

# Vaccines for Children (VFC) Program Policy Handbook



**Florida Department of Health**

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# Table of Contents

<b>VFC Program Overview</b>	<b>pg. 3–8</b>
<b>Eligibility</b>	<b>pg. 9–15</b>
<b>Enrollment</b>	<b>pg. 16–20</b>
<b>Compliance and Monitoring Visits</b>	<b>pg. 21–25</b>
<b>Staff and Responsibilities</b>	<b>pg. 26–28</b>
<b>Vaccine Management</b>	<b>pg. 29–37</b>
<b>Storage and Handling Requirements</b>	<b>pg. 38–47</b>
<b>Temperature Incidents</b>	<b>pg. 48–49</b>
<b>Restitution Policy</b>	<b>pg. 50–52</b>
<b>Fraud and Abuse</b>	<b>pg. 53–58</b>
<b>VIS and VAERS</b>	<b>pg. 59–62</b>
<b>Resources</b>	<b>pg. 63–67</b>
<b>Vaccine Management Plan Template</b>	<b>pg. 68–74</b>
<b>Emergency Management Plan Template</b>	<b>pg. 75–76</b>

# VFC Program Overview

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## **Introduction**

Florida's Vaccines for Children (VFC) Program is a component of the Immunization Section within the Florida Department of Health, Division of Disease Control and Health Protection, Bureau of Epidemiology. 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.

## **Vaccines for Children Program Overview**

The VFC Program represents an unprecedented approach to improving vaccine availability nationwide by making federally purchased vaccine available to both public and private immunization providers. The program has succeeded in raising immunization coverage rates among children and reducing disparities in access to health care. The Vaccines for Children 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. The Florida VFC Program distributes over \$200 million worth of vaccines annually to over 1,600 public and private health care providers and hospitals throughout the state.

Funding for the VFC Program is approved by the U.S. Office of Management and Budget and allocated through the Centers for Medicare and Medicaid Services 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).

## **What are the benefits of the VFC Program?**

- Reduces vaccine cost as a barrier to vaccinating VFC-eligible children on appropriate vaccination schedules.
- Eliminates the need to refer children to public clinics for vaccinations and reduces the risk of the loss of continuity of care.
- Maintains the provider's present system of purchasing vaccines for private-paying patients.

## **Advisory Committee on Immunization Practices**

The Advisory Committee on Immunization Practices has existed since 1964. In 1993, Congress gave ACIP 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 ACIP are to provide advice that will assist the U.S. Department of Health and Human Services and the nation in reducing the incidence of vaccine-preventable diseases and to increase the safe use of vaccines and related biological products.

### **ACIP's Role in VFC**

ACIP makes its immunization recommendations for the entire US population and is legislatively linked to the VFC Program. Therefore, in addition to recommending vaccine use for the general population, ACIP also approves the specific recommendations for inclusion of a vaccine in the VFC Program. ACIP publishes these recommendations as VFC resolutions. ACIP issues resolutions by vaccine type following licensure and as recommendations for usage change. VFC resolutions passed by 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 ACIP in the VFC resolutions. For more information, visit [www.CDC.gov/vaccines/acip](http://www.CDC.gov/vaccines/acip).

## ACIP-Recommended Vaccines Available through the 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)
- Pneumococcal Polysaccharide (PPSV23)
- Rotavirus
- Tetanus and Diphtheria (Td)
- Tetanus, Diphtheria, and Acellular Pertussis (Tdap)
- Varicella
- Combination Vaccines (Kinrix®, Pediarix®, Pentacel®, ProQuad®, and Quadracel®)

## Florida State Health Online Tracking System (SHOTS)

Florida State Health Online Tracking System is the immunization information system for the state that assists VFC providers in updating patient medical records, managing VFC inventory, completing VFC orders, and documenting VFC storage unit temperatures. The benefits of using Florida SHOTS are:

- Produces the legal immunization record (DH Form 680) required for school and day care 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 provider's computers.
- Provides reliable immunization history for any child.
- Identifies patient's previously reported contraindications.
- Provides definitive information, reminders, and recalls on immunizations that are due or overdue, and reduces paperwork.
- Provides current recommendations for vaccines.

