

ALLERGEN THERAPY AND ALLERGEN IMMUNOTHERAPY CLINICS

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) directive revises policy for the safe and proper administration of allergen immunotherapy through the storage of allergen extracts and the establishment of allergen immunotherapy clinics in Department of Veterans Affairs (VA) medical facilities.

2. SUMMARY OF MAJOR CHANGES: This directive:

a. Includes definitions to clarify compounding and dilution of allergen extracts (see paragraph 3).

b. Updates the policy statement to require the use of the United States Army Centralized Allergen Extracts Laboratory (USACAEEL) for acquisition of allergen extracts (see paragraph 4).

c. Adds responsibilities for the VA medical facility Director; Chief Officer, Specialty Care Program Office; VA medical facility Chief of Staff; VA medical facility Associate Director for Patient Care Services; VA medical facility allergist or designated allergy provider; and VA medical facility Nurse Manager (see paragraph 5).

d. Removes responsibilities of the Director of the National Allergy and Immunology Program and assigns these responsibilities to the National Program Executive Director (NPED), National Allergy and Immunology Program (see paragraph 5).

e. Updates Appendix A to clarify the dilution and compounding of allergen extracts to align with United States Pharmacopeia General Chapter <797>, Pharmaceutical Compounding-Sterile Preparations.

f. Includes a SharePoint site where information and forms related to this directive can be found. This includes a formal Enrollment Request Checklist for VHA Allergen Immunotherapy Clinics to submit to the NPED, National Allergy and Immunology Program, as well as nursing competencies templates. This site is available at <https://dvagov.sharepoint.com/sites/vhascco/AllergenExtract/SitePages/Home.aspx>.

NOTE: *This is an internal VA website that is not available to the public.*

3. RELATED ISSUES: VHA Directive 2013-006, The Use of Unlicensed Assistive Personnel (UAP) in Administering Medication, dated March 5, 2013.

4. RESPONSIBLE OFFICE: The National Allergy and Immunology Program in the Office of Allergy and Immunology (11SPEC1) is responsible for the content of this directive. Questions may be directed to: VHA11SPECActions@va.gov.

5. RESCISSIONS: VHA Directive 1148, Allergen Therapy and the Establishment of Allergy and Immunotherapy Clinics, dated December 8, 2016, is rescinded.

6. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of June 2027. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Erica M. Scavella, MD, FACP, FACHE
Acting Assistant Under Secretary for Health
for Clinical Services/CMO

NOTE: *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

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ALLERGEN THERAPY AND ALLERGEN IMMUNOTHERAPY CLINICS

1. PURPOSE

This Veterans Health Administration (VHA) directive states policy for allergen immunotherapy clinics in Department of Veterans Affairs (VA) medical facilities to obtain allergen extracts from the United States Army Centralized Allergen Extracts Laboratory (USACAEL), procedures for compounding and diluting allergen extracts and safe administration requirements within allergen immunotherapy clinics. **AUTHORITY:** 38 U.S.C. § 7301(b).

2. BACKGROUND

a. Allergen immunotherapy is an effective, evidence-based treatment that involves administering specific allergens to patients in order to desensitize them to their known allergic triggers. Allergen immunotherapy is widely used in the field of Allergy and Immunology and has been practiced for over 100 years. It is currently recommended to patients diagnosed with allergic rhinitis, asthma, allergic conjunctivitis or, in some cases, atopic dermatitis who fail to significantly improve on medications.

b. Allergen immunotherapy clinics focus on administration of allergen immunotherapy to patients with appropriate safety measures detailed in The Journal of Allergy and Clinical Immunology, available at: [https://www.jacionline.org/article/S0091-6749\(10\)01503-4/fulltext](https://www.jacionline.org/article/S0091-6749(10)01503-4/fulltext) and the United States Pharmacopeia General Chapter <797>, Pharmaceutical Compounding-Sterile Preparations (USP <797>), available at: https://dva.gov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Regulatory_and_Required/Forms/AllItems.aspx?id=%2Fsites%2FVHAPBM%2FPharmacy%5FOperations%2FRegulatory%20and%20Required%2FUnited%20States%20Pharmacopeia%20%2DUSP%2FUSP%2FUSP%20797%20References&viewid=57558d2a%2D2cdb%2D4de1%2Dabf0%2D00b3445c659f. **NOTE:** The latter link is an internal VA website that is not available to the public. Key practice parameters are also detailed in Appendix A.

