MODULE

1

OVERVIEW

Immunization Section—Vaccines for Children Program

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MODULE 1: Overview

Introduction

The Immunization Section is a part of the Florida Department of Health, Division of Disease Control and Health Protection, Bureau of Communicable Diseases. The Immunization Section focuses on increasing immunization levels in Florida and decreasing vaccine-preventable diseases.

Mission:

To protect, promote and improve the health of all people in Florida through integrated state, county, and community efforts.

Vision:

To be the Healthiest State in the Nation.

Values:

- Innovation—We search for creative solutions and manage resources wisely.
- Collaboration—We use teamwork to achieve common goals and solve problems.
- Accountability—We perform with integrity and respect.
- Responsiveness—We achieve our mission by serving our customers and engaging our partners.
- Excellence—We promote quality outcomes through learning and continuous performance improvement.

One way of accomplishing our vision is by using federal and state funds to obtain vaccines for distribution to eligible health care providers through the Florida Vaccines for Children (VFC) Program. This program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of their inability to pay. The Omnibus Budget Reconciliation Act of 1993 created the VFC Program as a new entitlement program, required as part of each state's Medicaid plan. The program was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative. Funding for the VFC Program is approved by the Office of Management and Budget and allocated through the Centers for Medicare & Medicaid Services (CMMS) to the Centers for Disease Control and Prevention (CDC). Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).

Highlights of the VFC Program:

- Provides public-purchased vaccine for eligible children at no charge to VFC-enrolled public and private providers in all states, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.
- Provides all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP).
- Saves parents and VFC-enrolled providers out-of-pocket expenses for vaccine.

- Provides cost savings to states through bulk purchase of vaccine using CDC contracts at lower prices and eliminates state-to-state variations in price.
- Eliminates or reduces vaccine cost as a barrier to vaccinating eligible children.
- Reduces the practice of referring children for vaccination from the private sector to the public sector.

ACIP

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 fifteen 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: **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)
- Meningococcal B Conjugate (MenB)
- Measles, Mumps, and Rubella (MMR)
- Pneumococcal Conjugate (PCV13)
- Polio (IPV)
- Rotavirus
- Tetanus and Diphtheria (Td)
- Tetanus, Diphtheria, and Acellular Pertussis (Tdap)
- Varicella and MMR/V
- Combination Vaccines (Kinrix®, Pediarix®, Pentacel®, ProQuad®)

The following vaccines are available by request for high-risk clients only. Contact a VFC representative at 1-800-483-2543 for further information.

- Diphtheria and Tetanus (DT-Pediatric, county health departments only)
- Pneumococcal Polysaccharide (PPSV23, county health departments only)

The CDC's ***Vaccine Management, Recommendations for Storage and Handling of Selected Biologicals*** lists the guidelines and recommendations on each individual vaccine and is located at: **www.immunize.org/packageinserts/**.

For more information on the Florida VFC Program visit our website at: **www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/index.html.**

Florida State Health Online Tracking System (Florida SHOTS)

Florida SHOTS assists VFC providers in managing their VFC inventory, completing their VFC orders, and documenting the VFC storage unit temperatures. In addition, it helps ensure that the required immunization records for childcare centers and school attendance are easy to locate, children's immunizations are up-to-date, prevents unnecessary duplicative vaccinations, and consolidates immunization records from multiple health care providers. The benefits of Florida SHOTS are:

- Produces the legal immunization record (*DH Form 680*) required for school and daycare center attendance.
- Consolidates immunization records from all providers into one record per patient.
- Immunization information is accessible 24 hours a day, seven days a week.
- The immunization tracking software never has to be downloaded or upgraded on your computer.
- Provides reliable immunization history for any child.
- Identifies patient's previously reported contraindications.
- Provides definitive information, reminders, recalls on immunizations that are due or overdue, and reduces paperwork.
- Generates immunization reports for managed care organizations.
- Provides current recommendations, information, and new vaccines.

For more information about the Florida SHOTS Program, call the toll-free telephone number at 1-877-888-SHOT or send an email to: **FLShots@FLHealth.gov**.

Immunization Section Contact Information

VFC Program
Phone: 1-800-483-2543
Email: **FloridaVFC@FLHealth.gov**

Florida State Health Online Tracking System (SHOTS)
Phone: 1-877-888-SHOT (7468)
Email: **FLSHOTS@FLHealth.gov**

General Information
Phone: (850) 245-4342
Email: **Immunization@FLHealth.gov**

MODULE

2

ELIGIBILITY

Immunization Section—Vaccines for Children Program

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MODULE 2: Eligibility

VFC Eligibility Categories

The Vaccines for Children (VFC) Program offers vaccines at no cost to enrolled providers for eligible children. In order for children to receive their vaccinations through the VFC program, eligibility screening and documentation must take place at each immunization visit. Children through 18 years of age who meet at least one of the following criteria are eligible to receive VFC vaccine:

- Medicaid-eligible: A child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably and refer to children who have health insurance covered by a state Medicaid Title XIX program).
- Uninsured: A child who has no health insurance coverage.
- American Indian or Alaska Native: As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
- Underinsured:
    - A child who has health insurance, but the coverage does not include vaccines, or
    - A child whose insurance does not cover all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines. The child would be eligible to receive those vaccines not covered by the insurance.

Please note: Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC), or under an approved deputization agreement. For a list of Florida's FQHCs, visit the Florida Association of Community Health Centers website at www.fachc.org. For a list of Florida's RHCs, visit the Florida Department of Health's website at: **www.floridahealth.gov/programs-and-services/community-health/rural-health/rural-health-networks.html** or see **Appendix 2**.

Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met.

Children enrolled in the Florida KidCare Program, including MediKids and the Healthy Kids Program, are insured and therefore not eligible to receive VFC Program vaccine. The KidCare (health insurance) programs cover vaccines and administration fees.

Please note: Underinsured, limited coverage, and "caps" should be rare instances with the implementation of the Affordable Care Act (ACA).

Eligibility Determination and Documentation

To ensure VFC Program vaccine is given to eligible patients only, a *Patient Eligibility Screening Record* (PESR) (see **Appendix 2** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/patient-eligibility-screening-record-vfc.pdf**) must be completed for all children at each immunization encounter, and verified

during subsequent visits. Each PESR must be kept in the patient's medical record for three years. If an eligible child becomes ineligible, the PESR record must reflect the change and the date of change.

Per *Federal Law 42 US Code 300aa-25*, the following must be documented in the patient's medical record for each vaccine administered:

- Vaccine name
- Date administered
- Publication date of Vaccine Information Statement (VIS)
- Date VIS provided to patient
- Name of vaccine manufacturer
- Vaccine lot number
- Name and title of vaccinator
- Clinic address

Providers who utilize Florida State Health Online Tracking System (SHOTS) to document vaccine administration data should enter the patient's eligibility status and vaccine administration information within 14 days of the visit.

Fee Policies

Providers may not charge VFC-enrolled patients for the cost of a vaccine provided by the VFC Program. However, providers may bill office visits and Medicaid and/or Medicaid Health Maintenance Organizations (HMOs) for vaccine administration fees.

Families not covered by Medicaid or Medicaid HMOs may be charged a vaccine administration fee. This administration fee should not exceed the maximum regional charge (see **Appendix 2** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/max-region-charges.pdf**). Providers may not refuse the administration of a vaccine to a VFC-eligible client due to an accompanying adult's inability to pay an administration fee.

Special Populations

The VFC Program recognizes several situations where the use of special VFC eligibility screening forms may improve the efficiency of the provider's implementation of the VFC Program, or are necessary because of the individual's situation.

1) Comprehensive Certifications

   If a provider exclusively serves children through 18 years of age who are American Indian or Alaska Native, or serves Medicaid enrolled patients only, he/she may use the appropriate comprehensive certification form (See **Appendix 2** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/comp-cert-form-medicaid.pdf**). These certification forms would be in lieu of individual VFC screening forms, and must be signed annually.

   The VFC Program will verify the information against the most current provider profile, and ensure the provider's VFC eligible and non-eligible population does not change during the 12 months covered by the certification.

2) Minors Under 19 Years of Age at Family Planning Clinics

Another population requiring specialized VFC screening is minors under 19 years of age without insurance, presenting at Title X family planning clinics. The Title X Family Planning Program was enacted in 1970 as Title X of the Public Health Service Act. Title X is the only federal grant program dedicated solely to providing individuals with comprehensive family planning and related preventive health services.

A person under 19 years of age who may have insurance, but does not have access to the insurance because of confidential circumstances for seeking services in a family planning clinic/sexually transmitted disease clinic, is considered uninsured for the purposes of the VFC Program.

a. The family planning clinic must screen these adolescents for VFC eligibility using the *Patient Eligibility Screening Record for Children in Family Planning Clinics* (see **Appendix 2** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/patient-eligibility-screening-family-planning.pdf**).
b. In addition, each family planning clinic must document all VFC vaccines administered to unaccompanied minors without insurance information on the administration log titled *Family Planning Clinic Unaccompanied Minor without Insurance Information VFC Vaccine Log* (see **Appendix 2** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/family-plan-clinic-unaccomp-minor-wo-insurance.pdf**).
c. Each clinic should submit the completed logs to the VFC Program monthly.
d. The VFC Program will review each clinic's log, and
    1) Collect aggregate information annually on the number of children without insurance who are provided VFC Program vaccine in family planning clinics.
    2) This information must include the type and number of VFC Program vaccines administered to these children.