**For more information about the Florida SHOTS Program, call the toll-free telephone number at 1-877-888-SHOT (7468) and select option 2, or send an email to [FLSHOTS@flhealth.gov](mailto:FLSHOTS@flhealth.gov).**



# Eligibility

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## VFC Eligibility at a Private Provider Office

The Vaccines for Children Program offers vaccines at no cost to enrolled providers for eligible children. 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:**
  1. A child who has health insurance, but the coverage does not include vaccines; or
  2. A child whose insurance does not cover all ACIP-recommended vaccines. The child would be eligible to receive those vaccines not covered by the insurance.  
*Must be referred to a county health department (CHD) or Federally Qualified Health Center (FQHC).*

Children enrolled in the Healthy Kids Program or in MediKids, which is part of the KidCare Program, are insured and not eligible to receive VFC vaccines.

**Please Note:** Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center 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](http://www.FACHC.org).

## VFC Eligibility at County Health Departments and Federally Qualified Health Centers or Rural Health Clinics

All county health departments and Federally Qualified Health Centers or Rural Health Clinics can provide vaccine to children from birth through 18 years of age that meet one of the following criteria:

- **Medicaid-eligible:** A child enrolled in the Medicaid Program (for the purposes of the VFC Program, the terms Medicaid-eligible and Medicaid-enrolled are equivalent and refer to children who have health insurance covered by a state Medicaid program).
- **Uninsured:** A child who has no health insurance coverage.
- **American Indian or Alaskan Native:** As defined by the Indian Health Services Act (25 U.S.C. 1603).
- **Underinsured\*\* children include:**
  1. A child who has health insurance, but coverage does not include vaccines; or
  2. A child whose insurance covers only selected vaccines is eligible to receive only those vaccines that are not covered by the child's insurance through the VFC Program.

*\*\*Underinsured children seen at a CHD will receive vaccine purchased with state funds. If seen at a FQHC or RHC they are eligible for VFC vaccine.*

**Please Note:** Children covered by insurance plans that require deductibles or copays do not meet the criteria for VFC-underinsured status.

## **Eligibility Determination and Documentation**

To ensure VFC Program vaccine is given to eligible patients only, providers must appropriately screen for eligibility. Screening to determine a child's eligibility to receive vaccines through the VFC Program must take place with each immunization visit. A Patient Eligibility Screening Record should be used to record the status of the patient at each immunization visit. Providers must maintain Patient Eligibility Screening Records on file for a minimum of three years after the last shot date on record. The Patient Eligibility Screening Record provides a means of recording parent responses to VFC eligibility questions. The parent, guardian, or provider may complete this form. Verification of parent or guardian responses is not required. The Patient Eligibility Screening Records can be completed electronically in the providers Electronic Health Records (EHRs), as long as all data fields are included. It is recommended that fields pertaining to eligibility be made required fields in EHRs. All children should receive Immunization Program vaccines; however, county health department staff need to categorize all vaccine recipients under the correct eligibility status:

- VFC vaccine for uninsured or Medicaid eligible children
- State funded vaccine for privately insured children

## **Documentation Methods for Vaccine Administration**

The following must be documented in the patient's medical record for each vaccine administered:

1. The vaccine manufacturer and lot number of the vaccine.
2. The date of administration of the vaccine.
3. The name, address, and title of the health care provider administering the vaccine.
4. The Vaccine Information Statement (VIS) edition date located in the lower right corner on the last page of the VIS along with the date the VIS is given.

The Immunization Section conducts an assessment on providers' eligibility screening and documentation practices. Providers are not notified in advance of charts that will be selected for review during site visits.