c. USACAEL is an established Interagency Agreement (IAA) that provides allergen extracts to the Department of Defense (DoD) and VHA. USACAEL facilitates the availability of uniform diagnostic and therapeutic allergen extracts in standardized formulations for patients receiving allergen immunotherapy. USACAEL receives its allergen extracts from Food and Drug Administration (FDA) licensed manufacturers.

3. DEFINITIONS

a. **Allergen Extracts.** Allergen extracts are biologics that contain allergenic proteins used to test for allergy and to treat allergic disease through allergen immunotherapy.

b. **Beyond-Use Date.** Beyond-use date is the date or time after which an allergen extract may not be stored or utilized.

c. **Compounding.** Compounding is the process of combining commercially prepared sterile allergen products and appropriate conventionally manufactured sterile added substances via sterile needles and syringes.

d. **Dilution.** For the purposes of this directive, dilution is the process of penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids to predetermined allergy diluent vials.

e. **Reconstitution.** For the purposes of this directive, reconstitution is the process of adding diluent to a solid Hymenoptera venom allergen extract.

4. POLICY

It is VHA policy that allergen extracts must be administered by qualified personnel as determined by the allergist or designated allergy provider at a participating VA medical facility through an established allergen immunotherapy clinic. It is also VHA policy that allergy programs at VA medical facilities must enroll in the VHA Allergen Extract Program and receive allergen extracts through USACAEL insofar as USACAEL resources allow.

5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Clinical Services.** The Assistant Under Secretary for Health for Clinical Services is responsible for:

(1) Ensuring the Chief Officer, Specialty Care Program Office (SCPO) has sufficient personnel to fulfill the requirements of this directive.

(2) Supporting SCPO with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/CNO is responsible for:

(1) Ensuring the Chief Officer, SCPO has sufficient personnel to fulfill the nursing requirements of this directive.

(2) Assisting the Chief Officer, SCPO to resolve nursing-related implementation and compliance challenges in all VA medical facilities for this directive.

d. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

e. **Chief Officer, Specialty Care Program Office.** The Chief Officer, SCPO is responsible for:

(1) Supporting the National Program Executive Director (NPED), National Allergy and Immunology Program in executing this directive.

(2) Ensuring that sufficient resources are allocated for the implementation of and compliance with this directive and working with the NPED, National Allergy Immunology Program when issues to this are identified.

f. **National Program Executive Director, National Allergy and Immunology Program.** The NPED, National Allergy and Immunology Program is responsible for:

(1) Reviewing and approving USACAEL enrollment requests submitted by the VA medical facility allergist or designated allergy provider to enroll their allergy immunotherapy clinics in USACAEL or other FDA-licensed manufacturer. **NOTE:** *All new and established allergy programs are required to enroll in the VHA Allergen Extract Program and receive allergen extracts through USACAEL, as specified under paragraph 4 of this directive, insofar as resources allow. Established allergy programs may continue to obtain allergen extracts from an FDA-licensed private allergen manufacturer if they are already doing so. Obtaining allergen extracts from a qualified private allergen manufacturer may also be allowable if USACAEL does not have product available.*

(2) Providing oversight to the VA medical facility Director to ensure each VA medical facility allergy immunotherapy clinic has the ability and resources to safely administer allergen immunotherapy, including reconstitution and dilution of allergen extracts, and notifying the Chief Officer, SCPO when issues to this are identified.

(3) Ensuring billing for each participating VA medical facility involved in the USACAEL allergen extract program is accurate by reviewing quarterly billing statements sent from USACAEL. When inaccurate billing concerns are identified, the NPED, National Allergy and Immunology Program is responsible for working with USACAEL and the VA medical facility to ensure concerns are appropriately addressed and corrected.

