Allergy Vial Preparations and USP 797

Donald W Aaronson MD JD MPH
Compounded Sterile Preparations (CSP) = USP 797 – History

• Compliance with USP 797 has always been in the law – with respect to physicians offices
• Because of problems with other parts of the law the USP 797 requirement was unenforceable
• Congress (in new Compounding Law) removed old law that made the section unenforceable
• Therefore current law now requires USP 797 be enforced
• Advice from our consultants – do not weaken the sterility provisions – this is Congress primary concern
USP 797 Provisions

- Allergen extracts as CSP’s are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by physicians and personnel under their **direct supervision**
- Allergen extracts as CSP’s are not subject to the personnel, environmental, and storage requirements for all (other products outlined in this chapter) **ONLY** when all of the following criteria are met:
The compounding process involves simple transfer, via sterile needles and syringes, of sterile allergen products and appropriate sterile added substances (e.g. glycerin, phenol in NaCl solution).

All allergen extracts as CSP’s shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in this chapter.
USP 797 Provisions (cont)

• Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under the fingernails, using a nail cleaner under warm water, followed by vigorous hand and arm washing to the elbows for at least 30 seconds, with either nonantimicrobial or antimicrobial soap and water
USP 797 Provisions (cont)

• Compounding personnel don hair covers, facial hair covers, gowns and face masks
• Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity
• Compounding personnel don powder-free gloves that are compatible with 70% isopropyl alcohol (IPA) before beginning compounding manipulations
USP 797 Provisions (cont)

- Compounding personnel disinfect their gloves intermittently with 70% IPA when preparing multiple allergen extracts as CSP’s.
- Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSP’s.
USP 797 Provisions (cont)

• The aseptic compounding manipulations minimize direct contamination (e.g. from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g. needles, opened ampuls, vial stoppers)

• Single-dose allergen extracts as CSP’s shall not be stored for subsequent additional use
USP 797 Provisions (cont)

• The label of each multiple dose vial (MDV) of allergen extracts as CSP’s lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers’ recommendations or peer-reviewed publications.

• Skin Test materials do not need to be for one patient – verbal communication from FDA
This checklist is not intended to take the place of an E/M visit. It is designed to demonstrate everything considered when a decision is made to continue allergen immunotherapy. There is space for comments which will be needed if changes in the vial are to be made. Actual changes in schedule should be reflected in the new vial order and not on this checklist.

Use of this checklist does not replace the requirement to evaluate the patient in person.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Current Medication Use</strong></td>
<td><strong>2. Response to Immunotherapy</strong></td>
</tr>
<tr>
<td>□ Patient is receiving appropriate medication for optimal control.</td>
<td>□ Symptoms improved</td>
</tr>
<tr>
<td></td>
<td>□ Symptoms unchanged</td>
</tr>
<tr>
<td></td>
<td>□ Symptoms poorly controlled</td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3. Reactions to Injections</strong></td>
<td><strong>4. Antigen Content of Vials</strong></td>
</tr>
<tr>
<td>□ Local reactions</td>
<td>□ Antigen formula is appropriate for current medical status</td>
</tr>
<tr>
<td>□ Systemic reactions</td>
<td>□ Antigen content is present at optimal concentration</td>
</tr>
<tr>
<td></td>
<td>□ Antigen content of vials needs to be adjusted</td>
</tr>
</tbody>
</table>
# Checklist for Renewal of CPT 95165

5. If no evidence of benefit, injections are:
   - [ ] Continued
   - [ ] Discontinued
   - [ ] Patient needs allergy re-evaluation

6. If immunotherapy >5 years, document justification for continuation

7. All of the above have been considered in making the decisions to continue immunotherapy.

Physician’s Signature: _______________________________________________________

Date: _____________________________________________________________________