The VFC Program does not in any way regulate the issue of medical consent for the provision of medical care to minors. The assumption is that the clinic provides any such care in accordance with Florida's medical consent laws as they pertain to minors.

MODULE

3

PROVIDER ENROLLMENT

Immunization Section—Vaccines for Children Program

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MODULE 3: Provider Enrollment

Who May Enroll

Providers enrolling to receive vaccine from the Florida VFC Program must hold a license in Florida, have prescribing authority for vaccines, and be a person (or persons) who will be responsible (and liable) for the conditions outlined in the provider enrollment agreement for the facility or organization. Qualifying providers include: Medical Doctor (MD), Doctor of Osteopathy (DO), Advanced Registered Nurse Practitioner (ARNP), or Physician Assistant (PA) with their signing collaborating physician. Organizations self-identifying as a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) must include a copy of their federal documentation each year with annual enrollment that validates their FQHC or RHC designation.

Please note: *Providers enrolling in the Florida VFC Program to receive vaccines agree to all conditions contained in this handbook and the Provider Agreement signed by the licensed provider.*

Initial Enrollment & Annual Enrollment Process

Annually all providers are required to complete the Florida VFC Provider Agreement in order to participate in the VFC Program. The initial forms are the Florida VFC Program Provider Agreement and the Florida VFC Program Provider Profile/Update Form; they will be emailed upon enrollment request. Send an email to FloridaVFC@FLHealth.gov to receive further information and enrollment paperwork. As of April 2015, all currently enrolled VFC providers are required to complete the Annual Enrollment process within Florida State Health Online Tracking System (SHOTS).

Further instructions, are located on the Immunization Section website at: **www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/enrollment.html** and **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/reenrollment.html**.

To initially enroll:

- Send an email to FloridaVFC@FLHealth.gov requesting enrollment information.
- Complete the *Florida VFC Provider Agreement* and the *Florida VFC Program Provider Profile/Update form* received via email and email it to the VFC Program.
- If your facility is a FQHC or RHC, scan/email the additional federal documentation validating your designation.
- Must have proper vaccine storage equipment (see Module 5b) and submit copies of the certificate of calibration for each thermometer.
- Must submit one week of twice a day temperature readings for the refrigerator and freezer vaccine storage units. The provider must record temperature readings from a certified calibrated thermometer for the refrigerator and freezer on the *Temperature Log for Vaccines* form (Fahrenheit forms located at: **Appendix 3** and **www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/temp-logs-color-f-web.pdf**.
  Celsius forms located at: **Appendix 3** and **www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/temp-logs-color-c-**

web.pdf). As of **January 1, 2015**, providers are required to enter their twice a day temperature readings for each storage unit into Florida SHOTS.

- The refrigerator units must maintain the recommended temperatures of 35° to 46°F (2° to 8°C). The freezer compartment must maintain temperature of 5°F (-15°C) or colder.
- The enrolling provider, vaccine coordinator and the back-up coordinator must complete the CDC "You Call the Shots" training found at **http://www.cdc.gov/vaccines/ed/youcalltheshots.htm** and send in certificates of completion.
- Complete an Orientation Site Review (OSR) performed by your local Area Immunization Consultant that includes:
    - Review of the VFC Program requirements.
    - Review of vaccine storage and handling procedures.
    - Verification that provider's office has proper refrigerator/freezer vaccine storage units with a certified calibrated thermometer(s).
    - Answer provider or staff questions
- Upon completion of the OSR, the VFC Program will assign a Provider Identification Number (PIN). The PIN is a unique six-digit number per site location that should be used in all interactions with the VFC Program. Referencing the provider PIN in the subject line of any correspondence with the VFC Program staff will help expedite the processing of your information.
- Also upon completion of the OSR, the VFC Program will contact the provider to have ten doses of hepatitis B or Tdap vaccine shipped to the provider's office. This shipment is intended to confirm the provider's shipping location information is valid. As soon as the provider receives this shipment, they must contact the VFC Program at 1-800-483-2543 to receive the following form:
    - *VFC Order Worksheet*. The provider will choose their preferred vaccine brand and packaging to get them started in the VFC Program. The VFC Program representative will determine the preliminary number of doses of each vaccine type indicated to be shipped.

To annually enroll:

- Complete the Florida VFC enrollment within Florida SHOTS annually. The VFC Program will notify providers via email 60 and 30 days prior to their required annual enrollment deadline.
- The enrolling provider, vaccine coordinator and the back-up coordinator must complete the annual provider training. Each year the VFC Program will notify providers as how to meet the training requirement.
- Providers will be inactivated from the VFC Program if they do not complete the annual enrollment by the required deadline.

VFC Program Participation Requirements

The requirements to participate in the VFC Program are listed in the *VFC Provider Agreement.* The enrolling provider is required to sign this form to consent to adhere to the requirements of the program.

The VFC Program requires providers to:

- Screen all children birth through 18 years of age for eligibility at each immunization encounter.
- Comply with ACIP approved immunization schedules, vaccine dosage, and vaccine contraindications unless:

    - In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate.
    - The particular requirements contradict state law, including those pertaining to religious and medical exemptions.
- Immunize eligible children with vaccine at no charge to the patient for the vaccine.
- Do not deny an eligible child vaccine due to the inability to pay the administration fee.
- The vaccine administration fee for non-Medicaid children receiving vaccine may not exceed the Regional Maximum Charge of $24.01 per vaccine dose.
- Distribute the current Vaccine Information Statements (VIS) each time a provider administers a vaccine, and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at: **www.vaers.hhs.gov/**.
- Comply with the requirements for vaccine ordering, vaccine accountability, vaccine management, and agree to operate within the VFC Program requirements in a manner intended to avoid fraud and abuse.
- The enrolling provider must sign the *VFC Provider Agreement* and complete the *Florida VFC Program Provider Profile/Update form.*
- The enrolling provider, vaccine coordinator, and the back-up vaccine coordinator must complete annual training.
- Providers are required to notify the VFC Program immediately of any change including, but not limited to: the enrolling provider, vaccine coordinator, and the back-up vaccine coordinator, mailing/shipping address, and vaccine delivery hours.

Please note: Beginning on March 1, 2016, providers will be required to use a continuous temperature monitoring device with a probe buffered material in all of their VFC vaccine storage units. The temperature readings are required to be uploaded into Florida SHOTS. The VFC Program is supplying providers with a Log Tag for each of their VFC vaccine storage units to meet this new requirement. If a provider would like to purchase their own continuous monitoring device they will need to contact the VFC Program for more information.

Termination of the VFC Provider Agreement

The VFC Program, or the enrolled provider, may terminate this agreement at any time for personal reasons or failure to comply with these requirements. If the provider chooses to terminate the agreement, he or she agrees to transfer any unused and unexpired VFC vaccine. The provider should contact their VFC Area Immunization Consultant to assist in any vaccine transfers. The provider is responsible for completing and sending a copy of the *Florida VFC Program Disenrollment Form* (see **Appendix 3** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/disenrollment-form.pdf**) as a notification of the intent to terminate no later than 30 days prior to the actual dissolution to the VFC Program at FloridaVFC@FLHealth.gov. As soon as the VFC Program receives a copy of the disenrollment form, a VFC Program representative will contact the provider regarding the transfer of any VFC vaccine.

MODULE

4

VACCINE INVENTORY MANAGEMENT

Immunization Section—Vaccines for Children Program

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MODULE 4: Vaccine Inventory Management

Proper vaccine inventory management is essential to the VFC Program. The VFC Program ensures each provider receives the correct amount of vaccine with each order by reviewing vaccine doses administered, wastage and current on-hand inventory numbers reported by the provider at the time order is placed. The VFC Program recommends small, more frequent vaccine orders to minimize wastage due to storage and handling issues as well as expired vaccine. Accurate vaccine inventory management reduces waste of federal purchased vaccines and lowers cost to providers should any vaccine restitution be required.

Florida SHOTS Online Order Request

VFC providers are responsible for the proper maintenance of their vaccine inventory. The VFC Program resupplies vaccines based on the provider submission of vaccine usage and inventory within Florida SHOTS.

The ***Online Order Request Page*** details the usage of vaccines and current inventory establishing the amount of vaccines the VFC Program will ship to the provider for replenishment purposes. The VFC staff will calculate the amount of vaccine used over the reporting period and will use that calculated figure as the basis for the replacement order.

The provider will submit the order request online to the VFC Program at: **www.flshots.com/flshots/Signin.csp**.

How to Create an Electronic VFC Order Request

For a step-by-step guide on how to create a vaccine order request, go to **flshotsusers.com/wp-content/uploads/2013/07/Creating-Electronic-Order-5.16.14-small.pdf**. Once submitted, the VFC Program office will approve your electronic order request in Florida SHOTS or contact you regarding any discrepancies.

The VFC Program vaccine distributor delivers vaccine orders 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 or amount received differs from amount requested, providers should contact a VFC Program representative at 1-800-483-2543 ***immediately***.

For Florida VFC Program specific required vaccine storage equipment, refer to Module 5B.