(4) Ensuring an IAA between DoD and VHA, such as USACAEL, is active and up to date.

(5) For VA medical facilities that do not have a VA medical facility allergist, approving appointments for a VA medical facility designated allergy provider. **NOTE:**

For more information on VA medical facility designated allergy providers, see paragraph 5.j.

g. **Veterans Integrated Services Network Director.** The VISN Director is responsible for ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Approving USACAEL enrollment requests, including the USACAEL Enrollment Request Checklist, submitted by the VA medical facility Chief of Staff (CoS) and notifying the VA medical facility allergist or designated allergy provider of approval. **NOTE:** *Final submission of USACAEL enrollment request to the National Allergy and Immunology Program is the responsibility of the VA medical facility allergist or designated allergy provider (see paragraph 5.j.(4)). All new and established allergy programs are required to enroll in the VHA Allergen Extract Program and receive allergen extracts through USACAEL, as specified under paragraph 4 of this directive, insofar as resources allow. Established allergy programs may continue to obtain allergen extracts from an FDA-licensed private allergen manufacturer if they are already doing so. Obtaining allergen extracts from a qualified private allergen manufacturer may also be allowable if USACAEL does not have product available.*

(2) If the VA medical facility has an established allergy program and is obtaining allergen extracts from another FDA-licensed manufacturer, approving the FDA-licensed manufacturer and USACAEL Enrollment Request Checklist submitted by the VA medical facility CoS and notifying the VA medical facility allergist or designated allergy provider of approval. **NOTE:** *Final submission of USACAEL enrollment request to the National Allergy and Immunology Program is the responsibility of the VA medical facility allergist or designated allergy provider (see paragraph 5.j.(4)).*

(3) Approving remote sites of care within the VA medical facility where patients may receive allergen immunotherapy by a provider trained in anaphylaxis and overseen on-site or remotely by the VA medical facility allergist or designated allergy provider.

(4) Providing support to the VA medical facility CoS to ensure that adequate resources (e.g., appropriate location, supplies and competent personnel) are available to the VA medical facility allergen immunotherapy clinic to provide allergen immunotherapy, including reconstitution and dilution of allergen extracts, and notifying the NPED, National Allergy and Immunology Program when issues to this arise. **NOTE:** *VA medical facilities must refer to Appendix A for guidance on reconstitution and dilution of allergen extract formulations in compliance with USP <797> "Pharmaceutical Compounding-Sterile Preparations." VA medical facilities may create local standard operating procedures to enumerate specific steps for VA medical facilities to implement this directive.*

(5) Ensuring that allergen immunotherapy oversight is conducted by the VA medical facility allergist or designated allergy provider, either on site or remotely.

(6) Appointing qualified personnel to serve as the VA medical facility allergist or designated allergy provider for the allergen immunotherapy clinic. **NOTE:** *VA medical facility designated allergists must be approved by the NPED, National Allergy and Immunology Program.*

i. **VA Medical Facility Chief of Staff.** The VA medical facility CoS is responsible for:

(1) Reviewing and approving USACAEL enrollment requests, including the USACAEL Enrollment Request Checklist, submitted by the VA medical facility allergist or designated allergy provider and forwarding the requests to the VA medical facility Director for approval. **NOTE:** *Final submission of USACAEL enrollment request to the National Allergy and Immunology Program is the responsibility of the VA medical facility allergist or designated allergy provider (see paragraph 5.j.(4)). All new and established allergy programs are required to enroll in the VHA Allergen Extract Program and receive allergen extracts through USACAEL, as specified under paragraph 4 of this directive, insofar as resources allow. Established allergy programs may continue to obtain allergen extracts from an FDA-licensed private allergen manufacturer if they are already doing so. Obtaining allergen extracts from a qualified private allergen manufacturer may also be allowable if USACAEL does not have product available.*

(2) If the VA medical facility has an established allergy program and is obtaining allergen extracts from an FDA-approved manufacturer, reviewing and approving the FDA-approved manufacturer and USACAEL Enrollment Request Checklist submitted by the VA medical facility allergist or designated allergy provider and forwarding to the VA medical facility Director for approval. **NOTE:** *Final submission of USACAEL enrollment request to the National Allergy and Immunology Program is the responsibility of the VA medical facility allergist or designated allergy provider (see paragraph 5.j.(4)).*

(3) Ensuring implementation of the allergy immunotherapy clinic and ongoing quality assurance of the program.

