



Compounding of In Office Vials

Physicians with training and expertise in allergen immunotherapy are qualified to safely compound allergy immunotherapy vials in their own office if specific criteria are met. The revised USP 797 guidelines <http://www.usp797.org/> must be followed. In addition, the AAOA/JCAAI Joint Task Forces Immunotherapy Guideline: <http://www.jcaai.org> recommendations should be taken into consideration. Ultimately, a formal mixing standard should be adopted and implemented for each office. This standard should focus on guidelines for aseptic technique and sterility, adequate training of compounding personnel, and appropriate physician supervision.

The compounding bill, passed by Congress in November 2013, enforces regulation of compounding pharmacies. Note that the preparation of allergenic extract vials is considered compounding. The statute contains two provisions that do impact allergy immunotherapy:

1. All compound sterile preparations have a prescription.
2. Physicians must comply with all of the USP 797 sterile compounding rules.¹

¹ Lin, SY et al. *Impact of newly revised sterile medication compounding guidelines USP <797> on allergy vial prep.* Otolaryngology–Head and Neck Surgery (2008): 139, 5-6.

Note: American Academy of Otolaryngic Allergy's (AAOA) Clinical Care Statements attempt to assist otolaryngic allergists by sharing summaries of recommended therapies and practices from current medical literature. They do not attempt to define a quality of care for legal malpractice proceedings. They should not be taken as recommending for or against a particular company's products. The Statements are not meant for patients to use in treating themselves or making decisions about their care. Advances constantly occur in medicine, and some advances will doubtless occur faster than these Statements can be updated. Otolaryngic allergists will want to keep abreast of the most recent medical literature in deciding the best course for treating their patients.