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.