Allergy Injection Policy

1.0 Background

Millions of Americans suffer from perennial and seasonal allergic rhinitis. Allergy immunotherapy is an effective way to reduce or eliminate the symptoms of allergic rhinitis by desensitizing the patient to the allergen(s) by giving escalating doses of an extract via regular injections. Receiving weekly injections at a private physician’s office is time consuming, reduces productivity, and can quickly deplete an employee’s earned leave. FOH offers the convenience of receiving allergy injections at the OHC as a physician-prescribed service, reducing time away from work for many federal employees. While generally considered safe when administered under controlled circumstances, allergenic extracts do carry a small risk of inducing life-threatening reactions such as anaphylaxis.

2.0 Purpose

The purpose of this policy is to describe the procedures under which allergen immunotherapy may be safely administered in Federal Occupational Health (FOH) health centers. The policy was specifically designed to limit risks of severe reactions and to continue to provide the service in a safe manner.

3.0 Scope

The following policies and procedures apply to any employee within an affiliated agency who wishes to receive allergen immunotherapy in an FOH health center.

4.0 Procedures

4.1 Syringes

Only tuberculin syringes should be used for allergy injections. Do not use the syringes called “allergy” syringes in the Perry Point catalogue for allergy injections. These are meant for intradermal skin testing. They are not packed individually and will not be sterile if the plunger is pulled back beyond 0.1 cc.
4.2 **Forms Used**

Each employee should receive an immunotherapy forms packet to complete. This packet should include the attached forms: (Note: Each form B – E, has been reformatted)

a) Attachment A: General Information for Receiving Allergen Immunotherapy
b) Attachment B: Employee Information for Allergen Immunotherapy
c) Attachment D: Physician Letter – FOH-23: Allergen Immunotherapy, Other Medications & Treatments
d) Attachment E: Physician Treatment Orders – FOH-24 Form

4.3 **How to Complete Forms**

a) **Employee Information for Allergen Immunotherapy**: This should be read and signed by the employee. The signed original is kept with the medical record.

b) **Prescribing Physician Information Sheet**: This should be carefully read by the prescribing physician.

c) **Physician Letter - FOH–23**: This form is filled out and is given to the prescribing physician for review and signature. A signed original of this letter is kept with the employee’s medical record.

d) **Physician Treatment Orders – FOH-24 Form**: This form letter is stamped with the FOH center address and phone number and is completed and signed by the prescribing physician. The signed original is kept with the employee’s medical record. The prescribing physician may elect to use an alternate form to outline treatment orders. Should the prescribing physician choose not to use the FOH-24 Form; the alternate form **must** contain the following information:

- Employee’s name
- Exact name of the medication
- Interval of administration
- Medication dosage
- Reactions that may occur and measures to be taken in the event of a reaction
- Route of administration
- FOH center address
- Date of employee’s next appointment at private physician
- Physician telephone number
- Physician name and signature
- Method for handling first injection of multidose vials
4.4 Initial and Build-up Dosages

All build-up injections and the first two maintenance doses must be given at the private physician’s office, with the following exception:

If all of the following criteria are met, build-up doses may be administered in the FOH OHC after 3 reaction-free doses of allergy injection are given at the private physician’s office.

- There must be at least TWO (2) ACLS-certified staff present in the OHC, including at least ONE licensed physician
- Fluid resuscitation must be available onsite.
- Oral airways and oxygen must be available onsite.
- Injectable/IV medications to treat anaphylaxis should also be available as ordered by the ACLS trained physician
- Prior approval by the COM.

4.5 Maintenance Dosage

a) The FOH health care providers administering allergen immunotherapy should review all treatment orders provided by the prescribing physician. Questions regarding treatment orders should be clarified by the health care provider prior to beginning administration of an allergen injection.

b) Except as outlined in Section 4.4 above, maintenance dosages may be administered in an FOH center ONLY after the employee has received all build-up injections and the first two reaction-free maintenance injections in the prescribing physician’s office. For the purpose of this policy, a maintenance dose will be considered those doses given after the maximum dose at the expected maximum concentration has been administered at least twice in the prescribing physician’s office without significant reactions. It is recognized that physicians often lower and then subsequently raise the dose of antigen that is to be administered with each new multidose bottle of serum. However, for purposes of this policy, all such doses will be considered maintenance.

