

MODULE

4

ACIP AND VACCINE REPORTING

Bureau of Immunization-Vaccines for Children Program

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MODULE 4 - ACIP and Vaccine Reporting

What is the ACIP and what are its responsibilities?

The Advisory Committee on Immunization Practices (ACIP) has existed since 1964. Its original purpose was to provide advice and guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave the ACIP a unique statutory authority to determine the vaccines, number of doses, schedule and contraindications for the VFC Program and for the general population. The ACIP is the only entity in the federal government that has the authority to make such recommendations. The overall goals of the ACIP are to provide advice that will assist the Department of Health and Human Services (DHHS) and the nation in reducing the incidence of vaccine-preventable diseases and to increase the safe use of vaccines and related biological products.

The ACIP consists of 15 experts in fields associated with immunization and infectious diseases, including the chair and eight non-voting ex officio members. The ACIP:

- A. Develops technical recommendations on vaccine use and immunization practices.
- B. Approves vaccines that the VFC Program will provide.
- C. Recommends immunization schedules that are in harmony with other advisory groups, such as the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

The ACIP process to add vaccinations or to revise the United States immunization schedule is lengthy and deliberate. It can begin two-to-five years prior to licensure of a particular vaccine. The ACIP also considers changes in the epidemiology of vaccine-preventable diseases. Workgroups headed by ACIP members work with Centers for Disease Control and Prevention (CDC) staff and other consultants to examine issues around particular vaccines or disease epidemiology and present this information to the full ACIP membership several times throughout the year. Focused policy options, science, and other information supporting these policy choices are presented to, deliberated upon, and voted on by the ACIP in open public meetings.

Final immunization recommendations are published in the Morbidity and Mortality Weekly Report (MMWR) at <http://www.cdc.gov/mmwr/about.html>, when approved by the ACIP and the Director of the CDC.

ACIP's Role in the VFC Program

The ACIP makes its immunization recommendations for the entire U.S. population and is legislatively linked to the VFC Program. Therefore, in addition

to recommending vaccine use for the general population, the ACIP also approves the specific recommendations for inclusion of a vaccine in the VFC Program. The ACIP publishes these recommendations as VFC resolutions. The ACIP issues resolutions by vaccine type following licensure and/or as recommendations for change in use. VFC resolutions passed by the ACIP form the basis for VFC Program policies on vaccine availability and use. After a VFC resolution is in place, CDC establishes contracts for vaccines available through the VFC Program. Providers must administer VFC vaccines according to the guidelines outlined by the ACIP in the VFC resolutions.

ACIP-approved Vaccines and Biologicals Available through the VFC Program

The following vaccines are available through Florida's VFC Program:

- Diphtheria, Tetanus, and Acellular Pertussis (DTaP)
- *Haemophilus influenzae* type b (HIB)
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Influenza
- Meningococcal Conjugate (MCV4)
- Measles, Mumps, and Rubella (MMR)
- Pneumococcal Conjugate (PCV7)
- Polio (IPV)
- Rotavirus
- Tetanus and Diphtheria (Td)
- Tetanus, Diphtheria, and Acellular Pertussis (Tdap)
- Varicella and MMR/V (supplied by Merck via a separate reporting process)
- Combination Vaccines (Comvax®, Kinrix®, Pediarix®, Pentacel®, ProQuad®)

The following vaccines are available by request for high-risk areas only. Contact a VFC representative at (800) 483-2543 for further information.

- Diphtheria and Tetanus (DT-Pediatric)
- Pneumococcal Polysaccharide (PPV23)

The CDC's ***Vaccine Management, Recommendations for Storage and Handling of Selected Biologicals*** (see Appendix 5) lists the guidelines and recommendations on each individual vaccine.

Vaccine Reporting Requirements

The CDC and the Florida Department of Health require VFC providers to submit vaccine reports during their designated ordering vaccine schedule on the ***Vaccine Report Form*** (see Appendix 4) and the ***Varicella-containing Vaccine Order Form*** (see Appendix 4). Failing to comply with these reporting requirements will delay vaccine delivery or result in exclusion from the VFC Program.