Vaccine Utilization Reporting

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 may document their administered doses either by

using Florida SHOTS as their immunization registry and running the Vaccine Utilization Report or using the Vaccine Usage Worksheet.

Please Note: Beginning January 1, 2016, all VFC providers will be required to enter their vaccine administration data directly into Florida SHOTS. The Vaccine Usage Worksheet will no longer be accepted by the VFC Program.

Vaccine Utilization Report within Florida SHOTS

All Florida VFC providers have the ability and are recommended to use Florida SHOTS as their immunization registry to track administered vaccines. Providers may run the Vaccine Utilization Report within Florida SHOTS to retrieve their VFC administration numbers of any time frame for immunizations entered into Florida SHOTS either manually or through data uploading from the provider's Electronic Medical Records software. This report documents VFC specific information such as lot number, manufacturer, expiration date, et cetera and enables providers to easily track administrations. To view a webinar on how to run the Vaccine Utilization report, please go to **https://attendee.gotowebinar.com/register/3000000000010677827**

Vaccine Usage Worksheet Form

The ***Vaccine Usage Worksheet Form***, found at: **www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vaccine-usage-worksheet.pdf,** allows the provider to manually track each dose of VFC vaccine administered by the practice if they are not using Florida SHOTS for their administrations, and assists the VFC Program in determining the amount of replacement vaccine needed by the provider.

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*

- Patient Name or ID: Record the VFC-enrolled child patient identification (ID) number or name.
- Shot Date: Record the date the provider administered the vaccine.
- VFC Eligibility: Place a checkmark in the appropriate box designating the VFC eligibility in the appropriate age sub-column.
- VFC Program Vaccines: Indicate the vaccine administered. Total the numbers for each vaccine type administered and enter that number in the last row of the chart.
- Lower Section: Record the total number of children immunized by age and eligibility.

Vaccine Inventory Balance

Accurate inventory will reduce or eliminate delays in the shipment of VFC vaccine. Print and use either your Order Request or Vaccine Order Worksheet to balance your vaccine inventory. This form is for your internal use only. Do not send this form to the VFC Program.

Vaccine Returns

The VFC Program requires providers to return expired and unserviceable vaccines to McKesson Specialty, the VFC Program centralized vaccine distributor. ***EXCEPTION***: *Under **no** circumstances should providers return syringes filled but not used (with or without needles), open vials, or any multidose vial from which providers have withdrawn doses. Providers must dispose of them according to usual medical biosafety procedures.* Providers are required to complete their return in Florida SHOTS.

Performing Return/Waste Adjustments

Wasted, expired, and spoiled vaccines should be adjusted out of the provider inventory in Florida SHOTS.

Once a month, you should check for expired/wasted/spoiled vaccine at your site and perform the appropriate inventory adjustment.

For a step-by-step guide on how to return/waste vaccines go to **www.flshotsusers.com/wp-content/uploads/2013/07/How-To-Manage-Vaccines-5.15.14.pdf**. The Returns/Waste section begins on page 10 of the guide.

MODULE

5

VACCINE STORAGE AND HANDLING

Immunization Section—Vaccines for Children Program

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MODULE 5-A: Vaccine Storage and Handling
Vaccine Management Requirements

An important responsibility of the providers is to work with the VFC Program to develop and implement accurate but simple plans for routine and emergency vaccine management. Refer to Appendix 5 for a sample of a vaccine management plan and an emergency storage and handling plan.

All providers must meet the following requirements in order to participate in the VFC Program:

Vaccine Coordinators

Designate one staff member to be the primary vaccine coordinator, and at least one back-up vaccine coordinator who is able to perform the vaccine storage and handling responsibilities in the event that the primary coordinator is unavailable. These positions will be responsible for some key requirements and will provide oversight for all vaccine management within the office. The primary vaccine coordinator and/or back-up coordinator are the VFC contacts for the office, as documented on the VFC Program Agreement.

The primary and back-up vaccine coordinators are responsible for the following vaccine management activities:

- Conduct a monthly vaccine inventory and document vaccine usage daily.
- Ensure that refrigerator temperatures are between 35° to 46°F (2° and 8°C).
- Keep the freezer temperature at 5°F or lower (-15°C or colder).
- Adjust the temperature of the vaccine storage unit as needed.
- Ensure temperature monitoring is occurring in each VFC vaccine storage unit; see temperature monitoring section on page 4 of this module.

Vaccine Management Plans

Providers should use the vaccine management template at: **www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vaccine-management-plan.pdf**. All Florida VFC Program providers must have current written vaccine management plan available for review.

The vaccine management plan includes the following aspects:

- Contact information of the person(s) responsible for managing the VFC vaccine.
- VFC Program roles and VFC Program activities tied those roles.
- Vaccine Storage and Handling Guidelines.

- Staff Training on Vaccine Management and VFC Program Requirements.
- Signature Log.

At a minimum, providers must review and update the vaccine management plan annually, or when there is a change in staff that has specific responsibilities in the plan. The Immunization Section Field Operational team and/or VFC Program staff may request a copy of the plan for review and evaluation at any time.

Vaccine Emergency Storage and Handling Plans

Providers should have a vaccine emergency response plan that includes the following:

- Role of vaccine coordinator and alternate (back-up).
- Emergency contact list.
- Storage unit specifications.
- Alternate storage facilities.
- Written instructions for after hours.
- Adequate supplies for packing and transport.
- Protocol for packing.
- Protocol for transport.

Review the May 2014 VFC Storage and Handling Toolkit, located at **http://www.cdc.gov/vaccines/recs/storage/toolkit/**, for information you might include in each of the above sections of a complete emergency plan. For a sample plan see **Appendix 5A** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/emergency-response-plan.pdf**

Vaccine Storage Equipment

Please refer to Module 5B for detailed vaccine storage equipment information.

Temperature Monitoring

Temperature monitoring is the responsibility of the primary and back-up vaccine coordinators. If other staff must monitor temperatures, the primary or back-up coordinator should train these individuals on how to respond to and document actions taken when temperatures are outside the appropriate range.

Manage a Temperature Log using one of the following options:

- Upload a data file into Florida SHOTS from a continuous temperature monitoring data logger once during a seven calendar day period.* You do not need to maintain a paper temperature log if the data file includes

inspection marks which shows that someone reviews the storage unit's temperature twice each day. Maintain a paper log if the data file does not have these marks.

- Manually input twice daily temperatures within Florida SHOTS at least once during a seven calendar period.* If data is manually entered into Florida SHOTS a physical **Fahrenheit** or **Celsius Temperature Log** must be posted and completed on the storage unit door (see **Appendix 3**).

**Florida SHOTS will freeze ordering capabilities and require a provider to contact the VFC Office for assistance if a provider does not input temperatures for their VFC storage units into Florida SHOTS at least once during each seven day period.*

Please note: Beginning on March 1, 2016, providers will be required to use a continuous temperature monitoring device with a probe buffered material in all of their VFC vaccine storage units. The temperature readings are required to be uploaded into Florida SHOTS. The VFC Program is supplying providers with a Log Tag for each of their VFC vaccine storage units to meet this new requirement. If a provider would like to purchase their own continuous monitoring device they will need to contact the VFC Program for more information.

Record the following information if maintaining a paper temperature log daily:

- Staff initials of the individual recording the information.
- Room temperature when recording the unit temperature.
- Unit temperature and exact time/date of recording first thing in the morning.
- Unit Temperature and exact time/date of recording last thing at the end of the day
- Minimum and Maximum temperature of the unit for the previous 24 hours first thing in the morning.
- Record refrigerator/freezer temperatures on the ***Temperature Log for Vaccines Form*** twice a day (beginning and end), ensuring that refrigerator temperature ranges are between 35° to 46°F (2° to 8°C). Keep the freezer temperature 5°F or lower (-15°C or colder).
- Monitoring and recording temperatures twice a day is required, even if a continuous graphing/recording thermometer or a digital data logger is used.
- Correct improper vaccine storage conditions immediately, including inappropriate exposure to light or storage temperatures outside the recommended ranges. Document the actions taken on the ***Emergency Response Plan Form*** (see **Appendix 5**).
- Maintain and store three years' worth of completed ***Temperature Log for Vaccines Forms*** or data logger data files on your computer. The Florida Immunization Section Field Staff will review this information when they conduct VFC Compliance site visits.

- Monitor vaccine storage temperatures by using a centrally located, certified, calibrated thermometer or continuous recording thermometer both in the refrigerator and freezer. Follow the manufacturer's recommended schedule for recalibration of the thermometers.

Vaccine Shipments

- Immediately check the vaccine cold chain monitors when vaccine arrives at the office or clinic.
- If upon the arrival of the vaccine shipment there is a vaccine viability concern (i.e., if the monitor is not activated or if there is damage to the package), contact a McKesson Specialty representative at 1-877-836-7123 or VFC Program representative at 1-800-483-2543 within the contractual two-hour window.
- Develop a policy with protocols and procedures for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. You can access the CDC storage and handling guidelines, *Maintaining the Cold Chain during Transport*, at: **http://www.immunize.org/catg.d/p3049.pdf**.

