



FAQs on the Compounding Appeals

Appeals Status

1. What is the status of the Appeals on the USP Compounding Chapters?

On March 12, 2020, the USP Appeals Panel issued decisions on the Appeals to <795>, <797>, and <825>. Click [here](#) for more information.

As background, USP published revisions to General Chapter <795> for nonsterile compounding and General Chapter <797> for sterile compounding, as well as a new General Chapter <825> for radiopharmaceutical compounding on June 1, 2019. After publication of the revised and new compounding standards, USP received appeals on certain provisions in <795>, <797>, and <825>. In accordance with [USP's Bylaws](#), the responsible Expert Committees considered the information raised in the appeals and issued decisions on the appeals (see Expert Committee Decisions on Appeals to USP <795> and <797> and <825>). As part of the formal USP appeals process, four (4) stakeholders who submitted appeals to the compounding chapters requested further review by an appointed Appeals Panel. An Appeals Panel was convened (see question 6 below for details), and hearings on the appeals were held on January 21 and 22, 2020 (see question 8 below for details).

After thoughtful deliberation and evaluation of the record and hearings from the appellants, the Appeals Panel made the following decisions on the appeals (see [Appeals Panel Decision](#)).

- ▶ The Appeals Panel granted the appeals to General Chapters <795> and <797> and has remanded the chapters to the Compounding Expert Committee (CMP EC) with the recommendation for further engagement on the issues raised concerning the beyond-use date provisions.
- ▶ The Appeals Panel denied the appeal to General Chapter <825> and has encouraged the appellant to submit the narrower request presented at the hearing before the Panel to the Chemical Medicines Monographs 4 Expert Committee (CHM4 EC) as a request for revision.

Per [USP's Bylaws](#), the decisions of the Appeals Panel are final.

2. What does the final appeal decision mean for the revised General Chapters <795> and <797>?

Due to the remand of these chapters, the currently official versions of <795> (last revised in 2014) and <797> (last revised in 2008) remain official. The Appeals Panel did not determine that the Chapters require revision but noted that the issues raised in the appeals warrant additional dialogue and consideration. It is the purview of the CMP EC to determine the appropriateness of future revisions to the chapters, if any.

Recognizing the public health impact of these standards, USP is committed to further stakeholder engagement through stakeholder forums, roundtables, and other avenues to gather more input on the issues raised in the appeals. USP and the CMP EC are committed to moving forward in an open, transparent, and balanced manner as soon as practicable to enable the chapters to be finalized and implemented in a timely manner. To download the official chapters [click here](#).

3. What does the final appeal decision mean for General Chapter <825>?

Consistent with the Appeals Panel decision to deny the appeal to <825>, the responsible Expert Committee, CHM4 EC, may reinstate the official date of <825>. Based on USP's Bylaws, the Expert Committee must provide at least another six-month implementation period for this Chapter. The CHM4 EC will announce an official date once it is determined.



General Chapter <825> will be **informational and not compendially applicable**. From a compendial standpoint, a USP general chapter numbered below <1000> becomes applicable and compendially required through reference in General Notices, a monograph, or another applicable general chapter numbered below <1000>. Since <825> is not referenced in the General Notices, a monograph, or another applicable general chapter numbered below <1000>, <825> is an informational chapter unless otherwise required by a regulatory body. [Download the chapter here](#).

4. What is the role of the Appeals Panel going forward?

With decisions on these appeals having been made and communicated, the Appeals Panel has concluded its service. The members of the Appeals Panel will maintain strict confidentiality in connection with their involvement in the adjudication of the appeals. Any questions about these Chapters or the USP appeals process should be directed to USP Healthcare Quality & Safety staff at CompoundingSL@usp.org.

5. What sections, or provisions, in USP General Chapters <795>, <797>, and <825> were appealed?

First Level of Appeals

After the revisions were published on June 1, 2019, USP received appeals on key topics covered in USP <795>, <797>, and <825> including:

- ▶ Beyond-Use Date (BUD) provisions in <795>, <797>, and <825>
- ▶ Removal of Alternative Technology provision from <797>
- ▶ Applicability of <795> and <797> to veterinary practitioners
- ▶ Compounding from sterile substances in <825>
- ▶ Applicability of <825> within the radiopharmaceutical regulatory context

For a summary, see [Decision on Appeals to <795> and <797>](#) (August 16, 2019). Regarding <795> and <797>, the CMP EC reviewed the appeals, deliberated on the information related to <795> and <797> at an EC meeting on August 8, 2019, and issued decisions on all appeals on August 16, 2019.

Regarding <825>, the CMH4 EC reviewed the appeal, deliberated on the information related to <825> at an EC meeting on August 15, 2019, and issued its decision on August 19, 2019. For a summary, see [Decision on Appeals to <825>](#) (September 13, 2019).

