,200 comments from more than 300 organizations for <797> and 200 comments from more than 50 organizations for <795>.

## Next Steps

With the completion of the open public comment period, the CMP EC is continuing its deliberation process, which involves careful and additional input received on the compounding chapters through the stakeholder engagement activities and public comments. The CMP EC intends to publish final revisions to the compounding chapters in the USP-NF. At this time, USP does not have an anticipated date for the final publication.

USP will keep stakeholders updated as more information becomes available, and we encourage stakeholders to [sign up](#) for updates. Any questions on these chapters should be directed to USP Healthcare Quality and Safety staff at [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org).