Action Plan/Vaccine Wastage

What to do if a power failure occurs, staff left the refrigerator door open, the temperature was too cold or too hot, the refrigerator plug was pulled, or in any other situation that would cause improper storage conditions:

- Transfer and store the vaccines at appropriate temperatures in a refrigerator/freezer that is working properly. Do not throw out the affected vaccines. Ensure the exposed vaccines are separated to prevent inadvertent administration, and label with "DO NOT USE", until the provider receives a response from the vaccine manufacturer indicating that the vaccine is still potent.
- Do not discard any vaccine, unless directed to do so by the VFC Program Office.
- Close the door and/or plug in the refrigerator/freezer.
- Record the current temperature of the refrigerator/freezer on the ***Temperature Log for Vaccines Form***. Return refrigerator/freezer to acceptable temperature ranges and monitor temperatures on an hourly basis.
- Contact the VFC Program Office to report the potential vaccine loss and obtain the VFC Incident Checklist (See **Appendix 5A** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vfc-incident-checklist.pdf**) which provides the steps providers take to

address the situation.

- Contact the manufacturer(s) (phone numbers located on the VFC Incident Checklist) to obtain letters specific to each vaccine's viability.
- If directed to by the VFC Program Office, return the vaccines (except syringes that you filled but did not use, syringes with or without needles, open vials or any multi-dose vial from which any dose has been withdrawn) to McKesson Specialty in the recyclable insulated vaccine containers in which the vaccines were originally shipped.
- To ensure accountability for expired or unserviceable vaccines, adjust out the spoiled doses from your VFC inventory and document these vaccines within Florida SHOTS under ***Report Returns/ Waste.***
- Include a copy of the Florida SHOTS ***Vaccine Return and Waste Form*** with all expired or unserviceable vaccines in the shipping container.
- Request a shipping label when completing the Return and Waste Form within Florida SHOTS. This information will be submitted to McKesson who will then send the provider a return label.

Vaccine Security and Equipment Maintenance

Safeguard the electrical supply to the VFC storage units and post warning notices at both the electrical outlet and the circuit breaker to prevent accidental disconnection of power.

- Plug the storage units into an outlet in a restricted access area.
- DO NOT plug a VFC storage unit into a surge protector. If the power goes out, anything plugged into a surge protector will not turn on when power is restored.

- Label the refrigerator, electrical outlets, fuses, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and the immediate steps the provider will take in case of interruption of power. Contact the VFC Program at 1-800-483-2543 to request "***DO NOT UNPLUG***" stickers or print them here: **http://www.immunize.org/catg.d/p2090.pdf** and **http://www.immunize.org/catg.d/p2091.pdf**.
  - Limit access to the vaccine supply to authorized personnel only.
  - Install locks on refrigerators and, if possible, the electrical plug.
  - Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
  - Provide a source of back-up power (generators) and a security system to

alert appropriate personnel in the event of a power outage. If the provider's building has auxiliary power, use the outlet supplied by that system.

- Test back-up generators quarterly and maintain back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

MODULE 5-B: Vaccine Storage and Handling
Vaccine Storage Equipment

Storage and Handling

Even a small practice is likely to have thousands of dollars' worth of vaccine in the refrigerator at a time. Think of your vaccine storage equipment as an insurance policy to protect patients' health and your facility against costly vaccine replacement, inadvertent administration of compromised vaccine, and other potential consequences (e.g., the costs of revaccination and loss of patient confidence in your practice). Vaccines must be stored appropriately in order to maintain potency. A temperature controlled environment used to maintain and transport vaccines in optimal condition is called the vaccine cold chain. The vaccine cold chain relies on three main elements:

- Effectively trained personnel
- Appropriate transportation and storage equipment
- Efficient management procedures

A staff member at each facility must be designated as the vaccine coordinator who will be responsible for ensuring that all vaccines are stored and handled correctly. One back-up vaccine coordinator must be designated who can assume the same responsibilities in the absence of the primary vaccine coordinator.

Vaccine Storage Units

Providers must have appropriate equipment that is used only for vaccine storage (i.e., no food or drink is in the unit) and maintains proper temperature required conditions for vaccine storage.

Refrigerators and Freezers

It is highly recommended that providers use stand-alone refrigerator and freezer units, meaning a self-contained unit that only refrigerates or freezes and is suitable for vaccine storage. These units can vary in size, from a compact, under-the-counter style to a large, stand-alone, pharmaceutical grade storage unit. However, a combination refrigerator/freezer unit sold for home use is acceptable for vaccine storage if the unit has **dual controls** (i.e., the refrigerator and freezer thermostats are controlled separately) and the refrigerator and freezer compartments each have **separate external doors**.

The refrigerator and freezer units must:

- Have enough room to store the year's largest inventory without storing vaccines against the walls, floor, ceiling, and vents of unit.
- Have enough room to store water bottles (in the refrigerator) and frozen gel packs (in the freezer) to stabilize the temperatures and minimize temperature excursions that can impact vaccine potency. The addition of

water bottles in the refrigerator (not coolant packs) reduces the risk of freezing due to the tremendous latent heat released from water prior to freezing.

- Have a calibrated thermometer with Certificate of Traceability and Calibration Testing centrally located with the vaccine inside each storage unit.
- Reliably maintain the appropriate vaccine storage temperatures year-round.
- Be dedicated to the storage of vaccines. Food and beverages should NOT be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.

Please note: Beginning on March 1, 2016, providers will be required to use a continuous temperature monitoring device with a probe buffered material in all of their VFC vaccine storage units. The temperature readings are required to be uploaded into Florida SHOTS. The VFC Program is supplying providers with a Log Tag for each of their VFC vaccine storage units to meet this new requirement. If a provider would like to purchase their own continuous monitoring device they will need to contact the VFC Program for more information.

Protecting Power Supply

To prevent problems with the power supply, take the following steps:

- Plug only one storage unit into an outlet to avoid triggering a safety switch and turning off power, and to avoid creating a fire hazard.
- Use a safety-lock plug or an outlet cover to prevent unplugging.
- Post warning signs at plugs and on storage units alerting staff, custodians, electricians, or other workers not to unplug units (Do NOT unplug).
- Label fuses and circuit breakers to alert people not to turn off power to storage units. Labels should include immediate steps to take if power is interrupted. If your building is owned by a third party and you do not have access to circuit breakers, work with your building manager.

Avoid using power outlets with:

- Built-in circuit switches (they have little red reset buttons).
- Outlets that can be activated by a wall switch.
- Multi-outlet power strips.

These can be tripped or switched off, resulting in loss of electricity to the storage unit.

Dormitory or bar-style refrigerators are not permitted for ANY vaccine storage. A dormitory or bar-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one external door and has an evaporator plate (cooling coil) which is usually located inside the "freezer" within the refrigerator. Dormitory or bar-style refrigerators place vaccine at a high risk of freezing.

Storage Unit Placement

Good air circulation around the storage unit is essential. Place the unit(s) in a well-ventilated room with space around the sides and top. Allow at least 4 inches (10 cm) of space between unit and wall. Nothing should block the cover of the motor compartment, which is normally located at the back or side of the unit. Make sure the unit stands firm and level and wheels or leveling legs are adjusted so the bottom of the unit is 1 to 2 inches (2.5 to 5 cm) above the floor. Refer to the manufacturer-supplied owner's manual for additional guidance on placement.

Storage Unit Temperatures

Refrigerator storage units must maintain temperature between 35°F and 46°F (2°C and 8°C) at all times. Setting the temperature control to achieve an average of 40°F will provide the best safety margin.

Freezer storage units must maintain temperatures between -58°F and +5°F (-50°C and -15°C) at all times.

It is recommended that water bottles are placed in the refrigerator and gel packs are placed in the freezer to help stabilize internal temperatures, including those times in which power outages occur. (Additionally, this practice will provide readily available cold packs for storing or moving vaccine in the event you need to activate your emergency plan.) Label water bottles with "Do NOT drink."

Vaccine Storage and Handling Best Practices

The Centers for Disease Control and Prevention's Vaccine Storage and Handling Toolkit is a comprehensive resource for providers on vaccine storage and handling recommendations and best practice strategies. It includes considerations for equipment both storage units and temperature monitoring devices, strategies for

maintaining the cold chain, routine storage and handling practices, inventory management and emergency procedures for protecting vaccine inventories. The toolkit can be found at: **www.cdc.gov/vaccines/recs/storage/toolkit/default.htm**.

Vaccine Storage

Always refer to the manufacturer's product information/package insert for the most up-to-date storage and handling recommendations for specific vaccines and diluents.