Vaccine Report Form

VFC providers are responsible for the proper maintenance of their vaccine inventory. In most cases, the VFC Program resupplies vaccines based on the submission and the information obtained from the ***Vaccine Report Form***, explained in this section of the handbook.

The ***Vaccine Report Form*** details the usage of vaccines and establishes the amount of vaccines the VFC Program will ship to the provider for re-stocking purposes. The VFC staff will calculate the amount of vaccine used over the reporting period and will use that figure as the basis for the replacement order.

The provider will fax or mail this report form to the VFC Program office to:

Florida Department of Health, Vaccines for Children Program
4052 Bald Cypress Way, Bin A-11
Tallahassee, Florida 32399
Fax number: (850) 245-4734

The VFC Program vaccine distributor ships vaccine orders weekly, with the exception of varicella-containing vaccines, Monday through Friday. There must be someone in the provider's clinic to open vaccine packages, check the temperature monitor reading, inspect, and store the vaccines immediately at appropriate temperatures after the carrier delivers the vaccine. If the vaccine is not viable at receipt, providers should contact a McKesson Specialty representative at (877) 836-7123 ***within two hours***.

The provider must have temperature-monitored, alarm-equipped, stand-alone refrigerators and freezers. The refrigerator units should maintain the recommended temperature ranges of 35° to 46°F (2° to 8°C). The freezer compartment should maintain an average temperature of 5°F (-15°C) or colder. A combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage.

NOTE: *The Florida VFC Program does not approve dormitory-style refrigerators for VFC vaccine storage.*

How to Complete the Vaccine Report Form

- **VFC PIN:** The PIN is the six-digit Provider Identification Number assigned by the VFC Program. The PIN appears on the packing slips that accompany the vaccine shipments.
- **Name of Physician's Office, Practice, Clinic:** The provider will use the same facility name used for enrollment in the VFC Program. The facility name appears on the packing slips that accompany the vaccine shipments. If the facility name has changed, the provider will notify the VFC Program in writing; will complete the **Additional Information Form** (see Appendix 4), the **Provider Recertification Form** (see Appendix 3) and fax them along with the **Vaccine Report Form**, to (850) 245-4734.
- **Vaccine Delivery Address (Number and Street - No P.O. Boxes), E-mail, Contact Person:** Provide the vaccine delivery address, telephone and fax numbers, e-mail, and contact person. The name of a contact person is important in case the VFC Program staff have questions regarding the vaccine request. If this is a new address, the provider will complete the **Additional Information Form** and the **Vaccine Report Form** and fax them to (850) 245-4734.
- **Column labeled "Place an X" if you don't need this vaccine/Doses Shipped:** The provider will place a ✓ or X in the box for a particular vaccine to indicate they have sufficient supply to hold them until their next vaccine order.
- **Column A (Name of the Vaccine):** This column provides a list of all the vaccines available through the VFC Program.
- **Column B (Vaccine Brand Name):** This column provides a list of vaccine brands available through the VFC Program. Select only one brand choice for each vaccine. If the vaccine brand choice is not available, the VFC Program will send an equivalent brand that is in stock. If the provider does not specify a vaccine brand preference, the VFC Program will send the vaccine that is currently in stock.
- **Column C (Packaging/Preferred Presentation):** In this column, the provider will indicate packaging preference for the requested product. If providers do not specify a vaccine preference or packaging, the VFC Program will send the vaccine currently in stock.
- **Column D (Number of Vaccine Doses Used Since Last Order):** Record number of doses of all VFC vaccine administered since the submission of the last **Vaccine Report Form**.
 - List the number of doses used since the last vaccine order. Obtain this information from your **Vaccine Usage Worksheet** (see Appendix 4) or any other usage reports (example, registry-generated usage reports).