Second Level of Appeals

In accordance with [USP's formal appeals process](#), stakeholders who submitted appeals to the compounding chapters had the opportunity to request further review by an appointed Panel, and USP has received four (4) such requests.

The issues that were under further review were related to:

- ▶ Beyond-Use Date (BUD) provisions in <795> and <797>
- ▶ Framework and BUD provisions in <825>

6. What was the composition of the Appeals Panel that adjudicated the second-level appeals to <795>, <797>, and <825>?

The members of the Appeals Panel were:

- ▶ Jesse L. Goodman, M.D., M.P.H., President, USP Convention
- ▶ Mary Foster, Pharm.D., Council of Experts



- ▶ Dennis K.J. Gorecki, B.S.P., Ph.D., Council of Experts
- ▶ Amy J. Karren, B.Sc., Council of Experts
- ▶ Timothy R. Franson, B.S. Pharm., M.D., Board of Trustees
- ▶ Marilyn K. Speedie, Ph.D., Board of Trustees
- ▶ Thomas R. Temple, B.S.Pharm., M.S., FAPhA, Board of Trustees

7. What did the Appeals Panel consider in making their decisions on the appeals?

The Appeals Panel was charged with considering the sufficiency of the process used by the respective Expert Committees to develop and approve the Chapters under appeal. The Appeals Panel considered whether opportunity for public comment was provided, how the Expert Committees considered the input received from all stakeholders, and whether the basis for the resolution of such comments was communicated publicly. The Appeals Panel made no determination with respect to the scientific content of the Chapters under appeal.

8. When were the hearings on the appeals held?

The hearings for the appeals to <795>, <797>, and <825> were held at the following dates and times:

Tuesday, January 21

9:00 a.m. to 12:00 p.m.

Public hearing on <795> and <797>

- ▶ Appellants: Civic Center Pharmacy, Reed's Compounding Pharmacy, Camelback Compounding, Nationwide Compounding, White Mountain Pharmacy, Mountainview Pharmacy, Mixtures Pharmacy, Potter's House Apothecary, Raintree Apothecary, Mortar and Pestle Pharmacy, Community Clinical Pharmacy, Melrose Pharmacy, Rosy's Pharmacy, Prescription Lab Pharmacy, Acacia Pharmacy, MedMetrics Pharmacy, Strive Pharmacy, The Compounders Group (TCG)

1:30 to 4:30 p.m.

Public hearing on <825>

- ▶ Appellant: Fagron

Wednesday, January 22

9:00 a.m. to 12:00 p.m.

Public hearing on <795> and <797>

- ▶ Appellants: Alliance for Pharmacy Compounding, Innovation Compounding, and Wedgewood Village Pharmacy

1:30 to 4:30 p.m.

Closed hearing on <795> and <797> [Hearing closed to public based on appellants' request for confidential treatment (transcript available for public review)]

- ▶ Appellants: Five unnamed compounding pharmacies

The following is the agenda for each hearing:

- ▶ Administrative Opening Procedures (5-10 min.) – USP Legal
- ▶ Opening Remarks (5-10 min.) – Chair of Appeals Panel



- ▶ Appellants' presentation (2 hours) – Appellants
- ▶ Panel Opportunity to Ask Questions of Appellants (30 min.) – USP Appeals Panel
- ▶ Administrative Closing Procedures (5-10 min.) – USP Legal

9. How do I obtain transcripts of the hearings held on the appeals?

Transcripts of all hearings may be ordered directly from the court reporting service. Click [here](#) to submit your order.

USP Standard-Setting and Appeals Process

10. How does the USP standard-setting process work?

When it comes to the development and maintenance of quality standards, USP believes public input is critical to ensuring our standards have the intended effects of advancing quality and reducing patient risk. This is why USP has a robust standard setting process:

1. **Public Health Need:** USP – independently or with help from stakeholders – identifies a public health need and evaluates opportunities for possible standard development.
2. **Draft Standard:** USP convenes a committee of independent experts that are knowledgeable on the public health issue to develop the standard.
3. **Public Comment Period:** The draft standard is published for stakeholder input. USP actively seeks engagement with stakeholders throughout the standard-setting process through stakeholder meetings, advisory roundtables, and open-microphone webinars.
4. **Review and Approval:** Comments are evaluated and addressed. If needed, further revisions and comments and considered.
5. **Publication:** The final standard is published with an official date typically at least 6 months after publication.

For more information on USP's standard-setting process, please visit:

- ▶ [Healthcare Quality & Safety Standard-Setting Process](#)
- ▶ [Quality Matters Blog: Quality Standards that Combine Science, Expertise, and Experience to Protect Patients and Healthcare Workers](#)

11. How can I provide input into a standard?

There are multiple ways to contribute. Stakeholders can submit comments on USP standards or take part in one of our Expert Committees. USP welcomes stakeholder involvement in the standard setting process through the [2020-2025 Call for Candidates](#).

