

March 12, 2012

ALLERGEN THERAPY AND THE ESTABLISHMENT OF ALLERGY AND IMMUNOLOGY SERVICES

1. PURPOSE: This Veterans Health Administration (VHA) Directive provides policy for allergen immunotherapy and the minimum requirements for establishing Allergy and Immunology services in the Department of Veterans Affairs (VA) medical facilities.

2. BACKGROUND

a. Allergen immunotherapy is a basic therapeutic technique widely used in the practice of Allergy and Immunology. An established Department of Defense (DOD) sharing agreement with the United States Army Centralized Allergen Extracts Laboratory (USACAEL) has allowed the provision of standardized, high-quality allergen extracts for VA patients.

b. As more VA Medical Facilities establish Allergy programs, this Directive offers procedures for the minimum requirements needed to establish a safe allergen immunotherapy program.

3. POLICY: It is VHA policy that allergen extracts must be administered by qualified personnel as determined by the allergist or immunologist and facility privileging and/or scope of practice policy. *NOTE: Under no circumstances will allergen extracts be self administered by a Veteran patient.*

4. ACTION

a. **Office of Patient Care Service and Specialty Care Services.** The Office of Patient Care Services and Specialty Care Services is responsible for:

(1) Appointing a qualified board-certified allergist or immunologist or practitioner as National Director of VHA-DOD Allergen Extract Program.

(2) Defining the policy for allergen therapy and establishment of immunology services in VHA. They are the final authority.

b. **National Director, VHA Allergen Extract Program.** The National Director for the VHA Allergen Extract Program is responsible for ensuring:

(1) VHA medical facilities that have board-certified or board-eligible allergists or immunologists or practitioners with experience in immunotherapy, as determined by the National Director, are eligible to enroll in the VHA-DOD Allergen Extract Program.

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(2) Allergen extracts for testing and therapy are supplied by:

(a) The VHA-DOD Allergen Extract Program, or

(b) Recognized high-quality manufacturers. **NOTE:** *Established facilities are not required to enroll and may continue to obtain immunotherapy from a qualified private allergen company if they are already doing so. However, any newly established Allergy programs will be required to enroll in the VHA-DOD Allergen Extract Program.*

(3) Immunotherapy is safely given at all facilities providing this service. This includes ensuring that:

(a) If allergen immunotherapy is a part of the facility's service to Veterans, the facility has a board-certified or board-eligible allergist, immunologist, or practitioner who is trained in immunotherapy and who has supervision over the facility's program.

(b) All allergen testing and treatment is given by adequately-trained personnel (both physician and nursing), as determined by the board-certified or board-eligible allergist, immunologist or practitioner defined in subparagraph 4b(1) in a setting with access to adequate measures to treat an anaphylactic reaction.

(c) In cases where patient-specific allergen extracts (in multiple doses) require more than one patient visit and the patient-specific allergen extracts cannot be obtained or purchased from the VHA-DOD Allergen Extract Program, the extract can be compounded (diluted) by VA personnel. The standards of practice must be in accordance with subparagraph 5c and Attachment A. The standards of practice must be in accordance with subparagraph 5(c) and Attachment A.

(d) VA compounding of allergen extracts for immediate-use is only allowed in a clinical setting when performed and checked by a pharmacist (or if necessary, by a physician or specially-trained health care personnel) prior to issuance to the patient or the patient's agent in accordance with subparagraph 5(e) and Attachment A.

c. **Medical Facility Director.** The Medical Facility Director is responsible for ensuring that each facility administering immunotherapy to eligible Veteran Patients:

(1) Has a board-certified or board-eligible allergist or immunologist or practitioner (*with demonstrated experience and training in allergen immunotherapy as determined by the Medical Facility Director*) to oversee the ordering and administration of allergen immunotherapy.

(2) Has qualified personnel administering immunotherapy that follow the immunotherapy guidelines as stated in subparagraph 5a.

(3) Has personnel qualified to administer immunotherapy such as an adequately trained registered nurse, licensed vocational nurse, or nurse practitioner, as determined by the allergist or immunologist or practitioner defined in subparagraph 4b(1).

(4) Has practitioners (as defined in subpar. 4a(1)) trained in prescribing immunotherapy who are held responsible for ensuring the safe administration of immunotherapy, to include ensuring the appropriate location, supplies, and adequately trained personnel are available as cited in subparagraph 5(b).

5. REFERENCES

a. Allergen immunotherapy: A practice parameter third update. Journal of Allergy and Clinical Immunology. 2011; 127(1):S1-S55.

b. The diagnosis and management of anaphylaxis practice parameter: 2010 update. Journal of Allergy and Clinical Immunology. 2010; 126(3):477-80.e1-42

c. VHA Handbook 1108.05, and the United States Pharmacopeia (USP) Chapter 1075 “Good Compounding Practices.”

d. VHA Issue Brief July 2, 2009; “Compounding of Allergen Extracts” (see Att. A).

e. VHA Handbook 1108.05, and USP Chapter 797 “Immediate-Use Compounded Sterile Preparations” provisions on “Pharmaceutical Compounding-Sterile Preparations.”