- If the provider did not administer a particular vaccine, write zero (0).
- **Column E (Vaccine Doses on Hand/Current Vaccine Inventory):** Record the actual number of VFC vaccine doses remaining in the refrigerator/freezer.
 - Do not report inventories of privately purchased vaccines.
- **Column F (Returned Vaccines Since Last Order):** Record the number of doses of expired or unserviceable vaccines. Return expired or unserviceable vaccine doses to the vaccine distributor in the postage-paid containers the distributor uses to ship vaccine. Complete and fax a copy of the **Vaccine Return and Waste Form** (see Appendix 4) to the VFC Program at (850) 245-4734 and include a copy of the form in the container with the unserviceable vaccines.
- **Important: If your vaccine brand choice and packaging is not available (check one of the choices on the right side):**
 - Send another vaccine brand/packaging.
 - Send the vaccine brand/packaging I choose when available.

If the provider does not select a choice, the VFC Program will replace the vaccines with the product currently in stock.
- **Children Immunized/Eligibility:**
 - **VFC Eligibility:** List, by age and eligibility, the number of children immunized. Obtain this information from the **Vaccine Usage Worksheet**. The VFC Program will not process orders without the completion of this section.
- **Additional Information Form:** This form is used to notify the VFC staff of any changes. Complete and fax the form to (850) 245-4734. These changes may include:
 - A. Practice name.
 - B. Practice shipping and mailing address.
 - C. Contact person.
 - D. Services and office hours.
 - E. Special requests, such as extra vaccine for back-to-school rush.
 - F. Brand name changes.
 - G. Upcoming vaccine expiration dates.
 - H. Health fairs: Complete the **Special Vaccine Order Form for Off-site Immunization Activities** (see Appendix 4).
 - I. Upon receipt of the **Vaccine Report Form**, the VFC Program representative will fax a confirmation to the provider. If providers

do not receive confirmation within seven business days, they should contact a VFC Program representative at (800) 483-2543.

Varicella-containing Vaccine Order Form

The pharmaceutical manufacturer, Merck & Co., Inc. ships the varicella-containing vaccine directly to the provider generally within 15 working days after the VFC Program processes the order. Varicella-containing vaccine requires a self-contained freezer, with a separate door, that can consistently keep the vaccine at 5°F (-15°C) or colder. **NOTE:** *The Florida VFC Program does not approve dormitory-style freezers for VFC vaccine storage.*

The **Varicella-containing Vaccine Order Form** (see Appendix 4) records the number of vaccine doses administered per month (obtain this information from the **Vaccine Usage Worksheet**). The provider reports the date and number of doses of their last vaccine shipment, the number of doses on-hand, and the number of doses ordered. The VFC staff will use the number of doses on-hand and the number of doses requested to calculate the number of doses processed and shipped to the provider.

Please read the Varicella-containing Vaccine Storage and Handling Certification in the **Varicella-containing Vaccine Order Form** carefully. By checking "yes" on the form, the provider is certifying that their practice is following the appropriate vaccine storage and handling procedures. **NOTE:** If the provider does not check this box, VFC staff **will not** process the order form.

How to Complete the Varicella-containing Vaccine Order Form

VFC providers should submit their **Varicella-containing Vaccine Order Form** when they have sufficient stock to allow 2-3 weeks for the processing and delivery of their vaccine order.

Type or print the information on the **Varicella-containing Vaccine Order Form**.

- **Provider Name:** Use the same facility name used for enrollment in the VFC Program. The facility name appears on the packing slips that accompany the vaccine shipments. If the facility name has changed, the provider will notify the VFC Program in writing. The provider will complete the **Additional Information Form**, the **Recertification Form**, along with the **Varicella-containing Vaccine Order Form**, and fax them to the VFC Program to (850) 245-4734.
- **VFC PIN:** The PIN is the six-digit Provider Identification Number assigned by the VFC Program. The PIN appears on the packing slips that accompany the vaccine shipments.
- **Vaccine Delivery Address (Specific Address/Building or Room Number):** Provide the vaccine delivery address. If this is a new address,

the provider will complete the ***Additional Information Form*** and the ***Vaccine Report Form*** and fax them to (850) 245-4734.