4.6 Interruption of Dosage Schedule

a) Safety dictates that each employee follows the recommended schedule for treatment.

b) When an employee has interrupted the prescribed dosage schedule for 4 or more consecutive weeks, the health care provider must notify the prescribing allergist (physician) for further instructions (e.g., continue with previous dosage, lower dosage, return to physician’s office for injection).

c) An employee whose injection schedule has been interrupted for 12 weeks or more must receive five reaction-free injections with the prescribing physician before
being allowed to continue allergen injections at a FOH center. The last two doses must be at the maintenance dosage that is later expected to be given in the OHC.

d) If the OHC has ACLS certified staff and fluid resuscitation is available, interrupted doses may resume in the FOH OHC after 3 reaction-free doses of allergy injection are given at the private physician’s office.

4.7 Systemic or Severe Reaction

a) A systemic or severe reaction that requires an injection of epinephrine, or Benadryl (diphenhydramine HCL), and/or requires the employee to be transported to a hospital must be reported immediately to the prescribing physician. Any (even mild or local) reactions must also be reported before any other doses are administered.

b) No employee who has a history of a systemic or severe reaction will be allowed to receive allergen injections in the FOH OHC.

4.8 Modification of Orders and Mild Reactions

a) If a prescribing physician is called to modify or clarify an order, it must be appropriately documented and followed by a written physician’s order within 72 hours. A health care provider should record the telephone order in the employee’s medical record and ensure the physician’s formal written order is appropriately placed in the chart. Original or faxed orders are acceptable.

b) Treatment of a local/mild reaction should follow the prescribing physician’s orders or the national FOH policy.

4.9 Opening a Multidose Allergen Vial

a) The first dose from a new multidose vial (maintenance dose) may be given in either the prescribing physician’s office or a FOH center. Please follow the prescribing physician’s treatment orders – (FOH-24 Form or alternate treatment order form).

b) A multidose vial should be rotated to adequately suspend the allergen prior to withdrawing any injectable medication. Inadequate mixing of a multidose vial containing allergen extract may increase the opportunity of an adverse reaction to allergen extract.

c) If a reaction should occur from a dose taken from a multivial dose vial, the health care provider must notify the prescribing physician’s office for further instructions (e.g., continue with previous dosage, lower dosage, return to physician’s office for injections).
4.10 Waiting Period

Safety dictates all employees must remain in the OHC waiting room for 20 minutes after being given an injection, without exception.

4.11 Other Medications

a) An employee is frequently under the care of more than one physician. Health care providers should be alert to the possibility that an employee’s medication may unexpectedly change and potentially complicate the safety of allergen immunotherapy.

b) All employees must have a complete and current medication list including prescribed and over the counter (OTC) medication in their medical record.

c) The FOH health care providers administering allergen injections should question each employee prior to administering an allergen injection regarding changes in medications or the addition of new medication.

d) The FOH health care providers unfamiliar with the potential for cross reactions or contraindications of allergen immunotherapy and the employee’s other medications should review its contraindications in the appropriate reference or call the prescribing physician for further clarification.

4.12 Staffing

At least two persons with current CPR certification must be present when allergen immunotherapy is given. If the required FOH staffing is limited at a particular site, the second person may be an agency volunteer who accompanies the allergy client, except when the OHC is performing build-up immunizations. If build-up doses are administered, two persons with current ACLS certification must be present, and one of those must be a physician.

