

FAQs on the Compounding Appeals

Appeals Status

1. Which USP Compounding Chapters are being postponed?

Three USP Compounding Chapters are being postponed until further notice pending the resolution of the appeals:

1. Revised [<795> Pharmaceutical Compounding – Nonsterile Preparations](#)
2. Revised [<797> Pharmaceutical Compounding – Sterile Preparations](#)
3. New chapter [<825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging](#)

2. Which USP Compounding Chapters are currently official?

The current official chapters are [<795>](#) (last revised in 2014) and [<797>](#) (last revised in 2008). Download [here](#).

[General Chapter <800>](#) is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

USP plays no role in enforcement. State and other regulators may make their own determinations regarding the enforceability of <800>.

3. Why is the official date of the new and revised USP General Chapters <795>, <797>, and <825> (published on June 1, 2019) being postponed?

On June 1, 2019, USP published revisions to [<795> Pharmaceutical Compounding – Nonsterile Preparations](#) and [<797> Pharmaceutical Compounding – Sterile Preparations](#), as well as new chapter [<825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging](#). 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 worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals (see Decisions on Appeals to USP [<795> and <797>](#) and [<825>](#)). 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 under further review are related to:

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

USP's [Bylaws](#) provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, USP is **postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice.**

The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.



4. When are the new and revised compounding standards for USP General Chapters <795>, <797>, and <825> (published on June 1, 2019) expected to become official?

The official dates of <795>, <797>, and <825> will be postponed until further notice pending resolution of the appeals.

At this time, USP cannot predict or project a future official date for any of these chapters as the appeals process remains active. Regardless of the outcome of the appeals process, USP would not reestablish an official date for chapters <795>, <797>, or <825> without granting another six-month implementation period, at a minimum.

Any anticipated dates offered by third parties are not accurate as the appeals process is currently ongoing. USP is committed to communicate updates on the compounding chapters and appeals process.

5. What sections, or provisions, in USP General Chapters <795>, <797>, and <825> are being 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

Regarding <795> and <797>, the Compounding Expert Committee (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. For a summary, see [Decision on Appeals to <795> and <797>](#) (Aug. 16, 2019). Regarding <825>, the Chemical Medicines Monographs 4 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 under further review are related to:

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

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

The members of the Appeals Panel are:

- ▶ 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

The members of the Appeals Panel will maintain strict confidentiality in connection with their adjudication of the appeals. Any questions about the appeals process should be directed to USP staff by email at execsec@usp.org.

7. When will USP hold hearings on the appeals to <795>, <797>, and <825>?

USP is working with individual appellants to schedule hearings on the appeals. Once confirmed, hearing dates will be announced on the [Compounding Appeals webpage](#). USP intends to treat the hearings as open meetings unless appellants request otherwise (e.g., to protect confidential information).

8. What decisions can the Appeals Panel make with respect to the appeals?

Under Section 7.06(a) of USP's Rules and Procedures of the Council of Experts, new or revised documentary standards "must be voted on and approved by the responsible Expert Committee." The Appeals Panel is not the Expert Committee responsible for USP <795>, <797>, and <825>. Thus, the Appeals Panel is not authorized to revise the text or substance of the standards under appeal. For this reason, after due deliberation the Appeals Panel will either: (1) deny the appeals, resulting in the standards approved by the Expert Committee becoming official; or (2) grant one or more of the appeals, resulting in a remand of the standards to the responsible Expert Committee for further evaluation, stakeholder engagement, and/or revisions.

USP Standard-Setting and Appeals Process

9. 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](#)



10. How can I provide comment to 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](#). USP's public standards are in [continuous revision](#), and the Expert Committees are committed to ongoing engagement with stakeholders to develop additional resources.

11. 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

12. Is General Chapter <800> being postponed?

[General Chapter <800>](#) is not being postponed because it is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

13. 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.

14. 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.

15. Can facilities early adopt the revised (postponed) USP compounding standards while they remain under appeal?

While the postponements of the revisions to <795> and <797> are in place, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008), including the section *Radiopharmaceuticals as CSPs*, remain official. The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of revisions to these chapters.

From a compendial perspective, early adoption of revised standards in advance of the official date is permitted unless specified otherwise at the time of publication (USP General Notices 3.10). At the time of publication, USP did not prohibit early adoption.

3.10, Applicability of Standards:

Early adoption of revised standards in advance of the official date is allowed by USP unless specified otherwise at the time of publication. Where revised standards for an existing article have been published as final approved “official text” (as approved in section [2.10 Official Text](#)) but have not yet reached the official date (6 months after publication, unless otherwise specified; see “official date”, section [2.20 Official Articles](#)), compliance with the revised standard shall not preclude a finding or indication of conformance with compendial standards, unless USP specifies otherwise by prohibiting early adoption in a particular standard.

States, regulators, and accreditation bodies may make their own determination on implementation and enforcement of the currently official or revised (postponed) USP compounding standards. Stakeholders should speak with the appropriate regulators in their state to determine what may be required.

16. UPDATED: 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.

17. Given that the revised USP <795> and <797> and new chapter <825> are postponed until further notice, will the currently official chapters be available for free digitally? What about USP <800>?

Yes, you can download the currently official and postponed chapters at: <http://go.usp.org/l/323321/2019-05-31/2dfgw/>.

Please keep in mind that individual chapters are not sufficient for a comprehensive approach to pharmaceutical compounding. Additional chapters are required for complete implementation; see [USP Compounding Compendium](#) or [USP-NF](#).

Resources

- ▶ [NITR](#) Announcing Postponement
- ▶ [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](#)
- ▶ [Summary of updates for the new and revised \(postponed\) General Chapters <795>, <797>, and <825>](#)
- ▶ [Beyond-use dates \(BUDs\) for the revised \(postponed\) General Chapters <795> and <797>](#)

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