The following information is excerpted from the final USP (797) Chapter on Pharmaceutical Compounding-Sterile Preparations that take effect November 1, 2023. These are the minimum standards for allergy practice; individual states may enact more stringent requirements.

In-Office Allergen Extract Compounding

Documentation for Compounding Allergenic Extract Prescription Sets

All facilities where allergenic extract prescription sets are prepared must have and maintain written or electronic documentation to include (but not limited to) the following:

- Standard operating procedures (SOPs) describing all aspects of the compounding process
- Personnel training records, competency assessments, and qualification records including corrective actions for any failures
- Certification reports of the primary engineering control (PEC) if used, including corrective actions for any failures
- Temperature logs for refrigerator(s)
- Compounding records (CRs) for individual allergenic extract prescription sets (see box)
- Information related to complaints and adverse events including corrective actions taken
- Investigations and corrective actions

If you have questions, contact practicemanagement@aaaai.org

Compounding Records

CRs must include at least the following information:

- Name, strength or activity, and dosage form of the compounded sterile product (CSP)
- Date and time of preparation of the CSP
- Assigned internal identification number (e.g., prescription, order or lot number)
- A method to identify the individuals involved in the compounding process and individuals verifying the final CSP
- Name of each component
- Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s)
- Weight or volume of each component
- Strength or activity of each component
- Total quantity compounded
- Final yield (e.g., quantity, containers, number of units)
- Assigned beyond use date (BUD) and storage conditions
- Results of quality control procedures (e.g., visual inspection, filter integrity testing, pH testing)

If applicable, CR must also include:

- Manufacturer reference for the CSP
- Calculations made to determine and verify quantities and/or concentrations of components

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