6. RESPONSIBLE OFFICE: The Office of Patient Care Services (10P4), Specialty Care Services (10P4E) is responsible for the contents of this Directive. Questions may be referred to (202) 461-7120.

7, RESCISSION: VHA Directive 2010-015, dated March 25, 2010 is rescinded. This VHA Directive expires March 31, 2017.

Robert A. Petzel, M.D.
Under Secretary for Health

Attachment

DISTRIBUTION: E-mailed to the VHA Publications Distribution List 3/15/2012

ATTACHMENT A

VHA ISSUE BRIEF ON COMPOUNDING ALLERGEN EXTRACTS

1. Issue Title: What is the standard for Department of Veterans Affairs (VA) medical centers compounding allergen extracts?

2. Date of Report: July 2, 2009.

3. Brief Statement of Issue and Status: On June 25, 2009, an issue brief was presented by VA Boston Healthcare System (BHS) and Veterans Integrated Services Network (VISN) I Network, on the topic of over dilution of allergens at VA BHI. In the review of the facts, it was decided that VHA should conduct a survey to determine if more facilities may be compounding allergens at the medical center.

4. Action. Progress and Resolution Dates

a. VA allergy clinics administer antigens that are prepared as patient specific formulations. Patient specific formulations can be purchased and will minimize the requirement for VA personnel to compound (dilute) antigens for a patient.

b. VA Pharmacy Service ensures the use of proper sterile techniques in VA facilities, defined by the United State Pharmacopeia (USP) General Chapter 797 on "Pharmaceutical Compounding - Sterile Preparations," which sets practice standards to help ensure that compounded sterile preparations are of high quality. The preparation of allergenic extracts and dilutions following USP 797 ensures that these products meet their purported characteristics of acceptable sterility, purity, quality accuracy, and strengths. Compounded preparations should be performed by or under the supervision of pharmacists in pharmacies. When it is necessary to compound (dilute) an antigen, it should be done by VA Pharmacy Service.

c. Compounding of patient specific allergen extracts in multiple doses requiring more than one patient visit, must be prepared and dispensed as a prescription. This standard is found in VHA Handbook 1108.05 Outpatient Pharmacy and USP Chapter 1075, Good Compounding Practices.

d. Compounding of allergen extracts for immediate-use is only allowed in a clinic setting when performed and checked by a pharmacist (or if necessary by a physician or specially-trained health care personnel) prior to issuance to the patient or the patient's agent in accordance with VHA Handbook 1108.05 and USP Chapter 797.

5. Recommendations

a. Require facilities to purchase patient specific antigen formulations from a manufacturer or from the Walter Reed Immunotherapy Program, to reduce the requirement to dilute antigen products.

b. Monitor compliance with USP Chapter 797 standards in allergy clinic settings.

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c. Ensure that only a physician, pharmacist or specially trained health care personnel, competent to prepare antigens, is allowed to compound (dilute) allergen products for immediate use in clinic settings for identified patients.

d. Require that compounding of allergens that are not intended for immediate use are:

(1) Prepared in VA Pharmacy Service based on a written prescription, whenever a commercial purchase of patient specific antigen formulation is not available.

(2) Labeled for a specific patient with a beyond-use-date and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.

Allergy Clinic Standards for Outpatient Preparation of Allergens	Medication Order Requirement	First Method (Preferred)	Second Method (Acceptable)	Third Method (Acceptable with confirmation of compliance to USP 797)	Labeling Requirement when Prepared in Advance
Single Dose Antigen Formulation	Medication Order for Clinic Administration or Written Prescription	Purchase	VA Pharmacy Service	Physician or specially trained health care personnel	Patient's name, beyond-use-date, storage temperature range.
Multi-Dose Antigen Formulation	Written Prescription	Purchase	VA Pharmacy Service	Physician Only	Patient's name, beyond-use-date, storage temperature range.

6. Contact for Further Information: Deputy Chief Consultant, Pharmacy Benefits Management Services at 202-461-7356 or Chief Section Allergy/Immunology, Carl T. Hayden VA Medical Center at 602-277-5551 x5064.

7. References

a. United States Pharmacopeia General Chapter 797; USP 32 — NF 27, Rockville, MD; USP Convention: 2009: page 319.

b. United States Pharmacopeia General Chapter 795; USP 32 — NF 27, Rockville, MD; USP Convention: 2009: page 314.

c. VHA Handbook 1108.05.

d. United States Pharmacopeia General Chapter 1075, "Good Compounding Practices"; USP 32 — NF 27, Rockville, MD; USP Convention: 2009: page 523.