- Placement and organization within the storage unit is vital to maintaining vaccine stability. Store vaccines away from walls, floor, ceiling, and vents. The thermometer or probe is required to be centrally located in the storage unit.
- Avoid storing vaccines on top shelf. If top shelf of refrigerator must be used, place water bottles close to vent and only store vaccines that are not sensitive to coldest temperatures (e.g., MMR).
- Place the vaccines in the center of the refrigerator, leaving adequate space, 2 to 3 inches from wall, for air circulation. (Some areas of the refrigerator—e.g., in the door or near the sides— may hold different temperatures than the center of the unit.) Vaccines must be stored on the shelves of the refrigerator or freezer, not in the door or in crisper drawers. (Crisper drawers should be removed from the refrigerator.)
- Small trays may be used to help quickly move stock within a refrigerator, reducing the amount of time the door must remain open, potentially exposing vaccines to warmer air temperatures.
- Clearly identify the location of each specific vaccine type and diluent by attaching labels to shelves, trays, or containers/ bins where each is stored. Label pediatric and adult versions of the same vaccine to avoid confusion.
- Store all vaccines in their **original** box. Protect the following vaccines from light: Varivax, Zostavax, ProQuad, M-M-R II, Hiberix, Gardasil, Gardasil9 Afluria, Agriflu, Fluarix, Flublok, Flucelvax, FluLaval, Fluvirin, IPOL, MenHibrix, Menveo, Rotarix, and RotaTeq.
- VFC vaccines must be segregated and/or marked in such a way that they are easily distinguished from privately purchased vaccines. This does NOT mean that VFC and privately purchased vaccines must be stored in separate refrigerator(s) or freezer(s).
- Do not store food or drink in vaccine refrigerators or freezers.
- Do not place the vaccine directly under the outlet that blows air from the freezer into the refrigeration area.

Diluents

Some diluents must be stored in the refrigerator. Other diluents have an option of being stored at room temperature (no warmer than 77°F [25°C]) or in the refrigerator. Whenever possible, store diluent with the corresponding refrigerated

vaccine. Diluents for Pentacel (DTaP-IPV-Hib combination vaccine) and Menveo (meningococcal conjugate vaccine) contain antigen. They are packaged together with the corresponding lyophilized vaccine and must be stored together. NEVER store diluent in the freezer.

Medications and Other Biologic Products

If possible, other medications and biologic products should not be stored inside the vaccine storage unit. If there is no other choice, these products should be stored below the vaccines on a different shelf. This prevents contamination of the vaccines should the other products spill, and reduces the likelihood of medication errors. NEVER store these products in the same tray or container/bin as vaccines.

MODULE 5-C: Vaccine Storage and Handling Thermometers

The use of trade names and commercial sources in this section is for identification only, and does not imply endorsement by the U.S. Department of Health and Human Services (DHHS), the U.S. Public Health Service (PHS), the Centers for Disease Control and Prevention (CDC), or the Florida Department of Health Immunization Section.

Temperature Monitoring Devices

Thermometers are a critical part of good vaccine storage and handling practices. A storage unit is only as effective as the temperature monitoring system inside. Accurate temperature history that reflects actual vaccine temperatures is imperative to effective vaccine management. Every freezer and refrigerator unit used to store vaccine is required to have a certified calibrated temperature monitoring device. Investing in reliable temperature monitoring devices is less expensive than replacing vaccines wasted due to inaccurate temperature readings.

The VFC vaccine coordinator and back-up coordinator are responsible for temperature monitoring equipment and certifications. If additional staff is responsible, those persons must be trained on temperature monitoring equipment and documentation.

Thermomter calibration information must be entered into Florida SHOTS for each storage unit before a VFC vaccine order can be placed.

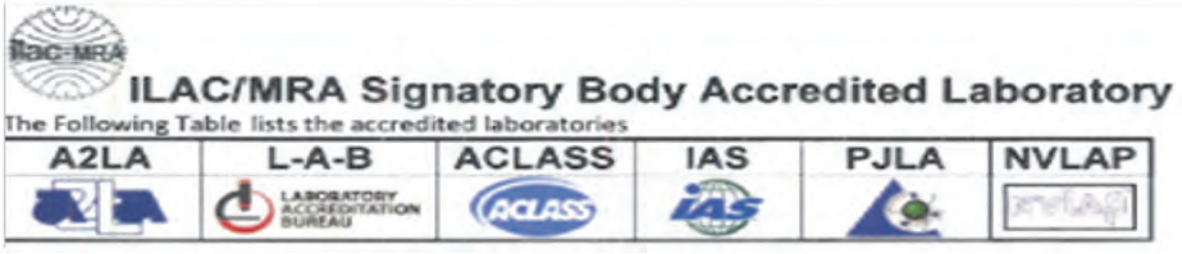
Types of Temperature Monitoring Devices

Calibrated Temperature Monitoring Devices

Providers are required to use calibrated temperature monitoring devices with a Certificate of Traceability and Calibration Testing (known as a Report of Calibration). Calibration testing and traceability that is performed by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) assures the user that testing performed meets the appropriate standard. Providers are responsible for maintaining up-to-date certificates of calibration.

ILAC/MRA accredited laboratories Certificate of Traceability must include:

- Clearly identifiable accreditation
- Name of device (optional)
- Model number
- Serial number
- Date of calibration (report or issue date)
- Measurement results that indicate passed testing and documented uncertainty within suitable limits (recommended uncertainty is +/-1°F [+/-0.5°C])



Non-ILAC accredited laboratories and manufacturers must provide a Certificate of Traceability that includes the following elements:

- Name of device (optional)
- Model number
- Serial number
- Date of calibration (report or issue date)
- Measurement results that indicate passed testing and documented uncertainty within suitable limits (recommended uncertainty is +/-1°F [+/-0.5°C])
- Measurement results of the device
- Statement that calibration testing conforms to ISO 17025.

Continuous Temperature Monitoring Devices

It is highly recommended that providers utilize a continuous temperature monitoring device for each storage unit. These devices can provide an indication of the length of time a unit has been operating outside the recommended vaccine storage temperature (excursion) and when an excursion occurred. Unlike a simple min/max thermometer, which provides only the information about warmest and coldest temperatures that were reached, the continuous monitoring device provides detailed information on all temperatures recorded at preset intervals. They are capable of recording hundreds or even thousands of individual temperature readings.

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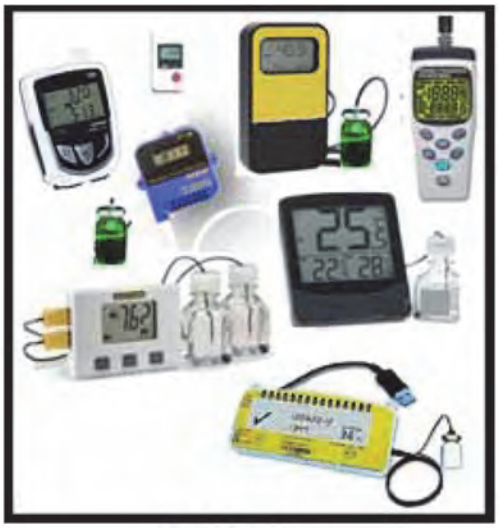

Digital data loggers

Digital data loggers come with special software, which providers install on a computer. This software allows the user to set the frequency of the temperature readings, download data from the device, and calculate temperature averages, minimums, and maximums. In order to review the temperature history, the user must download data from the digital data logger on a regular basis. Some data loggers may have an audible alarm to alert the user to out-of-range temperature conditions. Other data loggers may have external lights that alert the user to out-of-range temperature

events; a green light indicates temperatures have remained in range and a red light indicates temperatures are out of range.

Data loggers should have the following specifications and functionality:

- Provides continuous monitoring information with an active display.
- Displays current temperature, as well as minimum and maximum temperatures (visible from the outside of the vaccine storage unit).
- Reset button for the maximum and minimum temperatures recorded in a period; Hi/Lo alarm for out-of-range temperatures.
- Low battery indicator.
- Memory storage for approximately 4,000 or more readings. (Data should be downloaded weekly and the logger cleared/reset to ensure adequate capacity).
- Device will not write over data—stops recording when memory is full.
- Detachable temperature probe (or a logger that allows the probe to remain in the unit undisturbed while the temperature is displayed and data is recorded via computer).
- User programmable logging interval (or sampling rate) 15 minutes or less (Florida SHOTS will only log readings every 15 minute).
- Accuracy of +/- 0.5 degree Celsius or +/- 1 degree Fahrenheit as certified by a current Certificate of Traceability and Calibration.

Please note: Please note: Beginning on March 1, 2016, providers will be required to use a continuous temperature monitoring device with a probe buffered material in all of their VFC vaccine storage units. The temperature readings are required to be uploaded into Florida SHOTS. The VFC Program is supplying providers with a Log Tag for each of their VFC vaccine storage units to meet this new requirement. If a provider would like to purchase their own continuous monitoring device they will need to contact the VFC Program for more information.

Data logger manufactures and distributors:

Vendor	Website
Control Solutions	www.vfcdataloggers.com
Berlinger USA, LLC	www.berlinger.ch/en/berlinger/main/ambient-tag/temperature-monitoring/fridge-tag2.html
Dickson	www.dicksondata.com/products/find/data-logger
Lascar Electronics	www.lascarelectronics.com/usb-data-logger.php?panelchooser=1&cat[]=63
Accsense	www.accsense.com

Temperature Monitoring Devices that are NOT Acceptable

Some devices can be difficult to read and most only provide information on the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may not be detected. The following devices can

have significant limitations:

- Fluid-filled biosafe liquid temperature monitoring devices
- Bi-metal stem temperature monitoring devices
- Food temperature monitoring devices
- Household mercury temperature monitoring devices
- Chart recorders
- Infrared temperature monitoring devices
- Temperature monitoring devices that are not calibrated

Chart Recorder

Bi-metal stem thermometer

Fluid-filled biosafe liquid thermometer

Thermometer Placement

Prior to storing vaccines in a unit, it is important to determine where the most reliable and consistent temperature readings are and store your vaccines there. The probe is required to be centrally located with the vaccines in the referigertor and the freezer.

