COVID-19 Compounding Resources Q&A

1. What resources have USP developed to address compounding challenges during the COVID-19 pandemic?

The COVID-19 pandemic has been associated with shortages of garb and personal protective equipment (PPE), hand sanitizers, and essential medications. In response to stakeholder requests and input, the USP Compounding Expert Committee (CMP EC) rapidly convened and developed considerations to help facilities during the COVID-19 pandemic. The CMP EC has developed resources for shortages of garb and PPE, compounding hand sanitizers, and operational considerations for sterile compounding. USP is actively monitoring the evolving situation and will continue to develop and update resources for compounding during the COVID-19 pandemic.

2. Are the USP Compounding Resources developed in response to the COVID-19 pandemic[1] considered official USP standards?

The USP Compounding Resources documents are not official USP standards, nor do they reflect the CMP EC's opinions on future revisions to official text of the *USP-NF*. They are resources intended for informational purposes only and were developed by the CMP EC based on emergent public health needs, scientific and professional expertise, and input from regulatory agencies at the federal and state level.

3. How will the USP Compounding Resources be used for enforcement by regulatory bodies?

USP has no role in enforcement. During the COVID-19 pandemic, USP supports State Boards and other regulators using risk-based enforcement discretion related to the implementation of USP compounding standards. The Compounding Resources developed by the CMP EC are intended for informational purposes only and are intended to provide considerations for stakeholders and regulatory bodies during the COVID-19 pandemic. Independent of the informational resources provided by USP, enforcement bodies, such as FDA, have published guidance documents and other resources, implemented for the duration of the public health emergency. Parties relying on the information in the USP Compounding Resources bear independent responsibility for awareness of, and compliance with, any applicable federal, state, or local laws and requirements.

4. What is the role of the USP Compounding Resources where they are not aligned with the currently official General Chapters <795> *Pharmaceutical Compounding – Nonsterile Preparations* and <797> *Pharmaceutical Compounding – Sterile Preparations*?

USP Compounding Resource documents are intended to be informational only and are not intended to replace or supersede the currently official <795> and <797>. General Chapters <795> and <797> remain the currently official standards applicable to nonsterile and sterile compounding, respectively. The USP Compounding Resource documents provide considerations to support stakeholders during the pandemic. To address specific concerns about potential conflicts between the USP Compounding Resources and legal or regulatory requirements, USP recommends that stakeholders contact regulatory, enforcement, or accreditation authorities within their jurisdictions.

[1] Hereafter referred to as "USP Compounding Resources" for the purposes of this document

5. Do the USP Compounding Resources reflect the CMP EC's opinions on future revisions to official USP-NF standards?

The USP Compounding Resources do not reflect the CMP EC's opinions on future revisions to official USP-NF standards. Specifically related to <795> and <797>, the CMP EC remains committed to further stakeholder engagement on the issues raised in the appeals to these chapters. More information about upcoming stakeholder engagement activities will be announced when available.

6. What will happen to the USP Compounding Resource documents after the COVID-19 pandemic ends?

The USP Compounding Resource documents developed in response to the COVID-19 pandemic are intended as informational resources to serve the duration of the public health emergency. USP is actively monitoring the evolving situation and will update, modify, and withdraw these resources in the future as appropriate.

7. Are the USP Compounding Resource documents open for public comments?

Due to the public health emergency posed by the COVID-19 pandemic and the need to develop rapid and evolving responses, these resources were developed without a public comment period. USP encourages stakeholders to submit input on these and other resources to the Healthcare Quality and Safety team at CompoundingSL@usp.org.

8. Can I attend CMP EC meetings where these USP Compounding Resources are discussed?

The CMP EC is holding regular meetings to openly discuss development and revision of Compounding Resource documents in response to the COVID-19 pandemic. Meeting dates and times can be found here. Observers can register to attend here.