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November 30, 2018

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Gigi Davidson, R. Ph., DICVP
Chair of the Compounding Expert Committee
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790

[Submitted online at: <http://www.usp.org/compounding/general-chapter-797>]

Re: Proposed USP Chapter 797

Dear Dr. Davidson and Compounding Expert Committee Members:

On behalf of the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), I would like to thank you for the opportunity to comment on the United States Pharmacopeia (USP) revised draft Chapter 797 guidelines for sterile compounding. The AAO-HNS is the largest organization in the United States representing specialists who treat the ear, nose, throat, and related structures of the head and neck. Our first and foremost concern has been, and continues to be, providing safe, effective, quality care to patients treated by our specialty. As such, we are pleased to see changes in the most recent draft Chapter 797 that would help physicians maintain safe access to critical in-office treatments.

Allergy Immunotherapy Exception

The management of allergic disorders is an integral part of the specialty of otolaryngology-head and neck surgery. Such treatment is dependent upon the continued ability to compound individual treatment sets of allergen extracts for our patients in the office setting. Our specialty has used evidence-based standard protocols for all stages of allergy immunotherapy diagnosis and treatment for decades which have produced optimal clinical results while maintaining patient safety. Physicians have been preparing allergenic extracts in their offices for more than 100 years under general aseptic conditions, but outside of an ISO Classified environment, with no evidence of sterility problems or patient harm.

We thank the USP for its engagement with the AAO-HNS, the *American Academy of Otolaryngic Allergy (AAOA)*, and other impacted allergy specialties in the House of Medicine over the past three years. As a result of this collaboration, we applaud the USP Expert Compounding Committee's decision to reestablish an exception for allergen extracts mixed with aseptic technique, but without the environmental and other controls required for more dangerous compounding drugs.

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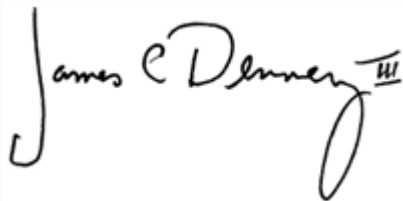
Specifically, **the AAO-HNS commends the Committee's decision to restore the partial exemption from the personnel, environmental, and storage requirements for allergen extract preparation.** We find acceptable the requirements relating to personnel training and evaluation, hygiene and garbing, and updated documentation, plus either installation of an ISO Class 5, Primary Engineering Control (PEC), OR a Dedicated Allergenic Extracts Compounding Area (AECA). We strongly urge these draft policies be finalized.

Administration Time Frame

While the proposed one-hour time frame included in the draft Chapter's definition of administration is reasonable for most otolaryngology in-office compounding, it may prove to be unnecessarily burdensome in certain clinical situations. Providing a blanket timeframe for all in-office compounding could have unintended consequences on patient access. For example, for procedures requiring buffered lidocaine as a local anesthetic, clinicians may be unable to reasonably work within the one-hour time frame, as lidocaine is buffered by physicians and/or their staff in advance of that day's patients. **The AAO-HNS urges USP and the Expert Committee to consider extending the time frame for administration under the Chapter, or to consider other alternatives or exemptions to the Chapter requirements,** to ensure physicians and their patients have continued access to required therapies routinely provided in office.

Thank you for your consideration of these comments. The AAO-HNS looks forward to continued collaboration with the USP, the Food & Drug Administration, state regulatory agencies, and other stakeholders, to guarantee the safety and availability of compounded medications to patients in the office setting. We remain committed to working with USP and its experts to ensure the Chapter 797 revisions are completed without any unintended negative consequences for our members and the patients they serve. If you have any questions regarding our comments, please contact the AAO-HNS Advocacy team at healthpolicy@entnet.org.

Sincerely,



James C. Denny III, MD
Executive Vice President and CEO