(4) Ensuring VA medical facilities demonstrate competency and have adequate resources and staff to safely provide immunotherapy services, including reconstitution and dilution of allergen extracts, and notifying the VA medical facility Director when issues to this arise. This includes ensuring:

(a) A board-certified VA medical facility allergist or designated allergy provider trained in immunotherapy has oversight, either on-site or remotely, over the clinic, including Community Based Outpatient Clinics (CBOCs), mobile clinics and other associated sites of care. VA satellite clinics must have an allergist review and oversee all allergen extracts and a designated provider trained in Basic Life Support (BLS) must be on site when allergen immunotherapy is administered.

(b) Immunotherapy extracts are prescribed only by the VA medical facility allergist or designated allergy provider.

(c) All allergen testing and treatment is administered by personnel competent in allergen immunotherapy administration as determined by the VA medical facility allergist

or designated allergy provider in a setting with access to adequate measures to treat an anaphylactic reaction. **NOTE:** For more information on anaphylaxis practice parameters, see [https://www.jacionline.org/article/S0091-6749\(20\)30105-6/fulltext](https://www.jacionline.org/article/S0091-6749(20)30105-6/fulltext).

(d) Immunotherapy may be administered at any VA medical facility, including CBOCs and satellite clinics if the criteria in this directive are met.

(e) The allergen immunotherapy clinic is staffed by an experienced provider trained in treating anaphylaxis, including administration of Automated External Defibrillators (AED), and other complications from the allergen immunotherapy administration during allergen immunotherapy clinic business hours. **NOTE:** For more information on anaphylaxis practice parameters, see [https://www.jacionline.org/article/S0091-6749\(20\)30105-6/fulltext](https://www.jacionline.org/article/S0091-6749(20)30105-6/fulltext).

(f) Storage equipment for allergen extracts is present, monitored and updated.

(g) The allergen immunotherapy clinic is equipped to deliver BLS. **NOTE:** AED must be on site and readily available to AED trained personnel in the area near where allergen immunotherapy is administered.

(h) There is sufficient space for patients to wait for at least 30 minutes after receiving allergen immunotherapy to conduct clinical evaluation for signs and symptoms of allergic reactions prior to leaving the clinic.

j. **VA Medical Facility Associate Director for Patient Care Services.** The VA medical facility Associate Director for Patient Care Services (ADPCS) is responsible for:

(1) Ensuring dedicated nursing staff is assigned to allergen immunotherapy clinic sessions to maintain safe delivery of patient care. If this is not possible (e.g., when the dedicated allergy nurse is on leave), the VA medical facility ADPCS is responsible for ensuring that only nursing staff members trained in assigned allergen protocols administer immunotherapy to patients. **NOTE:** *Unlicensed Assistive Personnel are not permitted to administer allergen immunotherapy. See VHA Directive 2013-006, The Use of Unlicensed Assistive Personnel (UAP) in Administering Medication, dated March 5, 2013.*

(2) Ensuring ongoing quality assurance of nursing services in the allergy immunotherapy clinic by reviewing quality assurance reports provided by the VA medical facility allergist or designated allergy provider. **NOTE:** *Quality assurance measures vary depending on the VA medical facility and are determined by the VA medical facility allergist or designated allergy provider.*

(3) Providing support to the VA medical facility allergist or designated allergy provider and the VA medical facility Nurse Manager in ensuring nursing staff members are competent in the administration of allergen immunotherapy. **NOTE:** For more information about competencies see paragraph 6 and <https://dvagov.sharepoint.com/sites/vhascco/AllergenExtract/SitePages/Home.aspx>. *This is an internal VA website that is not available to the public.*

k. **VA Medical Facility Allergist or Designated Allergy Provider.** ***NOTE:** The VA medical facility allergist or designated allergy provider must be board certified and trained in immunotherapy. Designated allergy providers must be approved by the NPED, National Allergy and Immunology Program. The VA medical facility allergist or designated allergy provider is responsible for:*

(1) Answering questions from health care providers regarding allergen immunotherapy (e.g., questions regarding patient reactions, the build-up phase) during allergen immunotherapy clinic business hours.