In the coming months, USP will additionally conduct further stakeholder engagement through stakeholder forums, roundtables, and other avenues to gather more input on the issues raised in the appeals. USP will announce information on these events once it is available. USP's public standards are in [continuous revision](#), and the Expert Committees are committed to ongoing engagement with stakeholders. [Sign up for updates to stay informed](#).

12. How does the USP appeals process work?

USP has an established process by which any interested party may appeal a published standard:



1. An appeal is considered timely if submitted within 60 days of a standard's publication date. USP requests that submitters include relevant information, including supporting data, context, and the basis for the appeal.
2. The responsible Expert Committee (EC) reviews the appeal(s) and has 90 days to issue a decision.
3. Following the EC's decision, the appellant(s) has/have 30 days to request further review by a panel consisting of three members of the Council of Experts appointed by the Chair, three members of the Board of Trustees appointed by the Chair of the Board, and up to three additional experts appointed by the President of the Convention in consultation with the Chair of the Council of Experts. The panel is chaired by the President of the Convention.
4. The panel is convened within 90 days of the request for an appeal, and the appellants are given the right to appear at a hearing of the panel. The panel's decision is final.

Compendial Applicability and Official Chapters

13. What is the status of General Chapter <800>?

General Chapter <800> is not subject to any pending appeals and became official on December 1, 2019. General Chapter <800> is informational and [not compendially applicable](#). USP encourages utilization of <800> in the interest of advancing public health and has published additional information on the [context for implementation](#) of this chapter.

14. What does "compendially applicable" mean?

The USP is an official compendium of the U.S., and USP standards are therefore considered "compendial standards."

USP General Notices and Requirements section 3.10 describes the applicability of standards. A general chapter numbered below 1000 becomes compendially applicable and is considered a required standard when:

- ▶ The chapter is referenced in a monograph,
- ▶ The chapter is referenced in another general chapter below 1000, or
- ▶ The chapter is referenced in General Notices.

Because chapter <800> is not referenced in an official chapter nor in the General Notices, it is [not compendially applicable](#).

States and other regulators with jurisdiction, may integrate <800> into their statutes and regulations, or through other steps in accordance with their own policy making processes, to apply and enforce <800> in their jurisdictions.

15. Does USP enforce standards?

USP plays no role in enforcement. State and other regulators may make their own determinations regarding enforceability of USP standards. USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to communicate updates on the compounding chapters and the appeals process.

16. What should facilities do if they early adopted the revised appealed chapters?

The Appeals Panel did not determine that General Chapters <795> and <797> require revision but noted that the issues raised in the appeals warrant additional dialogue and consideration. It is the purview of the CMP EC to determine the appropriateness of future revisions to the chapters, if any. The revised <795> and <797> published on June 1, 2019 did not become official and are not appropriate for early adoption based on the appeals decision. Facilities that have already early adopted the revised standards should work with their states, regulators, and accreditation bodies to determine what may be required.



Consistent with the Appeals Panel decision to deny the appeal to <825>, the responsible Expert Committee, CHM4 EC, may reinstate the official date of <825>. Based on USP's Bylaws, the Expert Committee must provide at least another six-month implementation period for this Chapter. The CHM4 EC will announce an official date once it is determined. General Chapter <825> will be [informational and not compendially applicable](#) unless otherwise required by a regulatory body.

17. How can facilities implement <800> in light of conflicts with provisions in currently official <797>?

For facilities that implement <800>, there are two sections that are not harmonized between the currently official <797> and <800>: 1) Segregated Compounding Area and 2) "Low volume" hazardous drug (HD) compounding. Below we point out the differences between USP <800> and currently official <797>. States, regulators, and accreditation bodies may make their own determination on implementation and enforcement of USP standards. Stakeholders should speak with the appropriate regulators in their state to determine what may be required.

1. Segregated Compounding Area (SCA)

- ▶ Currently official 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.
- ▶ 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 12 air changes per hour (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 currently official USP <797> and C-SCA in <800>.
 - Under <800>, low- and medium-risk level HDs may be prepared in a C-SCA provided it meets the requirements in <800> and the CSP is assigned a BUD of 12 hours or less.
 - If not implementing <800>, only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA (as described in <797>).

2. "Low volume" hazardous drug compounding

- ▶ Currently official 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., closed system transfer device (CSTD) within a biological safety cabinet (BSC) or compounding aseptic containment isolator (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.
- ▶ Under <800>, HDs must be prepared in a C-SEC meeting the requirements in <800>.
- ▶ If not implementing <800>, 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.

Resources

- ▶ [Download](#) USP compounding standards
- ▶ [USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations](#)
- ▶ [USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations](#)
- ▶ [USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings](#)
- ▶ [USP General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging](#)

For any questions, contact USP's Healthcare Quality & Safety Team at CompoundingSL@usp.org.