USP Chapters Updates

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USP Chapters ‹795› and ‹797› have been in limbo since the appeals process delayed the anticipated December 2019 official revision implementation date. On March 11, 2020, USP announced that multiple appeals dealing with Beyond Use Dates (BUD) have been combined into one announcement. A positive statement of those appeals pertaining to extended BUDs has been granted by the USP appeals panel. The BUD issues outlined in those appeals have been remanded to the USP Compounding Expert Committee. The committee will work with the appellants to review the technical aspects of the proposed BUD requirements. It is important to understand that the appeals were **NOT** granted on the technical requirements of chapter but rather we based on the appearance of a lack of transparency in the process.

Statement from USP "The Compounding EC was not involved in the deliberations or decision of the USP Appeals Panel and members of the Appeals Panel will maintain strict confidentiality in connection with their involvement in the adjudication of the appeals. Further information about the appeals, including decision summaries, may be found on the following website: https://www.usp.org/compounding/compounding-appeals . Any questions about the compounding chapters or the USP appeals process should be directed to USP Healthcare Quality & Safety staff at CompoundingSL@usp.org "

The granting of the BUD appeals will further push off the official implementation date of the chapter revisions. For the foreseeable future, the 2008 version of USP Chapter ‹797› and the 2014 version of USP Chapter ‹795› will be considered the official chapters per USP. However, USP does not enforce the Chapters. It is hoped that the individual governing bodies will clarify their positions over the next few weeks. For example, the Joint Commission has been allowing the pharmacy to decide which version of the chapter it will inspect to as long as that version of the chapter is used in its entirety. We have not received as much clarity from some boards of pharmacy but are hoping that this announcement by USP will prompt better communication in that regard. We will also be monitoring the Joint Commission for any changes to their position.

With regards to certification, this announcement will have a minor impact. Both the current and future versions of the USP chapters reference CETA CAG-003 for certification criteria. There is no need for any modification to how an existing sterile compounding facility is tested. There will need to be collaboration between the certifier and the pharmacies' designated persons to determine the acceptance criteria for new hazardous drug compounding facilities. There are minor differences between USP Chapter ‹800› and the 2008 version of USP Chapter ‹797›, so it will be important to establish acceptance criteria around the appropriate version of the chapter based on the regulatory authority responsible for that site. CEC will work with each site to make the appropriate determination for their location.

With regards to new facility design, we understand that there will be confusion, but realistically, there should be minimal real impact. It does not make sense to design a facility to the 2008 version of a standard when the replacement for that is already written, and the facility requirements in the replacement chapter will not change. We know what the future facility requirements will be. We do, however, need to understand the regulatory authority's position on which version of the chapter a renovated or a new facility will be inspected against until the chapter revisions are official. This, again, impacts hazardous drug compounding more so than non-hazardous compounding. Most of this concern will be regarding Containment Segregated Compounding Areas (C-SCA) used for compounding hazardous sterile preparations using Category 1 (2019 version) Beyond Use Dates (BUD). *Note that this is in reference to "Low-Risk with 12-hour BUD in the 2008 version of the chapter.* Many facilities have already built C-SCAs but the hazardous drug discussion in the 2008 version of Chapter ‹797› specifically states that SCAs are not appropriate for HD compounding. C-SCAs are permitted in Chapter ‹800› when combined with the 2019 version of Chapter ‹797› but not the current 2008 version of ‹797›. Any facility employing a C-SCA can only be certified to the new standards.

There are a few other areas of confusion brought on by these appeals, so we will need to work together to establish the best path forward to ensure compliance of your compounding facility.