(2) For VA medical facilities implementing a new allergy program, submitting an USACAEL enrollment request, including the USACAEL Enrollment Request Checklist, to the VA medical facility CoS to review, approve and forward to the VA medical facility Director. ***NOTE:** The USACAEL Enrollment Request Checklist can be found at <https://dvagov.sharepoint.com/sites/vhascco/AllergenExtract/SitePages/Home.aspx>. This is an internal VA website that is not available to the public. All new and established allergy programs are required to enroll in the VHA Allergen Extract Program and receive allergen extracts through USACAEL, as specified under paragraph 4 of this directive, insofar as resources allow. Established VA medical facilities may continue to obtain immunotherapy from an FDA-licensed private allergen manufacturer if they are already doing so. Obtaining immunotherapy from a qualified private allergen manufacturer may also be allowable if USACAEL does not have product available.*

(3) If the VA medical facility has an established allergy program and is obtaining allergen extracts from an FDA-approved manufacturer, submitting that manufacturer and USACAEL Enrollment Request Checklist to the VA medical facility CoS to review, approve and forward to the VA medical facility Director.

(4) For VA medical facilities implementing new allergy programs or established allergy programs obtaining allergen extracts from an FDA-approved manufacturer, submitting USACAEL enrollment requests that have been approved by the VA medical facility Director and VA medical facility CoS (see paragraphs 5.g. and 5.h.) to the National Allergy and Immunology Program. This entails submitting the USACAEL Enrollment Request Checklist to the National Allergy and Immunology Program SharePoint at <https://dvagov.sharepoint.com/sites/vhascco/AllergenExtract/SitePages/Home.aspx> and notifying the NPED, Allergy and Immunology Program of submission by emailing VHA11SPECActions@va.gov. ***NOTE** This is an internal VA website that is not available to the public.*

(5) Ordering, managing, procuring, tracking, storing and disposing of allergen extract formulations in the allergen immunotherapy clinic and inspecting all formulations to ensure product labeling, dating and quality. ***NOTE:** See Appendix A for more information on allergen extract formulations.*

(6) Determining appropriate quality assurance measures in collaboration with VA medical facility allergy immunotherapy clinic staff to set the priorities for quality and safe

patient care and reporting these measures to the VA medical facility ADPCS. Reporting frequency of quality assurance measures is also determined by the VA medical facility allergist or designated allergy provider in conjunction with the VA medical facility ADPCS, VA medical facility Associate Chief Nurse or VA medical facility Nurse Manager.

(7) Making recommendations to the VA medical facility CoS to ensure adequate resources (e.g., appropriate location, supplies and competent personnel) are available for the allergen immunotherapy clinic.

(8) Determining frequency of competency evaluation in allergen immunotherapy and ensuring all allergen immunotherapy clinic staff involved in administration of allergen immunotherapy continue to be competent in allergen immunotherapy administration. This may entail:

(a) Providing on-going allergen immunotherapy competency education to nursing staff.

(b) Collaborating with VA medical facility Nurse Manager to ensure nursing staff complete competency-based education related to all elements of allergen immunotherapy management. **NOTE:** For more information on allergen immunotherapy administration competency for nursing staff, see paragraph 6.

(c) Ensuring the VA medical facility Nurse Manager adequately documents completed nursing competencies for each nursing staff member.

(d) Notifying the VA medical facility ADPCS when any issues related to allergen immunotherapy administration competency arise.

(9) Notifying the VA medical facility CoS when staffing or resource needs related to the administration of allergen immunotherapy arise.

