The long-awaited new USP Chapter 797 standards on sterile compounding were released June 1 and take effect Dec. 1.

We are pleased to report that thanks to the vigorous collective advocacy of the allergy community, the final standards mirror the proposed standards released last July. We supported those standards in our comments to USP, and we believe they are reasonable and achievable. A summary of the standards is below, but we encourage you to download the complete version.

Final standards for allergen extract compounding under USP Chapter 797

Under the new standards, to continue in-office compounding of individual treatment sets for allergen immunotherapy, allergy practices will, beginning Dec. 1, need to comply with the following:

1. Personnel Qualifications

- Designate one person to oversee and evaluate compounding personnel.
- Provide training and testing on principles and procedures for new staff and annual evaluation for others for sterile compounding, garbing, hygiene, gloved fingertip and thumb sampling and media fill tests.
- Ensure that compounding personnel wear powder-free sterile gloves; non-cotton, low-lint sleeved garments that gather at the wrist and close at the neck; face mask and disposable cover for head and facial hair.

2. Facilities

- Compounding must occur in either (1) an ISO Class 5 Primary Engineering Control (PEC) **OR (2)** in a dedicated Allergenic Extracts Compounding Area (AECA), either of which must not be within one meter from a sink and can't be near unsealed windows, doors to the outside, or high traffic or other areas that present environmental control challenges such as bathrooms or kitchens.
- If used, a PEC must be certified every 6 months, and cleaned and disinfected before and after each compounding, and surface must be disinfected between each prescription set.
- An AECA must have a visible perimeter and meet the following conditions:
    - Access restricted to authorized personnel.
    - No other activity permitted during compounding.
    - All surfaces must be cleanable and kept clean.
    - No carpet is allowed.
    - No surfaces that can be damaged by cleaning and sanitizing agents.
    - Surfaces must be smooth, impervious, non-shedding, and free of cracks or crevices.
    - Overhangs should be avoided or must be easily cleaned.
    - Well lit, and temperature and humidity controlled for comfort of compounding personnel.
    - Work surface must be cleaned and disinfected before and after each compounding session, and disinfected between each new set, as well as at the time of any spill or contamination.
- Vial stoppers on packages of conventionally manufactured sterile ingredients must be disinfected with 70% IPA wipes before each use.
- Walls, doors, and door frames within and AECA must be disinfected monthly and when contamination is suspected.

- Ceilings in the AECA must be cleaned and disinfected when visibly soiled.

3. Documentation

- Labels on prescription sets must include patient name, type and fractional dilution with corresponding vial number, beyond use date, and required storage conditions.
- Standard Operating Procedures manuals describing required compounding process.
- Training, assessment results, evaluations, and qualification records for all compounding personnel, including any corrective actions following assessments and evaluations.
- Certification reports for PEC, if used.
- Temperature logs for refrigeration.
- Compounding records for individual extract prescription sets.
- Information on any complaints and adverse events.
- Investigations and corrective actions following any complaints and adverse events.

The American College of Allergy, Asthma & Immunology, American Academy of Otolaryngic Allergy and American Academy of Allergy, Asthma & Immunology are pleased that our work with the USP Expert Compounding Committee has resulted in standards that allow for the continued compounding of allergen extract prescription sets for individual patients. We wish to acknowledge Dr. Andrew Murphy, MD FAAAAI, who served as a physician consultant to the USP Expert Compounding Committee, for advocating for continued in-office compounding of allergen extracts to protect patient access to care.

While the lack of any reported cases of an infectious adverse event makes these seem unnecessary, the specialty is willing to acknowledge the USP Expert Compounding Committee's extensive work to create meaningful patient safety standards, and we therefore accept these additional requirements, to reflect our shared dedication to patient safety.

We look forward to ongoing engagement with the USP in policy and standards development and additional issues relevant to ensuring patient safety while protecting access to care and improving patient outcomes.

Stay tuned for information from each organization about upcoming training on how to fully comply with either facility option and other new requirements.