4.13 Medical Documentation

a) The FOH health care providers administering allergen immunotherapy are responsible for ensuring all physician orders and treatments are correctly documented in the medical record.

b) Original signatures are required to begin treatments. The original documentation verifying the prescribed treatment (FOH-24 form or alternate) must remain in the medical record. Once treatments have begun in an OHC, original documentation will be retained by FOH; however faxed signatures are acceptable for renewals. The prescribing physician may request a copy of the original if desired.
c) All physician orders must be updated at 12-month intervals by completing a new:

- FOH-24 Form or
- Alternate physician treatment order form that meets the criteria outlined in: 4.2 (d).

4.14 Contraindications to Providing Allergen Immunotherapy in a FOH OHC

a) Beta-blocking medications

- Allergen injections are contraindicated when an employee is currently using beta-blocking medication.

- A partial list of the commonly used beta-blocking medications is provided below. However, FOH OHC providers should carefully review each employee’s medication list and verify that no beta-blocking drugs are being taken.

<table>
<thead>
<tr>
<th>Generic</th>
<th>Brand Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>acebutolol</td>
<td>Monitan, Sectral</td>
</tr>
<tr>
<td>atenolol</td>
<td>Noten, Tenormin</td>
</tr>
<tr>
<td>carteolol</td>
<td>Cartrol</td>
</tr>
<tr>
<td>labetalol</td>
<td>Normodyne, Trandate</td>
</tr>
<tr>
<td>metoprolol</td>
<td>Lopressor, Betaloc, Toprol</td>
</tr>
<tr>
<td>nadolol</td>
<td>Corgard</td>
</tr>
<tr>
<td>propranolol</td>
<td>Inderal</td>
</tr>
<tr>
<td>penbutolol</td>
<td>Levatol</td>
</tr>
<tr>
<td>pindolol</td>
<td>Visken, Barbloc</td>
</tr>
<tr>
<td>timolol</td>
<td>Blocarden, Apo-Timol</td>
</tr>
</tbody>
</table>

b) Allergen injection is contraindicated in a FOH OHC whenever an employee has a past history of severe reaction to allergy immunotherapy.

c) Unstable asthma.

d) History of high degree of hypersensitivity.

4.15 Failure to Comply

Employee’s who fail to comply with any of the above provisions will be denied allergen injection services at a FOH OHC.
Instruction Packet for Allergen Immunotherapy

This packet of information is for Federal employees who are interested in receiving allergen injections in a FOH Occupational Health Center. Please note that these forms are for allergen immunotherapy. Forms for other prescribed medications or treatments are found in policy M.69. The following items should be attached to this packet:

<table>
<thead>
<tr>
<th>Attachment</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment A</td>
<td>General Information for Receiving Allergen Immunotherapy</td>
</tr>
<tr>
<td>Attachment B</td>
<td>Employee Information for Allergen Immunotherapy</td>
</tr>
<tr>
<td>Attachment C</td>
<td>Prescribing Physician Information for Allergen Immunotherapy</td>
</tr>
<tr>
<td>Attachment D</td>
<td>Physician Letter – Form FOH-23: Allergen Immunotherapy, Other Medications &amp; Treatments</td>
</tr>
<tr>
<td>Attachment E</td>
<td>Physician Treatment Orders – Form FOH-24</td>
</tr>
</tbody>
</table>
Attachment A: General Information for Employees Receiving Allergen Immunotherapy in the OHC