(10) Having immediate access to anaphylaxis medications at the allergen immunotherapy site. At a minimum, intramuscular epinephrine (e.g., Epi-Pen™, Symjepi™ or equivalent) is required. **NOTE:** For more information on recommendations, see *Allergen immunotherapy: a practice parameter third update* at [https://www.jacionline.org/article/S0091-6749\(10\)01503-4/fulltext](https://www.jacionline.org/article/S0091-6749(10)01503-4/fulltext). For more information on anaphylaxis practice parameters, see [https://www.jacionline.org/article/S0091-6749\(20\)30105-6/fulltext](https://www.jacionline.org/article/S0091-6749(20)30105-6/fulltext).

(11) Identifying a designated area for allergen preparation, such as a countertop, within the VA medical facility where personnel traffic is restricted and activities that might contribute to microbial contamination (e.g., eating and preparing food and storing used diagnostic devices, materials and soiled linens) are prohibited. For more information on designating allergen preparation area, see Appendix A.

(12) Ensuring allergen formulation dilutions are adequately labeled by an allergen immunotherapy clinical staff member competent in managing allergen extracts (e.g., allergy technicians, nursing staff). **NOTE:** For labeling requirements, see Appendix A.

(13) Ensuring VA medical facility allergen immunotherapy clinic personnel follow the Allergen Immunotherapy Extract Preparation Manual as stated in the practice parameters developed by the American Academy of Allergy, Asthma and Immunology, the American College of Allergy Asthma and Immunology and USP <797>. **NOTE:** The Allergen Immunotherapy Extract Preparation Manual can be found at <https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/Ch-9-Allergen-Immunotherapy-Extract-Preparation-Manual-correction-July-19-12.pdf>. This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

I. **VA Medical Facility Nurse Manager.** **NOTE:** Depending on the VA medical facility, there may be more than one VA medical facility Nurse Manager. The VA medical facility Nurse Manager is responsible for:

(1) Collaborating with the VA medical facility allergist or designated allergy provider to ensure nursing staff members assigned to allergen immunotherapy clinics are competent in allergen immunotherapy and notifying the VA medical facility ADPCS when issues to this arise.

(2) Maintaining documentation of completed nursing competencies for all nursing staff members. **NOTE:** Nursing allergen immunotherapy competencies can be found at <https://dvagov.sharepoint.com/sites/vhascco/AllergenExtract/SitePages/Home.aspx>. This is an internal VA website that is not available to the public. At a minimum this includes:

(a) Safe administration of subcutaneous immunotherapy.

(b) Knowledge of allergen immunotherapy dose adjustments.

(c) Recognition of anaphylaxis and follow-up according to local protocols. **NOTE:** For more information on anaphylaxis practice parameters, see [https://www.jacionline.org/article/S0091-6749\(20\)30105-6/fulltext](https://www.jacionline.org/article/S0091-6749(20)30105-6/fulltext).

(3) Ensuring nursing personnel involved in administration of allergen immunotherapy have no conflicting duties scheduled at the time the allergen immunotherapy is in session.

6. TRAINING

There are no formal training requirements associated with this directive, however all nursing personnel administering allergen immunotherapy must be evaluated in allergen immunotherapy management. Evaluation is determined by the VA medical facility allergist or designated allergy provider and must cover, at minimum, the required nursing allergy immunotherapy competencies (see checklist on allergen extract program

SharePoint below) and the Allergen Immunotherapy Extract Preparation Manual.

NOTE: For more information on required competencies, see

<https://dvagov.sharepoint.com/sites/vhascco/AllergenExtract/SitePages/Home.aspx>.

This is an internal VA website that is not available to the public. The Allergen Immunotherapy Extract Preparation Manual is available at:

[https://www.aaaai.org/Aaaai/media/Media-Library-](https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/Ch-9-Allergen-Immunotherapy-Extract-Preparation-Manual-correction-July-19-12.pdf)

[PDFs/Practice%20Management/Practice%20Tools/Ch-9-Allergen-Immunotherapy-](https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/Ch-9-Allergen-Immunotherapy-Extract-Preparation-Manual-correction-July-19-12.pdf)

[Extract-Preparation-Manual-correction-July-19-12.pdf](https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/Ch-9-Allergen-Immunotherapy-Extract-Preparation-Manual-correction-July-19-12.pdf). This linked document is outside

VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

7. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management must be addressed to the appropriate Records Officer.

