COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

1225 New York Ave. NW, Suite 600
Washington, DC 20005
(202) 756-2258 | communityoncology.org

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Submitted electronically to: CompoundingSL@usp.org

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer
U.S. Pharmacopeial Convention
12601 Twinbrook Parkway
Rockville, MD 20852-1790

Re: Comments to Proposed Revisions to USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations

Dear Dr. Piervincenzi,

On behalf of the Board of Directors of the Community Oncology Alliance (COA), we thank you for the opportunity to submit this comment letter in response to Proposed Revisions to USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.

The Community Oncology Alliance (COA) is a non-profit organization dedicated to advocating for community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to independent community oncology where most Americans with cancer are treated. The mission of COA is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities. For more than 15 years, COA has built a national grassroots network of community oncology practices to advocate for public policies that benefit cancer patients. Individuals from all perspectives of the cancer care delivery team – oncologists, administrators, pharmacists, physician extenders, oncology nurses, patients, and survivors – volunteer their time on a regular basis to lead COA and serve on its committees.

USP is updating General Chapter <797> Pharmaceutical Compounding – Sterile Preparations and aligning it with Chapter <800> Hazardous Drugs – Handling in Healthcare Settings for a December 2019 implementation. As the providers of care for the majority of Americans battling cancer, community oncologists are highly aware of the importance of standards for all health care workers to help ensure the safe handling of sterile and hazardous drugs throughout the health care system. COA believes that procedures for safe handling can protect both the medical staff and the patients they treat from potential harm.

Chapter <797> describes the minimum standards to be followed when preparing compounded sterile preparations (CSPs) for infusion or injection, which are very common in the practice of oncology. The proposed changes under consideration mean that oncology practices would be held accountable for compliance with new requirements related to personnel, training, facilities, monitoring, as well as storing and testing of finished preparations. **While COA is very committed to the safety of both patients and health**

care workers, we are concerned that these changes would place burdensome demands on both the space and the finances of physicians' practices.

We are pleased to see that the revised definition of the scope of Chapter <797> focuses only on sterile compounding activities and explicitly excludes preparing a conventionally manufactured sterile product by withdrawing a dose for immediate administration to an individual patient. This clarification would ensure that drug administration activities that are within the scope of medical practice and do not represent compounding are not subjected to these requirements.

One of the most important changes in Chapter <797> is the simplified risk levels associated with compounded sterile preparations – moving away from three risk levels (low, medium, and high) to two - Category 1 CSPs and Category 2 CSPs. This simplified categorization brings more stringent requirements for larger facilities in which these preparations are compounded using current beyond-use date (BUD) standards. COA is very concerned that this change may place serious financial and operational burdens on smaller community oncology practices. Oncologists would be required to modify workflow patterns, incur additional drug waste expense, and abandon efficiencies, likely requiring additional personnel. Considering the cost to the health care system that the additional oncology medication waste alone would sustain, we would like to suggest the beyond-use date standard be extended in Category 1 to those currently published, at a minimum those published by the manufacturer themselves.

In addition to the proposed Chapter <797> reforms, community oncologists continue to implement changes to comply with Chapter <800> requirements for handling hazardous drugs. Most small and rural practices lack the physical space to comply with the proposed guidelines.–Community oncology practices that are compounding or mixing chemotherapy must now undertake a series of requirements, including a separate storage location for drugs deemed hazardous, a separate compounding area, HVAC and facility changes, and the addition of dedicated personnel. The changes required to remain compliant with Chapters <797> and <800> represent significant and prohibitive financial and administrative burdens on oncology practices and clinics, especially smaller satellite clinics, or those in a rural setting. In many cases a community oncology practice will not have the physical space or the buildout option, if the facility is a non-owned space, to make the required physical plant changes. As Chapter <797> has recognized the unique setting of community oncology offices and granted exceptions we would ask USP to consider a "grandfather" clause for existing practices as an exemption. If this is not feasible, would USP at a minimum, grant a reasonable time period to meet the facility building changes or time for community practices to retain new treatment space that would satisfy USP <800> compliance. If forced to close, patients seen at these smaller clinics for chemotherapy would be required to travel out of their own communities to be cared for. As COA is a representative of community oncology, we see these standards as an unnecessary burden for patients and would request that this be discussed at future revisions of USP <800>.

In addition to the needed investment in new space and equipment, the two chapters envision ongoing staff training, environmental monitoring, and cleaning standards that add substantial time commitments and expense. We are pleased to see that USP responded to stakeholder feedback and moved away from its plan to require quarterly personnel qualifications, replacing it with biannual qualifications in the latest Chapter <797> version. We would request that this requirement be moved to an annual qualification. Additionally, USP plans to move away from surface sampling on "periodic basis" to monthly testing. COA understands the importance of maintaining clean and contaminant-free compounding areas, something that community oncology practices take very seriously, but we are extremely concerned about requiring monthly surface contamination

inspections, which can cost between $2000 to $3000 for a single surface test. We would request a return to "periodic testing" until it is no longer cost-prohibitive.

Last, but not least, USP Chapter <797> envisions increased documentation requirements for batch compounding, as well as other formulation and compounding records. USP Chapter <800> also refers to batch compounding and the need to clean between each medication. Chemotherapy is compounded on a patient by patient basis and treatments for one patient can consist of multiple medications. We would recommend that this be reviewed considering oncology clinic workflow to eliminate unnecessary administrative demands that do not apply and serve no purpose in the community oncology setting.

We appreciate the opportunity to provide insight and comments and, as always, welcome the opportunity to discuss any of our comments further.

Sincerely,

Jeff Vacirca, MD, FACP
President