The assessment includes county health departments and private providers who enter vaccine administration data into Florida SHOTS manually or electronically. For these providers, an Area Immunization Consultant (Field Staff) generates a Vaccine Utilization Report in Florida SHOTS no earlier than three days prior to the scheduled site visit. The report will go back one month for large providers and three months for smaller providers for the random selection of VFC-eligible and privately insured pediatric patients who have received vaccinations at that provider's office. The eligibility status in Florida SHOTS will be compared to the billing information in the provider's medical records or electronic medical record.

**Source:** <http://immunize.org/askexperts/documenting-vaccination.asp>.

## Fee Policies

Providers may not charge VFC-eligible patients for the cost of a vaccine provided by the VFC Program. Providers, Medicaid, and Medicaid Health Maintenance Organizations (HMOs) may bill for office visits and 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 of \$24.01 (per vaccine, not antigen) determined for Florida by the Centers for Medicare and Medicaid Services. **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.** Effective January 1, 2020, providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program. Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an

eligible child whose parents or guardians have unpaid vaccine administration fees.

## **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.

### **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 while seeking services in a family planning clinic/sexually transmitted disease clinic, is considered uninsured for the purposes of the VFC Program:

1. Each clinic must screen adolescents to ensure that each client meets the VFC eligibility criteria.
2. County Health Departments should account for administered vaccines by adjusting their vaccine inventory in Florida SHOTS.
3. Under Vaccine Inventory, select Adjust Inventory.
4. In the Selection Criteria for Inventory Records List, select the Immunization Service Site, Vaccine Type, Vaccine Manufacturer, and Lot Number, and select Program Component 01 for VFC Vaccine.
5. Select submit, and the administered VFC vaccine doses provided to unaccompanied minors in the Title X Family Planning Program will be reported.

The VFC Program does not in any way regulate the issue of obtaining 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.

# Enrollment

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## **Provider Enrollment**

Providers interested in enrolling into the VFC Program should send an email to FloridaVFC@flhealth.gov. The provider will be sent an email with the VFC Provider Agreement and Provider Patient Profile form to complete. The eligibility verification begins once the provider submits their enrollment forms. The VFC Program Office verifies that the interested provider has a Florida SHOTS account or obtains a Florida SHOTS account. This account is where the provider places VFC order requests and maintains VFC inventory. A copy of the License Verification through the Florida Department of Health website for each listed medical staff is attached to the application. The individual listed as the enrollee on the application form will be verified by the Office of Inspector General using the U.S. Department of Health and Human Services website.

As soon as the VFC Program Office verifies the provider is eligible to enroll, the approved VFC Provider Agreement Form is sent to the Florida SHOTS support team to create a VFC Site that is attached to the Florida SHOTS account. A temporary VFC EID number is assigned to the account until an Orientation Site Review (OSR) has been completed. Once all required documents are completed and returned to the VFC Program Office, an OSR is scheduled with the provider. All received paperwork is sent to the VFC Area Immunization Consultant for review along with an OSR Checklist to be completed during this site visit. Providers are fully enrolled in the VFC Program when a provider completes the OSR.

## **Types of VFC Providers**

The VFC Program recruits all types of providers as long as they serve the VFC-eligible population, meet the requirements to participate in the VFC Program, and are able to prescribe or administer vaccines under Florida law. This includes county health departments, pediatricians, general family practitioners, internists, federally qualified and rural health centers, community health centers, birthing hospitals, hospitals, Children's Medical Services clinics, OB/GYN providers, juvenile detention centers, pharmacies, and urgent care clinics.

## VFC Program Forms

Florida requires the following forms to be used when a provider enrolls into the VFC Program:

- CDC-approved VFC Provider Agreement
- Provider Profile Form
- Certificates of Calibration for the provider's digital data loggers
- VFC Required Provider Staff Training Certificates of Completion

## VFC Program Participation Requirements

The VFC Program uses the following criteria to determine if a provider may be enrolled into the program:

- Must be licensed in Florida to vaccinate.
- The provider(s) cannot be on the current List of Excluded Individuals and Entities (LEIE).
- Enrollee and other immunization providers listed on the application must not have any history of discipline or fraud against their medical licenses.
- Must serve children between 0 through 18 years of age or some sub-set of this age group.
- Completion of the VFC Program Provider Agreement Form.
- Documentation of proper vaccine storage equipment.
- Have the ability to order, receive, properly store, and handle vaccines.
- If provider or enrollee has had a previous account with the VFC Program, information is reviewed to determine if the closure of the account will have bearing on establishing a new account.
- Can enter vaccines administered either manually or through electronic data upload.