8. REFERENCES

a. 38 U.S.C. § 7301(b).

b. VHA Directive 2013-006, The Use of Unlicensed Assistive Personnel (UAP) in Administering Medication, dated March 5, 2013.

c. Academy of Allergy, Asthma and Immunology. Allergies.

<https://www.aaaai.org/Conditions-Treatments/Allergies>.

d. Academy of Allergy, Asthma and Immunology. Chapter 9 Allergen Immunotherapy Extract Preparation Manual. 2012: <https://www.aaaai.org/Aaaai/media/Media-Library-PDFs/Practice%20Management/Practice%20Tools/Ch-9-Allergen-Immunotherapy-Extract-Preparation-Manual-correction-July-19-12.pdf>. **NOTE:** This linked document is outside VA control and may not conform to Section 508 of the Rehabilitation Act of 1973.

e. The Journal of Allergy and Clinical Immunology. Allergen immunotherapy: A practice parameter third update. 2010: [https://www.jacionline.org/article/S0091-6749\(10\)01503-4/fulltext](https://www.jacionline.org/article/S0091-6749(10)01503-4/fulltext).

f. The Journal of Allergy and Clinical Immunology. Anaphylaxis—a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis - Journal of Allergy and Clinical Immunology (jacionline.org). 2020: [https://www.jacionline.org/article/S0091-6749\(20\)30105-6/fulltext](https://www.jacionline.org/article/S0091-6749(20)30105-6/fulltext).

g. United States Pharmacopeia. General Chapter <797> Pharmaceutical Compounding-Sterile Preparations. 2008:

https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Regulatory_and

[Required/Forms/AllItems.aspx?id=%2Fsites%2FVHAPBM%2FPharmacy%5FOperations%2FRegulatory%20and%20Required%2FUnited%20States%20Pharmacopeia%20%2DUSP%2FUSP%2FUSP%20797%20References&viewid=57558d2a%2D2cdb%2D4de1%2Dabf0%2D00b3445c659f](#). **NOTE:** This is an internal VA website that is not available to the public.

PREPARING ALLERGEN EXTRACTS

1. BACKGROUND

a. Veterans Health Administration (VHA) allergen immunotherapy clinics administer antigens that are prepared as patient-specific formulations. Patient-specific allergen extract formulations are ordered from the United States Army Centralized Allergen Extracts Laboratory (USACAEL) or purchased from a recognized Food and Drug Administration (FDA) or Center for Biologics Evaluation and Research approved and licensed manufacturer in order to minimize the need for Department of Veterans Affairs (VA) personnel to prepare the original undiluted patient-specific allergen extract.

b. If dilutions of allergen extract formulations are needed:

(1) A health care provider or qualified staff member, as determined by the VA medical facility allergist or designated allergy provider, can perform dilution at the allergen immunotherapy clinic; or

(2) Dilutions can be ordered directly from USACAEL.

2. GENERAL GUIDELINES

a. VA medical facility allergen immunotherapy clinic personnel are required to follow the Allergen Immunotherapy Extract Preparation Manual as stated in the practice parameters developed by the American Academy of Allergy, Asthma and Immunology, the American College of Allergy Asthma and Immunology and United States Pharmacopeia Chapter 797 (USP <797>). **NOTE:** For more information, see: <https://www.aaaai.org/Conditions-Treatments/Allergies>.

b. Allergen extracts must be diluted in accordance with the antigen manufacturer's instructions.

3. POTENCY

The expiration dates of the allergen extracts must be followed. Beyond-use dates for allergen extract dilutions must not exceed the expiration date of the reference stock allergen extract formulation from USACAEL or the manufacturer.

4. DELIVERY AND STORAGE

a. Allergen extracts may be mailed directly to the clinic or pharmacy depending on the VA medical facility's preference. Extracts must be refrigerated promptly upon arrival at the site.

b. Extracts must be stored at 2° – 8°C (36° – 46°F) to reduce the rate of potency loss or according to the manufacturer's instructions. Extracts stored beyond the

expiration date of the manufacturer are to be discarded. Extracts must be stored separately from food, medications and specimens in a designated refrigerator for only medications.