- **Telephone Number, Fax Number, Person Completing this Form, and Date:** Provide the telephone and fax numbers, and the name of the person completing this order form. The name of a contact person is important in case the VFC Program staff have questions regarding the vaccine request.
- **Please leave blank/Number of Doses Being Shipped:** For office use only, do not write any information in this column.
- **Date of Last Order:** The receipt date of the last varicella-containing vaccine order.
- **Number of Doses of Last Shipment:** The number of varicella-containing vaccine doses of the last shipment.
- **Number of Doses in the Freezer:** The actual number of doses of varicella-containing vaccine remaining in the freezer.
- **Number of Doses Needed:** The number of doses of varicella-containing vaccine needed.
- **Varicella-containing Vaccine Storage and Handling Certification:** By checking "yes" on the form, the provider is certifying that their practice is following the appropriate vaccine storage and handling procedures. If the provider does not check this box, VFC staff ***will not*** process the order form.
- **Additional Information Form:** The provider will complete and fax this form to the VFC Program to notify the VFC staff of any changes. These changes may include:
 - A. Practice name.
 - B. Practice shipping and mailing address.
 - C. Contact person.
 - D. Services and office hours.
 - E. Special requests, such as extra vaccine for back-to-school rush.
 - F. Brand name changes.
 - G. Upcoming vaccine expiration dates.
 - H. Health fairs: Complete and fax the ***Special Vaccine Order Form for Off-site Immunization Activities*** to the VFC Program at (850) 245-4734.

Vaccine Usage Worksheet Form

The ***Vaccine Usage Worksheet Form*** allows the provider to track each dose of VFC vaccine administered by the practice, and assists the VFC Program in determining the amount of replacement vaccine needed by the provider.

VFC providers must record each VFC vaccine administered. Undocumented use may result in a smaller vaccine re-supply shipment, which may leave the provider with less vaccine than is needed. Providers will retain the ***Vaccine Usage Worksheet Form*** for three years from the latest shot date on the individual worksheet page. This form is for internal use only; providers should not send copies of the ***Vaccine Usage Worksheet Form*** to the VFC Program unless otherwise instructed.

How to Complete the Vaccine Usage Worksheet Form

- **Column A (Patient ID #):** Record the VFC-enrolled child patient identification (ID) number.
- **Column B (Shot Date):** Record the date the provider administered the vaccine.
- **Column C (VFC Eligibility):** Place a check-mark in the appropriate box designating the VFC eligibility in the appropriate age sub-column.
- **Column D (Vaccines):** Indicate the vaccine administered. Add the number of vaccines administered and total the number of each vaccine administered in the last row of column D.
- **Columns E through I:** Record the total number of children immunized by age and eligibility.

Note: Record the totals of column D of the ***Vaccine Usage Worksheet Form*** in column D of the ***Vaccine Report Form***.

Vaccine Inventory Balance Sheet

Accurate reports will reduce or eliminate delays in the shipment of VFC vaccine. Use the ***Vaccine Inventory Balance Sheet*** (see Appendix 4) to balance your vaccine inventory. This form is for your internal use only. Do not send this form to the VFC Program.

How to Complete the Vaccine Inventory Balance Sheet

- **Column A (Name of the Vaccine):** Provides a list of all vaccines available through the VFC Program.
- **Column B (Column E of the last Vaccine Report Form):** Record the number of doses of column E of your last ***Vaccine Report Form*** in column B of your ***Vaccine Inventory Balance Sheet***.

- **Column C (Vaccines Returned/Expired/Unserviceable/Wasted):** Record the number of all unserviceable or expired vaccine doses returned to the VFC Program vaccine distributor.
- **Column D (Last VFC Vaccine Shipment):** Record the number of VFC vaccine doses received in the last VFC vaccine shipment.
- **Column E (Last Additional VFC Vaccine Shipment):** Record the additional number of VFC vaccine doses received since the last report.
- **Column F (Current Vaccine Inventory on Hand):** Record the number of VFC vaccine doses in the refrigerator/freezer. Develop and maintain a separate vaccine stock record for both public and private vaccines.
- **Column G (Vaccine Doses Used/from Vaccine Usage Worksheets):** Record the number of VFC vaccine doses administered since submission of the last *Vaccine Report Form*.
- **Column H (Vaccine Ending Inventory):** This column should match the number of VFC vaccine doses in your refrigerator/freezer.