Placement of Probe

Best practices for probe placement are as follows:

- Place the thermometer in the center of the compartment, away from the coils, walls, floor, and fan, in order to obtain a true reading of the temperature.

- In the refrigerator, place the thermometer on the middle shelf, adjacent to the vaccine, or hanging down from the upper shelf.
- In the freezer, suspend the thermometer from the ceiling of the compartment or place on a box or some other item, so that it is in the middle of the compartment, off of the floor.
- If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated.
- As of January 1, 2015, placing the thermometer in a central area of the storage unit with the vaccines is a requirement.

Thermometer Device Maintenance and Recertification

Certified-calibrated thermometers require periodic recertification and recalibration in order to remain accurate. Contact the manufacturer for instructions regarding recalibration procedures. When choosing a certified calibrated thermometer, consider the cost and frequency of required recalibration. Recalibration costs will vary by manufacturer, model, and type of thermometer. Keep documentation of recertification and recalibration for three years as part of the office records.

Calibration testing and traceability must be performed by:

- A laboratory accredited by an ILAC MRA signature body.
- An entity that provides documentation demonstrating the calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability.

Back-up Temperature Monitoring Device

As of January 1, 2015, VFC providers are required to have at least one back-up thermometer with a current certificate of calibration on-hand (not stored in unit along side current thermometer). This allows the back-up temperature monitoring device to be used in the event that something happens to the primary thermometer or if a thermometer needs to be sent out for recalibration.

The back-up temperature monitoring device should have:

- Current Certificate of Traceability and Calibration
- Detachable probe in a bottle filled with a thermal buffer such as glycol
- Different calibration testing schedule than the primary monitoring device

Temperature Alarms

Continuous monitoring temperature alarm/notification systems

Alarms are useful tools to alert staff to potential problems. However, any alarm is only as good as the people responding to it. Large vaccine losses and the need to revaccinate have occurred despite using alarmed, continuous monitoring systems. Issues around untrained staff who do not know how to read the monitor, unexpected events, poor monitoring and responses procedures, equipment failures, and improper maintenance have all been implicated in vaccine mishandling incidents.

MODULE 5-D: Vaccine Storage and Handling
Vaccine Transfers

On occasion, even with proper inventory management, a provider may experience a situation where they have vaccine inventory with a short expiration date. Where practical, and as long as the cold chain can be maintained, short-dated vaccine should be transferred to another provider so that it can be used prior to expiration. A VFC-enrolled provider may transfer a vaccine(s) to another VFC-enrolled provider within three months of the expiration date. Do not transfer opened vials. It is the provider's responsibility to ship or transfer the vaccine safely and correctly. If the cold chain is broken and the vaccine becomes unserviceable, the VFC Program may charge providers for the cost of the vaccine.

The VFC Program does not recommend transferring varicella-containing vaccines to another provider or location because of storage temperature requirements. Additionally, a partially used multi-dose vial may not be transferred.

It is not recommended to reuse shipping materials to transport vaccine. Transport is recommended in a portable refrigerator unit or in a hard-sided cooler with at least two-inch thick walls. Place at least two inches of "conditioned" coolant packs for vaccine transfers or returns; a "conditioned" coolant pack is one which has been left out for one to two hours to allow for some defrosting so as not to freeze the vaccine. It is recommended to place an insulating barrier between the coolant pack and the vaccines such as bubble wrap. A calibrated temperature monitoring device must be used for monitoring during transport. The provider must complete the transfer in Florida SHOTS.

Vaccine Transfer Process

The provider transporting the vaccines will create the transfer request in Florida SHOTS. The provider receiving the vaccines should accept the Pending Receipt in their Florida SHOTS account. The provider receiving the vaccine is responsible for all VFC vaccines in their possession and must ensure all vaccines are stored properly upon receipt.

How to Create the Transfer using Florida SHOTS

For a step-by-step guide on how to create the vaccine transfer within Florida SHOTS go to **flshotsusers.com/wp-content/uploads/2013/07/How-To-Manage-Vaccines-5.15.14.pdf**. The Transfer section begins on page 14 of the guide.

Packing Vaccine for Transfer

All public and private providers enrolled in the Vaccines for Children (VFC) Program are responsible for the proper maintenance of their vaccine inventories. When the providers transport vaccines from their clinic to another location they should follow proper vaccine transportation procedures to ensure protection of the vaccine supply.

Health care providers and staff are responsible for maintaining vaccine quality from the time a shipment arrives until the moment they administer a vaccine dose. The following are general guidelines for packing vaccine when transporting to another location or for off-site activities like health fairs and immunization clinics.

Transporting Refrigerated Vaccines

- Pack refrigerated vaccines before packing frozen vaccines.
- CDC recommends transport with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls may be used if it can maintain recommended temperature range (between 35°F and 46°F [2°C and 8°C]).
- Place a layer (at least 2 inches) of "conditioned" coolant packs in transport container first. Coolant packs that are frozen must be "conditioned" by leaving them at room temperature for 1 to 2 hours until edges have defrosted and packs look like they have been "sweating." Frozen coolant packs that are not "conditioned" can freeze vaccines.
- Place an insulating barrier layer on top of coolant packs (e.g., bubble wrap or Styrofoam pellets).
- Next, place a calibrated temperature monitoring device (preferably with a probe in a thermal buffer, e.g., glycol) on top of barrier.
- Stack vaccines with temperature monitoring device on top of barrier.
- Place another insulating barrier layer on top of vaccines.
- Place another layer of "conditioned" coolant packs on top of barrier.
- Always ensure there is no direct contact between coolant packs and vaccines.
- Place a final insulating barrier layer (at least 2 inches) on top of coolant packs along with a list of vaccines in container.
- Pack vaccines in their original packaging. Do not remove vaccine vials from boxes, and do not draw up vaccine in advance.
- Use a properly placed thermometer near the vaccine but not in contact with the frozen packs.

Transporting Varicella-Containing Vaccines

The vaccine manufacturer does not recommend transporting varicella-containing vaccines (VAR and MMRV).

If these vaccines must be transported (e.g., during an emergency):

- CDC recommends transport in a portable freezer unit that maintains temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent in some places.
- If not using a portable freezer, use same packing layers as noted above.
- Coolant packs should be frozen.

If necessary, varicella-containing vaccines that have not been reconstituted may be transported at refrigerator temperature between 36°F and 46°F (2°C and 8°C) for up to 72 continuous hours prior to reconstitution (package inserts). Follow these steps:

- Place a calibrated temperature monitoring device (with a probe in a thermal buffer) in the container as close as possible to vaccines. If transported in same container with refrigerated vaccines, place insulating material (e.g., bubble wrap) around refrigerated vaccines to protect from freezing temperatures and use rubber bands around frozen vaccines to keep them separate.
- Record:
    - Time vaccines are removed from storage unit and placed in container
    - Temperature during transport
    - Time at end of transport when vaccine returned to main storage unit

- Immediately upon arrival at facility:
    - Place varicella-containing vaccines in freezer between -58°F and +5°F (-50°C and -15°C). Any stand-alone freezer that reliably maintains a temperature between -58°F and +5°F (-50°C and -15°C) is acceptable for storage of varicella-containing vaccines.
    - Document time vaccines are removed from container and placed in the storage unit.

Do NOT use dry ice, even for temporary storage or emergency transport. Dry ice may expose varicella-containing vaccines to temperatures colder than -58°F (-50°C).

Transferring Multi-Dose Vials

A partially used vial may NOT be transferred to another provider or transported across state lines.

Monitoring Temperatures at Off-Site/Satellite Clinics and/or Events

Immediately upon arrival at off-site/ satellite facility, store vaccines at recommended temperature range in an on-site refrigerator or freezer. Place a calibrated temperature monitoring device(s) in storage unit(s) with vaccines. Read and record temperatures a minimum of two times during the workday if the vaccines are stored in a refrigerator and freezer.

CDC does not recommend keeping vaccines in a transport container(s) unless it is a portable refrigerator or freezer unit. If vaccines must be kept in a transport container(s) during an off-site clinic, temperature(s) should be read and recorded at least hourly. In addition:

- Container(s) should remain closed as much as possible.
- A calibrated temperature monitoring device(s) (with a probe in a thermal buffer) should be placed as close as possible to vaccines.
- Amount of vaccine needed at one time (no more than 1 multi-dose vial or 10 doses) for preparation and administration by each vaccinator.
- If you have concerns about vaccines or diluents that may have been compromised (exposed to inappropriate conditions/temperatures or handled improperly), label them “Do NOT Use” and store them under appropriate conditions (set apart from other vaccines).
- 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.

Refrigerated/frozen packs.

Place bubble wrap, crumpled brown packing paper, or Styrofoam™ peanuts between the frigerated/frozen packs and the vaccines.

Place a thermometer next to the vaccine but not in contact with the refrigerated/frozen packs.

- Label the outside of the cooler containers to clearly identify the contents as being valuable and fragile vaccines. Below are some examples of labels the provider can attach to the coolers.

What to do After the Off-Site Activity is Over

The designated staff will unpack, check, and immediately store the vaccines at the recommended temperature ranges of 35° to 46°F (2° to 8°C); and the freezer temperature of 5°F (-15°C) or colder when they return to the clinic from the off-site activity.