5. PREPARATION (RECONSTITUTION OR DILUTION)

The VA medical facility allergist or designated allergy provider must identify a designated area to prepare allergen preparations, such as a countertop, within the VA medical facility where personnel traffic is restricted and activities that might contribute to microbial contamination (e.g., eating and preparing food and storing used diagnostic devices, materials and soiled linens) are prohibited.

a. The surface of the designated area must be cleaned with sterile 70% Isopropyl Alcohol prior to beginning preparation, between preparation of multiple allergens for the same patients and between doses prepared for each patient.

b. Reconstitution of solid Hymenoptera venom extracts is not considered compounding.

c. Follow all steps stipulated by USACAEL for reconstitution or dilution. **NOTE:** *Depending on the VA medical facility, reconstitution falls under the scope of practice for VA medical facility allergist, designated allergy provider, allergy nurse or allergy technician. Reconstitution pertains to extracts that are delivered as a solid and need to be converted to liquid.*

d. Preparation of allergens must be in accordance with USP <797> and may be prepared outside of an International Organization for Standardization Class 5 environment. **NOTE:** *USP <797> guidelines can be found at: https://dvagov.sharepoint.com/sites/VHAPBM/Pharmacy_Operations/Regulatory_and_Required/Forms/AllItems.aspx?id=%2Fsites%2FVHAPBM%2FPharmacy%5FOperations%2FRegulatory%20and%20Required%2FUnited%20States%20Pharmacopeia%20%2DUSP%2FUSP%2FUSP%20797%20References&viewid=57558d2a%2D2cdb%2D4de1%2Dabf0%2D00b3445c659f. This is an internal VA website that is not available to the public.*

(1) Allergen extracts are to be injected subcutaneously. Allergen extracts must not be administered intravenously as risks are substantially greater.

(2) Allergen extract formulations purchased from an FDA-licensed manufacturer that require further reconstitution and dilution by the VA medical facility allergen immunotherapy clinic must be diluted in accordance with the Journal of Allergy and Clinical Immunology 2010 practice parameters for the specific patient with an expiration date (beyond-use date) and storage recommendations that are assigned based on the pharmaceutical manufacturers' recommendations or peer-reviewed publications. The Journal of Allergy and Clinical Immunology 2010 practice parameters can be found at [https://www.jacionline.org/article/S0091-6749\(10\)01503-4/fulltext](https://www.jacionline.org/article/S0091-6749(10)01503-4/fulltext). It is imperative that the VA medical facility allergist or designated allergy provider contact the

pharmaceutical manufacturer supplying the allergen extracts to obtain the correct date of expiration for the allergen extract or delegating this task as seen fit. There is a defined table that lists expirations based on the extract dilution (e.g., 1:10, 1:100, 1:1000 v/v) (see Recommended Beyond-Use Date for Allergen Extracts Based on Dilution Table posted to

<https://dvagov.sharepoint.com/sites/vhascco/AllergenExtract/SitePages/Home.aspx>.

NOTE: *This is an internal VA website that is not available to the public).*

6. LABELING

a. Immunotherapy vials must be clearly labeled with the patient's name and the expiration date (e.g., beyond-use date provided by USACAEL or determined based on dilution).

b. The VA medical facility allergist or designated allergy provider must ensure that allergen formulation dilutions are adequately labeled according to this directive to include, but not limited to: patient name and date of birth, the allergen extract formulation's identity, strength, storage recommendations, expiration date and name or initials of preparer. The VA medical facility allergist or designated allergy provider is responsible for inspecting all allergen extract formulations stored in the clinic to ensure product labeling, dating and quality. The VA medical facility allergist or designated allergy provider can assign allergy immunotherapy clinical personnel competent in managing allergen extracts (e.g., allergy technicians, nursing staff) to handle this task. Allergen extracts must not be given to patients for storage at home. Extracts must always be maintained at required storage conditions under refrigeration within the clinic premises.