American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

November 30, 2018

United States Pharmacopeial (USP) Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: USP Proposed General Chapter <797> Pharmaceutical Compounding – Sterile Preparations and USP <800> Hazardous Drugs Effective Date

To Whom It May Concern:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the United States Pharmacopeial (USP) Convention's currently established effective dates for both general chapter <797> - *Pharmaceutical Compounding – Sterile Preparations* and general chapter <800> *Hazardous Drugs – Handling in Healthcare Setting*, as well as the proposed revisions to general chapter <797>. General chapters <797> and <800> currently have an implementation date of Dec. 1, 2019.

Protecting health care personnel from harm resulting from occupational exposure to environmental hazards is a top priority for hospitals and health systems. USP guidelines play a critical role in keeping our hospital staffs and the patients they care for safe. However, we reiterate concerns we have previously shared regarding the compliance challenges that these two sections create. In our comments on the proposed creation of general chapter <800>, we cited significant issues with the cost of compliance that hospitals and health systems would likely face. Since general chapter <800> was finalized, our impacted members have continued to work toward compliance in advance of the Dec. 1, 2019 effective date; however, two specific issues have made achieving this goal incredibly difficult, which is why **we urge USP to delay the effective dates of general chapters <797> and <800> by at least 18 months.**

First, the effective date of general chapter <800> is tied to the effective date of the proposed revisions to general chapter <797>, meaning that the final adopted version of

general chapter <797> may impact or modify the efforts that are being taken by hospitals and health systems to comply with chapter <800>. General chapter <797> is slated for final publication on June 1, 2019, with only a six month implementation period. This is, quite simply, not enough time. Second, the burden on hospitals and health systems to comply is high – both related to the cost and timeframe required to achieve compliance. The creation of general chapter <800>, coupled with any additional changes that are adopted in general chapter <797> have already required and will continue to require many hospitals and health systems to undertake very substantial changes to their facilities. The changes involve large capital investments, and, in some cases, the construction of entirely new buildings.

Further, because these changes affect national standards, every hospital and health system involved in the compounding of hazardous drugs or sterile compounding will need to evaluate their respective needs and make all necessary compliance-related changes at exactly the same time. Ultimately, this timeline has resulted in a high demand for contractors and supplies, making it very challenging for all facilities to come into compliance by the effective date. In addition, the financial burden hospitals face to comply with these changes cannot be overlooked. Current trade tariffs coupled with a truncated timeline and high demand for construction services and equipment not only make these changes financially burdensome, but also difficult to budget and plan for in a fiscally responsible way.

For the reasons above, we urge USP to delay the effective dates of general chapters <797> and <800> by at least 18 months. This delay would establish a new effective date of June 1, 2021, at the earliest, allowing our members to better prepare, plan, and budget for all required changes and upgrades. Alternatively, if USP is unwilling or unable to extend the current effective date, we respectfully request that it adopt a grace period for compliance. Such an option would allow hospitals and health systems to submit a plan for achieving compliance within a reasonable time beyond the Dec. 1, 2019 effective date. This option would provide affected hospitals and health systems the necessary time to comply, while also holding those facilities accountable should they fail to meet the timeline and goals set forth in their plan.

In addition to our concerns regarding the Dec. 1, 2019 effective date for general chapters <797> and <800>, we appreciate the opportunity to comment on proposed revisions to general chapter <797>. Overall, the AHA commends USP for simplifying many of the provisions of this chapter, while not sacrificing any of the critical safety provisions it contains. The September 2018 redraft of general chapter <797> is a vast improvement from previous versions; however, we do have some specific concerns regarding beyond-use dates, repackaging and temperature metrics.

Our detailed comments corresponding to specific line numbers within the proposed revisions to general chapter <797> follow.

- Lines 6 and 84-88: Repackaging is not part of sterile compounding and should be removed from this chapter. Repackaging does not hold the same risks as combining, admixing, diluting, pooling or reconstituting. While there are some risks in repackaging, they do not rise to the level of inclusion under sterile compounding. Therefore, the AHA continues to strongly recommend the removal of repackaging language from Chapter <797>.

- Lines 24-28: The AHA recommends removal of the proposed one-hour exclusion for the preparation of non-hazardous Compounded Sterile Preparations (CSPs). Without a specific rationale, including scientific evidence, for this timeframe, the AHA cannot support this proposed language.

- Lines 158-162: The AHA believes that requiring requalification every 12 months is unnecessary and may be overly burdensome. Currently, standard laboratory practices require all personnel to be evaluated regularly. Therefore, unless USP is able to provide a rationale for this requirement, we ask that it be removed from this section.

- Lines 332-333: With regard to hand hygiene under personal hygiene and garbing, this proposed revision states, "[b]rushes must not be used for hand hygiene because of the potential for skin irritation and increased bacterial shedding." We urge USP to remove this provision, as the Food and Drug Administration (FDA) has approved the use of brushes, and the mere possibility that a brush could cause a skin irritation is not enough reason to exclude the allowance of its use from this proposal.

- Lines 1224-1382 and 1609: In both the Sterilization and Depyrogenation and Establishing Beyond-Use Dates, USP seemingly provides the recommended and required temperatures in Celsius only. We ask USP to either specify the scale that is being used or list temperatures in both Celsius and Fahrenheit.

- Lines 1706 – 1719: We urge USP to withdraw this section, as this section specifically applies to conventional manufacturing, not drug compounding.

Please contact me if you have questions or feel free to have a member of your team contact Mark Howell, senior associate director, policy, at mhowell@aha.org or (202)-626-2274.

Sincerely,

/s/

Ashely B. Thompson
Senior Vice President
Public Policy Analysis and Development.