APhA
American Pharmacists Association

March 17, 2022

Brenda Jensen, Chair
Compounding (CMP) Expert Committee Roster
12601 Twinbrook Parkway
Rockville, Maryland 20852

[Submitted electronically to: CompoundingSL@usp.org]

Dear Chair Jensen:

The American Pharmacists Association (APhA) is pleased to submit comments on Proposed Revisions to <795> Pharmaceutical Compounding – Nonsterile Preparations.

APhA is the only organization advancing the entire pharmacy profession. Our expert staff, and strong volunteer leadership, including many experienced pharmacists, allow us to deliver vital leadership to help pharmacists, pharmaceutical scientists, student pharmacists and pharmacy technicians find success and satisfaction in their work, while advocating for changes that benefit them, their patients and their communities.

APhA appreciates USP's significant public outreach to open a dialogue with pharmacists, other health care professionals, and regulators to discuss the proposed revisions and respond to stakeholder concerns. We agree the safety and efficacy of all prescription drugs, whether commercially manufactured, prepared or compounded, is paramount to the protection of public health. The standards set forth in the proposed revision to Chapter <795> on nonsterile compounding are of great interest to APhA and our members and we offer the following recommendations developed with input from our members, including feedback from our APhA Academy of Pharmacy Practice and Management (APhA-APPM) Compounding Pharmacy Special Interest Group (SIG), consisting of over 5,000 members, and Nuclear Pharmacy Practice SIG, consisting of over 2,200 members.

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Recognize State Board of Pharmacy policies on flavoring of conventionally manufactured commercially available medications and exemption to <795>

APhA recognizes that the Compounding EC clarified in updated FAQs that adding flavorings to formulations is considered compounding. The CMP EC recommends that compounders assign default BUDs to such preparations unless they have stability data that supports longer BUDs.

Pharmacies continue to be challenged by USP's interpretation that "flavoring is compounding," and thus subject to all the requirements in <795>. APhA has previously requested that USP clarify that custom flavoring of conventionally manufactured liquid medications does not constitute nonsterile compounding. The burden of complying with <795> for one basic service would be prohibitive for any pharmacy that does not otherwise engage in compounding. Accordingly, APhA recommends USP clarify that pharmacies that add flavoring must use the default BUD on the bottle and are not subject to all provisions of <795>.

Twenty-five state boards of pharmacy have adopted specific language that permits pharmacists to improve the taste of commercially available medicines with small quantities of flavoring to promote effective medication use by patients. Additionally, the National Association of Board of Pharmacy (NABP), in its Model Pharmacy Act/Rules, excludes flavorings from its definition of compounding.

Pharmacists today routinely flavor oral liquid medicines for tens of millions of patients, most of whom are children, to successfully improve palatability and compliance, with beneficial results.. APhA is concerned that subjecting pharmacies to all of the provisions of <795> could have the unintended consequence of causing harm to the millions of children who rely on flavoring to get the benefit of their medicines. Accordingly, APhA recommends clarifying this exemption from the provisions of <795> that recognizes State Boards of Pharmacy language providing for the simple flavoring of conventionally manufactured commercially available medications.

1.1.2 Practices not subject to the requirements in this chapter

APhA is strongly supportive of the following statement in the revised chapter to avoid confusion regarding the applicability of <795> to radiopharmaceuticals.

"*Nonsterile radiopharmaceuticals*: Compounding of nonsterile radiopharmaceuticals is not required to meet the standards in this chapter and is subject to the requirements in *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging* ⟨825⟩."

APhA has been a strong advocate for clear and effective USP public standards for radiopharmaceuticals that meet patient and practitioner needs for today and in the future and supports USP <825> which clearly delineates the differences between the activities performed by nuclear pharmacists.

10.5 Extending BUDs for CNSPs

APhA recognizes the intention behind this language and agrees compounders should perform antimicrobial testing before assigning beyond use limits (BUDs) that exceed the USP maximum limits, especially for new formulations without significant historical use or experience.

However, the revision of this language from "should" to "must" creates limitations for formulations that have decades of experience without issue and utilize other quality control measures such as physical inspection and pH testing. Significant cost burden without added value would exist for pediatric health systems and other compounding pharmacies that dispense a wide variety of products to achieve compliance with this language change. It would create barriers to patient access and increase complexity of pharmacy operations that seem to far outweigh the benefit for most, if not all, formulations currently in use at these pharmacies. Accordingly, APhA recommends a revision of "must" to "should" as it relates to antimicrobial testing in section 10.5 of USP <795>.

"If the BUD of the CNSP is extended beyond the BUDs in *Table 4*, an aqueous CNSP ~~must~~ should be tested for antimicrobial effectiveness…"

APhA's members are also concerned that under USP's proposed revision to <795> that no non-sterile compound can be assigned a BUD of >180 days, even if stability study data demonstrates stability beyond 180 days. For example, to provide an aqueous non-sterile compound such as metronidazole oral liquid with a BUD of >35 days, or a nonaqueous oral liquid such as calcitriol oral oil with a BUD of >90 days, compounders will be required to perform costly tests (roughly $30,000 per active ingredient), meaning the price of these medications will drastically increase.

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If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org. We look forward to continuing to work with you on USP Chapter <795> and other USP standards.

Sincerely,

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Senior Vice President, Pharmacy Practice and Government Affairs

cc: Brian Serumaga, PhD. Senior Manager, Personalized Medicines–Healthcare Quality Standards

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