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Dear Mr. Piervincenzi and Ms. Davidson:

The undersigned physician organizations thank the United States Pharmacopeia (USP) for its tireless efforts revising and updating the USP chapters on drug compounding. We appreciate the work of both USP staff and the members of the Expert Committee on Compounding, especially given the significant number of comments received on the proposed revisions to items such as Chapter 797. However, the physician community continues to have concerns about the potential impact of a revised Chapter 797 on physician practices and patient access to critical sterile drug products.

As a routine part of medical practice, physicians across a number of specialties frequently prepare sterile drug products in their offices for administration to patients. Preparation of sterile drug products for patients can include activities such as drawing up a steroid joint injection or botulinum toxin injection with a local anesthetic, preparing allergy/immunotherapy injections for individual patients, buffering lidocaine, and a number of others. In the majority of cases, these activities are routine practices that physicians have been engaging in for years safely. In many cases, they represent the standard of care for a particular condition. Physicians across specialties have a long history of preparing sterile drug products that provide safe and effective treatments to patients. There is no compelling body of evidence showing these activities, when performed in physician offices, pose any increased risk to patients of infection or other adverse events. In contrast, the lack of timely access to such treatment to meet specific patient need would have predictable and a clear negative impact on patient health status and outcomes.

The preparation of sterile drug products at the point of care for administration to patients is **not** a drug compounding activity. It is, however, activity that falls well within the scope of medical practice. To limit a physician's ability to exercise his/her independent medical judgement in offering the appropriate course of treatment to his/her patients interferes with the practice of medicine. Further, physicians are already struggling under the weight of significant regulatory burdens from new quality reporting programs, electronic health record requirements, and others. If additional burdensome regulatory requirements that would require both significant capital expenditures and construction projects are levied on physician practices, we anticipate that patients will lose access, have inferior outcomes, and costs will increase—in short, the opposite of the triple aim.

Our organizations share USP's goals of ensuring drug products administered to patients are sterile and that they are safe. While the safety of our patients is undoubtedly the foremost concern of our member physicians, no amount of safety precaution can ever fully negate the risk

of infection to a patient in a given setting. However, should physician practices be subject to the overly-burdensome requirements initially proposed by the Food and Drug Administration and USP, we are confident that risks to the health of our patients will increase significantly, as treatments are delayed, require follow-up visits, become more expensive, or are made unavailable altogether.

We remain committed to working with USP to ensure that the Chapter 797 revisions are completed without any unintended negative consequences to the patient community. We are encouraged by recent Expert Committee discussions on this topic, however, we strongly encourage USP and the Expert Committee on Compounding to continue to fully engage the physician community in an open and transparent manner on this issue. Given the current lack of physician representation on the Expert Committee, it is critical that USP and the Expert Committee regularly solicit input from the physician community regarding the potential impacts of the Committee's work on medical practice. We also respectfully request the opportunity to provide input or comment during the work of the Expert Committee on any definitional issues that may impact Chapter 797's applicability to physician offices.

Again, thank you for your efforts to ensure the safety of the nation's compounded drug supply. We look forward to continuing to work with USP and the Expert Committee as we move towards finalization of the revised chapters on compounding. Please do not hesitate to reach out to any of our organizations at any time.

Sincerely,