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 notify the primary vaccine coordinator. If the primary vaccine coordinator is not available, the staff should report the problem to the immediate supervisor. The designated staff, the primary vaccine coordinator, or the immediate supervisor should follow these steps:

- Store the potentially compromised vaccines under appropriate conditions in a properly functioning refrigerator/freezer.
- Separate the potentially compromised vaccines, and label “DO NOT USE”, to prevent inadvertent administration, until the vaccine manufacturer(s) determine the integrity and potency of the vaccines.
- Contact the VFC Program for guidance.
- Do not discard any vaccine unless directed to do so by the VFC Program.

If the VFC Program determines that the vaccine becomes unserviceable, account for these doses using the ***Vaccine Returns/Waste functionality within Florida SHOTS*** and follow the VFC Program vaccine return procedures (see Module 4).

MODULE 5-E: Vaccine Loss and Waste

Vaccine loss is both costly and preventable. There are many reasons for vaccine loss, including heat and/or light exposure, inappropriate freezing, broken vials and syringes, poor reconstitution practices, contamination and suspected contamination, discarding doses at the conclusion of outreach sessions, missing inventory, and theft. However, the most significant cause of vaccine loss is attributed to poor vaccine management (e.g., loss due to expiration and loss due to cold chain failures).

Vaccine Loss Due to an Incident

The VFC Program will require providers to privately purchase replacement doses for vaccine that has been wasted due to provider negligence. Examples of negligence may include, but are not limited to the following examples:

A. Vaccine left out of storage unit(s).

B. Loss of power to storage unit(s).

C. Leaving the door of storage unit(s) ajar resulting in unacceptable ranges.

D. Storage of vaccines in recorded, unaccepted temperature ranges.

E. Failure to properly read and record storage unit temperatures.

F. Transporting vaccine inappropriately, thus breaking the cold chain.

G. Failure to notify the VFC Program of change of office hours, address, and other pertinent provider information.

H. Discarding or allowing spoilage of vaccine prior to the expiration date.

I. Expiration due to over-ordering. Providers are required to notify the VFC Program 60 days prior to expiration date of vaccine to attempt a transfer.

Please note: The VFC Program considers temperatures recorded within Florida SHOTS official documentation when determining vaccine viability.

Please review the Florida VFC Program Vaccine Restitution Policy at:
http://www.floridahealth.gov/programs-and-services/immunization/publications/_documents/vfc-vaccine-restitution.pdf

Reporting a Vaccine Incident

To minimize vaccine loss, contact a VFC Program representative **immediately** upon notice of an incident at 1-800-483-2543. In most cases, you will be informed to isolate the affected vaccine and label “Do Not Use.” However, do not remove the vaccine from a properly functioning storage unit as viability is still to be determined. The VFC Program representative will send you an “Incident Checklist” (see **Appendix 5**) to begin completing. This checklist includes the phone numbers of vaccine manufacturers to contact with information on the

parameters of the incident. You will be required to submit various documents along with temperature logs (if not documented within Florida SHOTS) and current inventory of the vaccines involved in the incident. Email **all** requested documents on the checklist to **FloridaVFC@FLhealth.gov** with your VFC PIN and the word "incident" in the subject line. Review of these documents will determine liability and vaccine viability. During review of the incident, the provider's PIN will be unable to place vaccine orders.

Replacing VFC Program Wasted Vaccine

Instances of wasted or expired vaccine will be reviewed on a case-by-case basis. If negligence is determined, the VFC Program will send the enrollee a letter informing them of the number and type of wasted doses to be replaced and the possible need for patient recall. The provider will purchase the replacement doses from the private supplier of their choosing and submit all invoices/packaging slips to the VFC Program at **FloridaVFC@FLhealth.gov**. Additionally, the provider is required to replace the vaccine by adjusting their inventory within Florida SHOTS upon receipt of vaccines using the adjustment reason of "Payback VFC Vaccine."

MODULE

6

VACCINE INFORMATION STATEMENTS

Immunization Section—Vaccines for Children Program

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MODULE 6: Vaccine Information Statements and Vaccine Adverse Event Reporting

What is a Vaccine Information Statement?

Vaccine Information Statements (VIS) are information sheets produced by the Centers for Disease Control and Prevention (CDC) that explain both the benefits and risks of a vaccine. Federal law (National Childhood Vaccine Injury Act (NCVIA) 42 U.S.C. § 300aa-26) requires health care staff to provide a VIS to a patient, parent, or legal representative before each dose of a certain vaccination is given. This includes all vaccines administered through the VFC Program. VISs may be provided by paper copy; reviewing a permanent office copy; reviewing on a computer monitor; or downloading to an electronic device to be read when convenient.

Provider Responsibilities

A. Give the patient, parent, or legal representative a VIS, for each dose of vaccine, *prior* to vaccine administration.

B. Record the following specific information in the patient's medical record (which can include an electronic medical record), or in a permanent office log. The record should be both permanent and accessible.

- Vaccine name
- Date administered
- VIS publication date
- Date VIS provided to patient
- Name of vaccine manufacturer
- Vaccine lot number
- Name and title of vaccinator
- Clinic address

Providers may add the name, address, and contact information of their practice to an existing VIS, but may not make any substantive changes. In addition to providing a VIS, the provider may read it aloud, provide video version, or provide additional printed material, or in any other way that will help patients understand the disease and vaccine.

VISs are required for the following vaccines:

- Diphtheria, tetanus and pertussis containing vaccines (DTaP, DT, Td, and Tdap)
- *Haemophilus influenzae*, type b (Hib)
- Hepatitis A
- Hepatitis B
- Human Papillomavirus (HPV)
- Influenza (both Inactivated and Live, Intranasal vaccines)
- Measles, Mumps, and Rubella (MMR)
- Measles, Mumps, Rubella, and Varicella (MMRV)

- Meningococcal (MCV4, MPSV4 and MenB)
- Pneumococcal Conjugate (PCV)
- Polio (IPV)
- Rotavirus
- Varicella (VZV)

Multi-Vaccine VIS

This VIS may be used in place of individual VISs for any or all routine birth through 6-month vaccines (DTaP, IPV, Hib, hepatitis B, PCV, and rotavirus) administered, or when combination vaccines were used. Using the multi-vaccine VIS is an alternative to providing single-vaccine VISs for each of these six vaccines. Providers could use this VIS when two or more of these vaccines were given together. Current VISs may be found at:

CDC's Vaccines and Immunizations website at:
www.cdc.gov/vaccines/hcp/vis/index.html
CDC's Contact Center:
Call 1-800-CDC-INFO (or 1-800-232-4636)
Immunization Action Coalition website at:
www.immunize.org/vis/

Vaccine Adverse Event Reporting System (VAERS)

The VAERS is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA) for collection of information about adverse events (possible side effects) following immunization with US-licensed vaccines. By monitoring such events, the VAERS helps to identify any important new safety concerns, and thereby assists in ensuring the benefits of vaccines continue to be far greater than the risks.

Federal law requires health care providers to report significant adverse events suspected to be caused by vaccines.

How Do I Report?

Internet:	Complete the electronic form at: **www.vaers.hhs.gov/esub/step1**
Mail:	Print form from: **www.vaers.hhs.gov/resources/vaers_form.pdf** and mail it postage free to: VAERS P.O. Box 1100 Rockville, MD 20849-1100
Fax:	Print form (from above link in "Mail") and fax it to: 1-877-721-0366 (toll-free)
E-mail:	Submit VAERS inquiries to **info@vaers.org**
Phone:	VAERS Hotline: 1-800-822-7967 (toll-free)

After a provider submits a report, the VAERS staff may contact the provider for follow-up. Be sure to provide a copy of your VAERS report to the:

Florida Department of Health
Immunization Section
4052 Bald Cypress Way, Bin A-11
Tallahassee, Florida 32399-1719

Or fax to the Immunization Section VAERS Coordinator at:
850-922-4195.

MODULE

7

Provider Compliance and Monitoring—Quality Assurance (QA) Visits, Assessments and Education

Immunization Section—Vaccines for Children Program

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MODULE 7: Provider Compliance and Monitoring—QA Visits, Assessments and Education

What are QA Visits, Assessment and Education?

Federal and state requirements mandate the Florida Immunization Section conduct Quality Assurance (QA) visits, assessments and education with each enrolled provider receiving VFC vaccine. To ensure the quality of VFC vaccine and the integrity of the VFC program, the Immunization Section is required to conduct:

- Enrollment Site Visits
- Compliance Site Visits
- Unannounced Storage and Handling Site Visits
- VFC contacts, as needed
- Annual Provider Training

VFC site visits help determine a provider's compliance with VFC program requirements. This includes identifying potential issues with VFC vaccine accountability and determining whether VFC vaccines are being handled, stored, and administered in accordance with the laws and policies governing the VFC program.

The review and evaluation of VFC provider practices involves assessing verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the VFC program.

The goals of these visits are to:

- Identify areas where providers are doing well and areas needing additional follow-up.
- Identify the educational needs of VFC providers in order to support them with meeting program requirements.
- Ensure that VFC-eligible children receive properly managed and viable vaccine.

Additionally, site visits are critical opportunities to engage provider staff and develop and strengthen ongoing relationships.

