

Thank you for your patience as our Market Access and clinical team members reviewed the proposed USP <795> and <797> updates. Please see below for summaries of both. Avalere found that the updates may impact community practices in the following ways: Personnel, Process, Waste, or Financial Burdens:

1. Personnel: Number of staff and additional training required to complete an added task.
2. Process: A revision requiring a change in standard operating procedure (SOP), more paperwork/documentation, and additional training for staff to carry out the SOP.
3. Waste: When a product intended for use is wasted. For example, in USP <795>, once removed from the original container, any component not used in compounding should be discarded and not returned to the original container.
4. Financial Burden: personnel burden, process burden, and increased waste of resources all cause an increase in financial burden (supplies, expenses, staffing).

The changes noted below are simply meant to address the criteria of potential administrative/financial burdens and do not necessarily denote areas where COA should or may disagree with the specific updates. Comment period closes on January 31, 2022.

Thank you,
Blair

<795> Pharmaceutical Compounding – Nonsterile Preparations

Overall, the proposed <795> is a more thorough and comprehensive document than the previous version. The expansion of “summary” statements and the tables related to BUD (Beyond Use Date) provide additional clarity and detail for the reader.

- **How the revisions may increase personnel, process, or financial burdens for community practices**
 - Temperature Monitoring. Temperatures in the storage area(s) must be monitored manually at least once daily on days that the facility is open, or continuously with a temperature recording device. The readings must be documented on a log or stored in the continuous temperature recording device and must be retrievable. All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months.
 - Cleaning and Sanitizing. The minimum frequencies of cleaning and sanitizing surfaces and equipment in the nonsterile compounding areas, are proposed as follows:
 - Work surfaces: beginning and end of each shift, after spills, following known or suspected surface contamination, between compounding CNSPs (compounded nonsterile preparation) with different components
 - Floors: daily, after spills, following known or suspected surface contamination
 - Walls and Storage shelving: every 3 months, after spills, following known or suspected surface contamination
 - Ceilings: when visibly soiled, following known or suspected surface contamination
 - CVE (containment ventilated enclosure): beginning and end of each shift, after spills, following known or suspected surface contamination; clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components
 - BSC (biological safety cabinet): beginning and end of each shift, after spills, following known or suspected surface contamination; clean and sanitize the horizontal work surface of the CVE between compounding CNSPs with different components; clean and sanitize under the work surface at least monthly

- Other devices and equipment used in compounding operations: before first use and thereafter in accordance with manufacturer's recommendations.
 - Containment device. Weighing, measuring, or other manipulation of an API or added substance in powder form that can generate airborne contamination from drug particles must be assessed to determine if these activities must be performed in a containment device (i.e., powder containment hood). The process evaluation must be documented. If a BSC or CVE is used, it must be certified at least every 12 months.
 - Component spill and disposal. Facility must maintain chemical hazard and disposal information (e.g., SDSs) and must document the review and update of its chemical hazard and disposal information at least every 12 months.
- **How the revisions may create waste for community practices**
 - Once removed from the original container, any component not used in compounding should be discarded and not returned to the original container.

<797> Pharmaceutical Compounding – Sterile Preparations

The most significant proposed revision to USP <797> is the inclusion of Category 3 compounded sterile preparations (CSPs), which included sterile preparation that can have longer beyond-use-dates (BUDs) to a maximum of 180 days, in addition to the Category 1 and 2 CSPs that were in the previously proposed revision to Chapter 797 in 2019. The addition of the third category involves a more detailed direction on how compounding pharmacies must operate.

- **How the revisions may increase personnel, process, or financial burdens for community practices:**
 - Beyond-Use-Dates
 - Category 3 sterile preparations (injections or ophthalmic solutions) must pass the appropriate particulate matter test once for each formulation.
 - Injections: must pass testing according to USP 788, Particulate Matter in Injections.
 - Ophthalmic solutions: needs to pass testing according to USP 789, Particulate Matter in Ophthalmic Solutions.
 - Additionally, the container closure systems used for injections and ophthalmic solutions must pass testing according to USP 1207, Package Integrity Evaluation — Sterile Products, for each formulation.
 - Endotoxin Testing
 - Category 3 sterile injectable preparations compounded from one or more nonsterile components must be tested for endotoxin content in accordance with USP 85.
 - Garbing Practices
 - A compounder and others who enter the classified area where Category 3 sterile preparations are compounded must meet additional garbing requirements:
 - Compounders are not allowed any exposed skin in the buffer room (e.g., face and neck must be covered).
 - All low-lint garb must be sterile.
 - Once a compounder leaves a classified area, disposable garbing items must be discarded, and laundered garb must not be reused without being laundered and re-sterilized with a validated cycle.
 - Environmental Monitoring and Surface Sampling

- Category 3:
 - Required to perform media fills with glove fingertip sampling and surface sampling of the direct compounding area at least every three months.
 - More frequent monitoring requirements.
 - Viable air sampling using an impaction device must be completed for each classified area monthly.
 - Surface sampling is required weekly and with each batch of sterile preparation.
- Cleaning and Sanitizing
 - Compounding of preparations in category 3 must apply a sporicidal agent to the primary engineering control (PEC), the equipment in the PEC, work surfaces outside the PEC, equipment outside the PEC, pass-throughs and floors at least weekly.
 - The process for cleaning the PEC has received more detailed directions. Compounders must:
 - Remove visible particles or residue from the equipment and interior surfaces of the PEC with an appropriate solution using sterile, low-lint wipes.
 - Apply a sterile cleaning agent followed by a sterile disinfecting agent (or an appropriate one-step disinfectant cleaner as described above) to equipment and interior surfaces of the PEC using sterile, low-lint wipes.
 - Ensure the cleaning and disinfecting agents are in contact with surfaces for the time specified by the manufacturer.
 - Apply sterile 70% isopropyl alcohol to equipment and all interior surfaces in the PEC using sterile, low-lint wipes.
 - Allow the surfaces and equipment to dry before beginning compounding processes.
- **How revisions may decrease Personnel, Process, and Financial burdens for community practices:**
 - Environmental Monitoring and Surface Sampling
 - For Category 1 and 2, viable air sampling using an impaction device must be completed for each classified area every six months. (2019 revision had monthly viable air sampling).

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