<table>
<thead>
<tr>
<th>What the employee must do:</th>
<th>What the physician must do:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Read and sign:</strong> Attachment B “Employee Information for Receiving Medications and Treatments Other than Allergen Immunotherapy”</td>
<td><strong>Read:</strong> Attachment C: “Prescribing Physician Information Sheet”.</td>
</tr>
<tr>
<td>Please carefully read and sign this document and return it to the FOH OHC. This signed sheet will be placed in your medical record. A copy will be provided to you upon request.</td>
<td><strong>Read and Sign:</strong> Attachment D: “Physician Letter - FOH-23 Form”</td>
</tr>
<tr>
<td><strong>YOU (the employee) return to the OHC the following forms before medications or treatments can be provided:</strong></td>
<td>When signed, this form should be returned to the Occupational Health Center (OHC). This letter verifies that your physician has determined that the employees you may safely receive the medication or treatment in a FOH OHC.</td>
</tr>
<tr>
<td>Attachment B “Employee Information”</td>
<td><strong>Complete and Sign:</strong> Attachment E: “Physician Treatment Orders – FOH-24 Form”</td>
</tr>
<tr>
<td>Attachment D “Physician Letter – FOH-23 Form”</td>
<td>When completed, this form should be returned to the OHC. This form outlines your physician’s specific treatment orders. If a physician chooses to use an alternate form in place of the FOH-24 Form, the following information must be included before treatments/injections are started:</td>
</tr>
<tr>
<td>Attachment E “Physician Treatment Orders – FOH-24 Form”</td>
<td>• Employee’s name</td>
</tr>
<tr>
<td></td>
<td>• Exact name of the medication</td>
</tr>
<tr>
<td></td>
<td>• Interval of administration</td>
</tr>
<tr>
<td></td>
<td>• Medication dosage</td>
</tr>
<tr>
<td></td>
<td>• Reactions that may occur and measure to be taken in the event of a reaction</td>
</tr>
<tr>
<td></td>
<td>• Route of administration</td>
</tr>
<tr>
<td></td>
<td>• FOH center address</td>
</tr>
<tr>
<td></td>
<td>• Date of employee’s next appointment at private physician</td>
</tr>
<tr>
<td></td>
<td>• Physician telephone number</td>
</tr>
<tr>
<td></td>
<td>• Physician name and signature</td>
</tr>
<tr>
<td></td>
<td>• Method for handling first injection of multidose vials</td>
</tr>
</tbody>
</table>
Attachment B: Employee Information for Allergen Immunotherapy

You have asked to receive allergen immunotherapy in the FOH, Occupational Health Center (OHC). By providing this service at your worksite, we can reduce the lost work time and inconvenience of frequent visits to your prescribing physician. Since receiving these injections in the OHC involves a team effort, this information sheet will define the responsibilities of the team members.

<table>
<thead>
<tr>
<th>The employee’s private physician must:</th>
<th>The employee must:</th>
<th>The FOH health care provider must:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete and sign the attached physician letter (FOH-23 Form).</td>
<td>Provide the OHC a list of all current medications</td>
<td>Inform the employee 2-3 weeks prior to an allergen extract becoming outdated or needing to be refilled.</td>
</tr>
<tr>
<td>Complete and sign the attached physician’s order (FOH-24 Form) or provide an alternate form which describes written instructions for administration of injections and treatment of possible reactions.</td>
<td>Inform the OHC staff of any medication changes.</td>
<td>Inform the employee when a physician order (FOH-24 Form) or the physician alternate form) needs to be updated.</td>
</tr>
<tr>
<td>Make certain all documentation is completed correctly and signed.</td>
<td>Obtain allergen extract from the prescribing physician. No outdated extract will be administered in the FOH OHC.</td>
<td>Indicate on Attachment C whether your site has ACLS and fluid resuscitation capabilities.</td>
</tr>
<tr>
<td>Administer all build-up and two reaction-free maintenance injections. IF ACLS and fluid resuscitations capabilities are available at the FOH center, only the first three doses are required to be given at the prescribing physician’s office.</td>
<td>Have the prescribing physician update the physician’s order (FOH-24 Form) every 12 months.</td>
<td>Make a reasonable effort to notify employee 1 week prior to a situation which might prevent administering an allergen injection in a FOH OHC.</td>
</tr>
<tr>
<td>Remain in the OHC 20 minutes after any allergen is administered.</td>
<td>Ensure ALL employees remain in the OHC 20 minutes following an allergen injection.</td>
<td></td>
</tr>
<tr>
<td>Have the injection site checked by the administering health care provider before leaving the FOH OHC.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inform the health care provider regarding any unusual or delayed reaction to an allergen reaction.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

I have read and understand the above responsibilities regarding administration of my allergen injections.