Guidelines for the Transportation and Administration of Vaccines to Off-site Immunization Activities

When transporting vaccines from your clinic to another location, make sure you follow proper vaccine transportation procedures to protect your vaccine supply. Work with the VFC Program representative or BOI field staff to review and ensure that your vaccine transportation protocol will protect your vaccine adequately. Keep the following points in mind as you develop your protocol for vaccine transportation:

- Prior to the planned activity, complete and fax the ***Special Vaccine Order Form for Off-site Immunization Activities*** to the VFC Program at (850) 245-4734. Allow two to three weeks for processing and delivery of the vaccines.
- Establish a protocol that includes keeping a temperature log with the insulated container when transporting vaccines to other locations. Refer to Appendix 4 for a ***Cooler Temperature Log Form***.
- Designate one individual as the vaccine coordinator, and one back-up person, and assign them the responsibility to inform all individuals who will be handling and administering vaccines about eligibility screening, specific storage requirements, and stability limitations of the vaccines they use at the off-site location.
- Carefully transport vaccines in insulated containers with an adequate number of cold packs. Be careful not to put too much cold mass in your container, as it may inadvertently freeze the vaccines. Include a

thermometer and check it when the staff members open the insulated containers.

- Varicella and MMRV vaccines have stringent temperature requirements and providers must transport them on dry ice. For this reason, the VFC Program does not recommend routinely transporting varicella and MMRV unless in an extreme emergency.

General Protocol for Staff Members who Handle or Administer Vaccines:

- Train all staff members involved in administering vaccines in the special handling and administration requirements of the varicella and MMRV vaccines.
- Transport inactivated vaccines carefully. Unpackaged vials of inactivated vaccines, such as DTaP, Hib, Hepatitis B, etc., must not touch the cold packs directly as the vaccine may freeze. It is best to keep vaccines in their original package during transport.
- Refrigerate diluents in advance, so they do not raise the temperature of the previously refrigerated vaccines carried in the insulated containers.
- In hot climates and summer seasons, keep the insulated containers in the air-conditioned interior of the car during transport, rather than in the trunk.
- The provider's responsibility at the off-site location is: to ensure all vaccines are stored properly; to ensure the cooler temperature range for storage is in the acceptable range; to keep a temperature log; and to monitor temperatures as often as possible (confer with a nurse to verify what is practical).
- Maintain the vaccine in an insulated cooler and keep the cooler closed as much as possible. Keep a thermometer in the cooler with the vaccines, and check and record temperatures periodically to ensure that the cold chain is not broken. The National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention recommends that, at a minimum, staff should check and record vaccine temperatures hourly.
- The designated staff will unpack, check, and immediately store the vaccines at the recommended temperature range when they return to the clinic from the off-site activity. The designated staff will fax a copy of the **Cooler Temperature Log Form** to the VFC Program at (850) 245-4734.

- If the designated staff has suspicion of a cold chain failure or evidence of vaccine exposure to temperatures outside the recommended temperature range, the staff should immediately take the following steps:
 - A. Contact the manufacturer(s) and the VFC Program for guidance.
 - B. Separate and label the vaccines "DO NOT USE" until notification from the vaccine manufacturer(s) or the VFC Program staff indicating the vaccines are still potent.
 - C. Do not discard any vaccine unless directed to do so by the vaccine manufacturer(s) or the VFC Program staff.
 - D. If the vaccine becomes unserviceable, the designated staff should:
 1. Account for these doses in the **Vaccine Return and Waste Form**.
 2. Contact a VFC Program representative at (800) 483-2543 prior to returning any vaccines.
 3. Fax a completed **Vaccine Return and Waste Form** to the VFC Program at (850) 245-4734.
 4. Place the original copy of the **Vaccine Return and Waste Form** with the unserviceable vaccines in the recyclable insulated container in which McKesson Specialty originally shipped the vaccines.
 5. If the provider does not have a postage-paid shipping label, they should contact the VFC Program at (800) 483-2543 to request one.
 6. Return the unserviceable vaccines to McKesson Specialty. No ice is necessary in the container since the vaccine is unserviceable.

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