Allergy Extract Preparation Guidelines

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NO CONFLICTS
Allergy Extract Preparation Guidelines

• 2006 – USP proposes amendments to Chapter 797
• Allergy/ENT notified and begin discussions with USP
• USP experienced consultant retained
• New Allergy extract preparation guidelines developed
• Guidelines approved by AAAAI, ACAAI, JCAAI, AAOA
• Guidelines published in Practice Parameters and are standard of care
Why Have Vial Extract Prep Guidelines

• Value Based purchasing of physician services coming

• Medicare database for 95010 and 95015 shows great variation in number of skin tests
  – This variation caused CMS to require us to re-establish work values for these codes

• Could be possible for other codes as well
  – We expect 95165 to be audited within the next 3-5 years
Allergy Extract Preparation Guidelines

• Extract Preparation Personnel Qualifications
  – Anyone who prepares vials must be trained – See Physician Instruction Guide – training materials online
  – Pass written quiz, every 5 years, on aseptic technique and extract preparation – quiz online [www.JCAAI.org](http://www.JCAAI.org)
  – Cannot fail test
  – Must pass media fill test annually – information available online
  – Failure on media fill test require re-training and re-testing

• NECC Scandal has changed the focus
  – New Compounding Law – Requires USP 797 Compliance
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:
USP 797 Provisions (cont)

• 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.
Allergy Extract Guidelines (cont)

• Trained physician responsible for training
• Responsible physician should review training materials with anyone in office who prepares vials – before they take quiz
• Recommend Keep Vial Prep Binder
  – Physician Instruction Guide
  – Record of all who are trained
  – Record of all who passed quiz and media fill test
  – Completed competency assessment form for each employee
Other Acceptable Training

• On the job training from qualified co-worker
• AAAAI or ACAAI workshops and seminars
• Manuals from allergen extract manufacturers
• Journal Articles
• Online courses (in process)
  – www.instanted.com click on Project Immune Readiness: password= paper
Allergy Immunotherapy-Physician Instruction Handbook

• Posted on line – [www.jcaai.org](http://www.jcaai.org)
• Practitioner Qualifications reviewed
• Allergen Extracts – types and sources
• Allergy Extract mixing conditions – as above
• Writing the prescription for extract
• Color coding, Labels and Expiration dates
Extract Instruction Handbook – cont

• Mixing individual patient allergy extract sets
  – How to do it in your shop
• Stinging Insect Allergen preparation
• Allergen extract stability
• Competency assessment checklist
• References
• You should instruct your staff personally
# Appendix 1: Initial and Ongoing Competency Assessment: Allergen Extract Mixing

<table>
<thead>
<tr>
<th>Allergen Extract Preparation</th>
<th>Date</th>
<th>Validated by</th>
<th>Comments or Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Passed a written test on aseptic technique and extract preparation.</td>
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<tr>
<td>Passed media-fill test or equivalent verifying aseptic technique</td>
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<tr>
<td>Reviews prescription(s) for accuracy</td>
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<tr>
<td>Accurately prepares labels and shipping material (if applicable)</td>
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## Appendix 1: Initial and Ongoing Competency Assessment: Allergen Extract Mixing (cont.)

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<tr>
<td>Checks expiration dating of antigens and diluents</td>
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<tr>
<td>Cleans mixing surface and washes and sanitizes hands as required by 797</td>
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<tr>
<td>Uses appropriate personal protective equipment</td>
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<tr>
<td>Checks stocks &amp; mixed extracts for turbidity/particulate matter</td>
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<tr>
<td>Swabs ampul necks and vial stoppers off with antiseptic (e.g.</td>
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<tr>
<td>alcohol swabs)</td>
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<tr>
<td>Draws up appropriate amounts</td>
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<tr>
<td>Disposes of syringes in an appropriate manner</td>
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<tr>
<td>Documents lot #’s and preparation details per clinic SOP</td>
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<td>Packages materials and supplies in a neat and efficient manner</td>
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I understand that of all the topics listed, I will be allowed to perform only those for my skill level/scope of practice and only after I have demonstrated competency.

Employee signature________________________________________________________

Date___________________
RECOMMENDATIONS FOR SAFE IT

• Annual CME/CUE in safe administration of IT
• Trained Qualified Vial/Extract Preparers
• Prepare vials in quiet environment
• All vials patient specific
• Standardized forms in IT parameter
• Triple identity checking
• Label vials as per Extract Preparation Guidelines

• Aaronson and Gandhi JACI 2006
RECOMMENDATIONS FOR SAFE IT (cont)

• Individual drawing up dose must be same one administering IT
• Do not draw up dose until patient in room
• Only one patient receiving IT allowed in room at time IT administered
• Advise all IT patient to wait 30 minutes after IT
• Office staff must report all incorrect injections immediately and all near misses as soon as possible
Requirements for Direct Supervision of Allergy Testing

• Medicare has rules for physician supervision of various in office procedures

• Allergy Skin testing – 2
  – Physician must be physically present in office suite and immediately available to furnish assistance
  – Physician work for Allergy skin test codes requires “test interpretation and report by physician”
New and Renewal Vials – What Should be Documented

• Review previous injection history
• Evaluate reactions, local and systemic
• Review chart and or patient, to determine response to injections – total and seasonal
• Physical findings
• Determine if extract needs revised composition or dosage schedule or concentration
• Review medications
• Determine if IT should be continued
• Do this at last injection of current vial
• JCAAI will develop checklist