Employee Signature __________________________ Date __________

To be completed by the Health Care Provider:

Witness Name __________________________ Date __________
Attachment C: Prescribing Physician Information
For Allergen Immunotherapy

The following information is provided to a physician who is requesting the Federal Occupational Health (FOH), to assist in administering a patient’s allergen immunotherapy at the worksite. The FOH feels that is a valuable service for both your patient and the patient’s employer. However, for you to determine if your treatment orders can safely be administered the following capacity and limitations of our worksite facility should be known.

Most FOH Occupational Health Centers (OHCs) are operated using nurse professionals with Basic Life Support (CPR) certification, and do not have routine physician coverage. Limited emergency drugs (i.e., epinephrine and Benadryl) are maintained, and no resuscitation equipment is available in these OHCs. In a limited number of locations, staff are trained in Advanced Cardiac Life Support (ACLS) and have fluid resuscitative equipment.

FOR YOUR REFERENCE:
- This Health Center has ACLS and fluid resuscitative capabilities
- This Health Center does not have ACLS/fluid resuscitative capabilities

You may decide that the treatment regimen for your patient does not lend itself to care in our facility. **If this is the case, stop here and advise your patient.** However, if your patient could safely receive allergen immunotherapy at our OHC, there are a number of limitations required by FOH. These are listed below:

1. **A Comprehensively Completed Physician Order (FOH-24 Form).** Medications or treatments can not be administered in an FOH OHC unless there is a complete physician order. Specifically, the order must address the nature and extent of side effects or reactions to be expected, and what, if any action must be taken.

2. **High Risk Patients.** No patient at “high risk” for an adverse reaction to a medication may receive this therapy in a FOH OHC. The following conditions are considered “high risk”:
   - Unstable asthma
   - History of previous systemic reaction to allergen immunotherapy
   - History of a high degree of hypersensitivity
   - Use of beta-blocker medications

3. **If it is determined that your patient has any of the above conditions they will NOT be allowed to receive allergen immunotherapy in a FOH OHC and will be referred back to you, or an emergency treatment facility if appropriate.**
4. **Build-up and Maintenance Dose.** An employee should not receive allergy injections in a FOH OHC until the prescribing physician considers the employee stable and at minimal risk for an allergic reaction. Patients must receive all build-up and at least two maintenance reaction-free injections with the prescribing physician prior to beginning therapy in a FOH OHC, unless ACLS capabilities and fluid resuscitation are available as indicated above. In this case, only 3 reaction-free doses are required to be given in the prescribing physician’s office.

5. **Interrupted Dosage Schedule.** Patients are expected to follow the recommended treatment schedule for frequency of injections. When this schedule is interrupted for 4 consecutive weeks, our health care provider will contact you for instructions prior to resuming any injection schedule in a FOH OHC. Interruption > 12 weeks will result in the employee being returned to your office for at least five reaction-free injections prior to resuming any injections schedule in a FOH OHC. The last two doses must be at the maintenance dose that is to be administered in the OHC. IF ACLS and fluid resuscitative capabilities exist at the OHC, only 3 reaction-free doses are required to be given at the prescribing physician’s office after a 12-week interruption.

6. **Expected Reactions and Treatments** The physician should outline the expected reactions and provide the appropriate treatment orders for those reactions occurring while in a FOH OHC. Local reactions that require a decrease in dosage, telephone notification, or referral to your office should be clearly written. Any telephone order REQUIRES you to provide a signed physician’s order within 72 hours. Fax orders are acceptable.

7. **Starting a New Multidose Vial of Allergen Extract.** The first dose from a new multidose vial (maintenance dose) may be given in either the prescribing physician’s office or a FOH OHC. The prescribing physician should determine the best location based on the employee’s clinical assessment. All treatment orders (FOH-23 Form or alternate) should clearly specify the prescribing physician’s decision. These instructions also apply when starting a new box/batch of single-dose allergen extract vials.

8. **Waiting Period After Allergen Injection.** Your patient must wait in our OHC 20 minutes after receiving an allergen injection. Any patient refusing to comply with this policy will be denied allergen immunotherapy services in the FOH OHC.