Types of QA Visits, Assessments and Education

Provider Enrollment: This visit is required prior to enrollment for newly enrolling facilities or facilities that have had a break between enrollments with the Florida VFC Program. The purpose of this appointment is to ensure providers and their staff are provided with education about requirements and have appropriate resources to implement program requirements.

Compliance: A compliance site visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state guidelines. It involves administration of a questionnaire, evaluating compliance with requirements and providing education. During the visit, there will be a formal review of vaccine management practices as well as a review of patient records and other documentation to assure appropriate vaccine eligibility screening and administration documentation is occurring. Providers will receive a report outlining visit findings, and if applicable, identifying areas of noncompliance in need of correction. Corrective actions with due dates for noncompliant practices will be provided at the time of the visit and completion required for continued participation in the VFC Program.

Unannounced Storage and Handling: The Florida VFC Program is required to perform unannounced storage and handling site visits to serve as "spot checks" on facility vaccine management practices.

When *Compliance* and *Unannounced Storage and Handling Visits* are completed, providers will receive a report outlining visit findings, and if applicable, identifying areas of noncompliance in need of correction. Corrective actions with due dates for noncompliant practices will be provided at the time of the visit and completion required for continued participation in the VFC Program.

Annual Provider Training Requirement: Certifying providers (enrollee), vaccine coordinators and back-up vaccine coordinators must view the Annual Provider Training webinar to meet the annual education requirements. Further instructions will be sent via Blast Communication each year.

AFIX Assessment: AFIX (Assessment, Feedback, Incentives, eXchange of information) is an assessment of your facility's immunization coverage. AFIX includes four components: Assessment of immunization levels, feedback of immunization information to key staff, incentives to motivate and/or recognize outstanding performance, and exchange of information on best practices to improve immunization coverage levels. The goal of AFIX is to ensure that viable vaccines reach all children served by the provider site in accordance with the ACIP schedule. A successful AFIX process requires implementation of all four components.

Standards for Pediatric Immunization Practices

CDC developed the *Standards for Child and Adolescent Immunization Practices*, resulting in collaboration with a 35-member working group representing 22 public and private agencies that had input from state and local health departments, physician and nursing organizations, and public and private providers involved in clinical care and prevention health services. The Standards represent the consensus of the National Vaccine Advisory Committee (NVAC) and the working group that address the most essential and desirable immunization policies and practices for an immunization service. *A Guide to Contraindications and Precautions to Immunization*, which reflects the current recommendations of the ACIP, as well as the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP), accompany the Standards.

Several medical and public health organizations have endorsed these Standards. These organizations encourage adherence to the *Standards for Child and Adolescent Immunization Practices* as a key element in our national strategy to administer vaccines more efficiently and effectively to the nation's children.

For links to the Standards see **Appendix 7** or **http://www.cdc.gov/mmwr/preview/mmwrhtml/00020935.htm**

MODULE

8

FRAUD AND ABUSE

Immunization Section—Vaccines for Children Program

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MODULE 8: Fraud and Abuse

Overview:

As the cost of childhood vaccines increases and the complexity of immunization programs grow, the federally funded Vaccines for Children (VFC) Program, administered by the Immunization Section, becomes more vulnerable to fraud and abuse. It is important that Florida's VFC Program has a well-defined process for prevention, identification, investigation, and resolution of suspected cases of fraud and abuse within the VFC Program.

The VFC Program, as a component of each state's medical assistance plan, is considered a Title XIX Medicaid Program. Section 1928 of the Social Security Act (42 U.S.C. §1396s) provides for purchase of vaccine for administration to VFC-eligible children—"federally vaccine-eligible children" and "state vaccine-eligible children" (i.e., those children for whom states purchase vaccine; may be limited to particular vaccines)—using federal Medicaid funds and state funds (including 317 federal grant funds), respectively. Medicaid-eligible children and those providers who provide care for the Medicaid population represent the majority of VFC federally vaccine-eligible children and VFC providers. Federal fraud and abuse laws apply to the entire VFC Program. In addition, for those portions of the VFC Program involving state funds, state fraud and abuse/consumer protection/medical licensure laws may also apply.

It is important for Florida's immunization program and the state Medicaid agency to collaborate on the development of policies and procedures regarding VFC Program fraud and abuse. In addition to using the services of state Medicaid agencies and Centers for Medicare and Medicaid Services (CMS), Florida, in collaboration with the state Medicaid Program (Agency for Health Care Administration-AHCA), also uses the fraud and abuse-related services of other state agencies that are responsible for investigating and prosecuting fraudulent health care activities and misuse of government funds.

Purpose:

This module defines the Florida VFC Program's policy for the prevention, detection, investigation, and resolution of fraud and abuse allegations.

Definitions:

A. **Wasted:** Any vaccine that provider cannot use. This includes expired, non-viable, and lost vaccines.

B. **Expired:** Any vaccine with an expiration date that has passed.

C. **Non-viable:** Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. **Always** consult the VFC Program and vaccine manufacturer before determining if the vaccine is non-viable.

D. **Lost:** The delivery service does not deliver vaccines or does not deliver vaccine in a timely manner. This does not include the provider's negligence to inform the VFC Program administration of updated address changes.

E. **Fraud:** An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

F. **Abuse:** Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid Program, (including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary; or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid Program.

G. **VFC compliance visit:** The purpose of the cpmliance visit is to review records of children immunized through the VFC Program and evaluate the provider's record keeping, vaccine storage and handling procedures and compliance with the requirements of the VFC Program.

H. **Assessment, Feedback, Incentive, and Exchange (AFIX) site visit:** A continuous quality improvement strategy that consists of:

1. Assessment of the health care provider's vaccine coverage levels and immunization practices.
2. Feedback of the results to the provider, along with recommended strategies to improve coverage levels.
3. Motivating the provider through incentives to improve vaccine coverage levels.
4. Exchanging health care information and resources necessary to facilitate improvement.

Identification (Suspicion) of Fraud and Abuse:

Fraud or abuse can be reported by (but not limited to) the following individuals: parent, employee, former employee, newspaper, provider, colleague of a provider, Medicaid officials, VFC officials, or any other local, state, or federal entity.

Fraud and Abuse Reporting Systems:

- Contact the Florida VFC Program Fraud and Abuse Hotline (Toll-Free) at 1-866-313-0644.

- Complete the Florida VFC Program ***Suspected Fraud and Abuse Report Form*** (see **Appendix 8** or **http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/fraud-abuse-form.pdf**), fax it to 850-922-4195 or mail it to:

  Florida VFC Program
  4052 Bald Cypress Way, Bin A-11
  Tallahassee, FL 32399

The VFC Program Manager, upon consultation with the Florida Department of Health, Section Administrator, has primary authority to:

A. Make decisions about where identified potential fraud/abuse situations are to be referred and into which category the fraud/abuse falls:

    1. Extenuating circumstances.

    2. No previous compliance issues.

B. Make the referral.

C. Notify appropriate governmental agencies (CDC), state Medicaid office, and others as appropriate).

In the absence of, or as directed by the VFC Program Manager, a delegated authority will act in this capacity. The Immunization Section will refer complaints identified as suspected fraud or abuse to:

Florida Medicaid Program Integrity Unit
Office of Attorney General
State of Florida Department of Health
The Capitol PL-01
Tallahassee, Florida 32399
Telephone: 1-866-966-7226

The Immunization Section will contact the CDC within 48 hours of an external referral.

The CDC contact information is:

Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., MS A-19
Atlanta, Georgia 30333
Telephone: 404-639-6220
Email: **emb1@cdc.gov**

Suspected Abuse:

If the initial investigation shows misuse of VFC vaccine or failure to adhere to proper enrollment processes, then further investigation by the VFC Program is indicated.

Resolution of Reported or Suspected Fraud and Abuse:

A. Baseless complaints will be closed with no further action.

B. The Florida Medicaid Program Integrity (MPI) Unit will investigate cases of suspected fraud.

C. If it is determined no fraud occurred, the VFC Program will close the case with no further action.

D. If fraud is discovered, the provider will be required to reimburse vaccine or other costs, may be terminated from the VFC Program, the provider's name may be added to the excluded provider list, and/or the provider may be referred for criminal prosecution.

E. If a provider in a case of abuse is determined to be willfully negligent, the VFC Program will require the provider to reimburse for vaccine or other costs, may terminate the provider from the VFC Program, and/or may add the provider's name to the excluded provider list.

F. If a provider in a case of abuse is determined not to be negligent because of a lack of knowledge or understanding, the VFC Program will implement an education and corrective action plan. Corrective action may include secondary education for the accused provider's staff. The VFC Program will conduct a follow-up visit two to six months after education is complete. The Immunization Section will make this determination on a case-by-case basis, depending on such factors as:

    1. The amount of money lost by the VFC Program.
    2. How the VFC Program identified the incident.
    3. Duration time of the incident.
    4. Provider's willingness to comply with VFC decisions regarding vaccine replacement, educational referral, and follow-up visits by field staff to assure problem is resolved.

Fraud and Abuse Prevention

The VFC Program will actively work with enrolled providers to help prevent fraud and abuse within the VFC Program. The best methods to prevent fraud and abuse are educational components discussed during VFC site visits. These provide the opportunity to identify and prevent situations that may develop into fraud and abuse.