## **VFC Program Re-Enrollment Process**

The Florida VFC Provider Enrollment Agreement and Provider Profile/Update must be completed annually. The Initial Enrollment Form is completed for initial enrollment and annual re-enrollment purposes. The VFC Program will notify providers through email 30–60 days prior to their required annual enrollment deadline. Providers who fail to re-enroll will have their account suspended and will be prohibited from ordering.

Florida VFC Providers can complete their annual program enrollment within Florida SHOTS unless they are changing their enrollee, primary coordinator, or back-up coordinator. A completed and signed Florida VFC Provider Agreement is required only if the enrollee changes. The enrollee of the VFC account will receive the VFC Program Provider Agreement within Florida SHOTS, sign, and submit the agreement electronically. Once signed and updated, the personnel information will be entered into Florida SHOTS. If changes are made to the primary or back-up coordinators, the enrollee may contact the VFC Program Office by telephone or email to report the changes. The Florida SHOTS annual enrollment process includes all fields documented in both the Florida Provider Agreement and the Provider Patient Profile form previously provided by the CDC.

The VFC primary coordinators will receive an email 60 days prior to their site's re-enrollment date. If the annual enrollment is not completed within Florida SHOTS 30 days before the site's last annual enrollment date, the primary coordinator will receive a second annual enrollment email reminder. If the provider does NOT complete their annual enrollment within 365 days from the date that the provider completed annual enrollment the previous year, it is noted on the provider's site maintenance page in Florida SHOTS, and the provider's ordering privileges are suspended.

The program's goal is to have providers continuously complete their annual enrollment based on the date they completed it the previous year.

## 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. The provider is responsible for completing and sending a copy of the Florida VFC Program Disenrollment Form 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](mailto:FloridaVFC@flhealth.gov). If the provider chooses to terminate the agreement, he or she agrees to transfer any unused and viable VFC Program vaccine. The provider should contact their Area Immunization Consultant to assist in any vaccine transfers.

**Florida VFC Program Disenrollment Form Link:** [FloridaHealth.gov/programs-and-services/immunization/vaccines-for-children/\\_documents/disenrollment-form.pdf](https://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/disenrollment-form.pdf).

## VFC Provider Identifiable Information

- **PIN** – Identification number that the VFC Program office assigns to a site.
- **Org Name** – Name of the organization as it is listed in Florida SHOTS.
- **Site Name** – Name of the site as listed in Florida SHOTS.
- **VFC Shipping Address** – Address to which the VFC Program office ships the site's VFC vaccine.

**Please Note:** Always check this information for accuracy and notify the VFC Program if there are any changes.

# **Compliance and Monitoring Visits**

## Compliance and Monitoring Visits

As a participant in the Vaccines for Children Program, it is a federal requirement for the Florida Immunization Section to conduct site visits. These visits serve as assessments and education to enrolled providers receiving VFC vaccine. To ensure the quality of VFC vaccine and the integrity of the VFC Program, the Immunization Section is required to conduct the following types of site visits:

- Enrollment Visit/Orientation Site Review (OSR)
- Compliance Site Visit (CV)
- Unannounced Storage and Handling Site Visit (USH)
- Immunization Quality Improvement for Providers (IQIP) Site Visit
- Clinical Quality Improvement (CQI) Site Visit (Only for county health departments)
- Annual Provider Staff Training (completed through online webinar or CV)
- VFC contacts, as needed

VFC site visits help determine a provider's compliance with federal and state 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 involve assessing verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the VFC Program. At a county health department, a CQI Site Visit will be included to review county immunization rates and discuss other immunization components in respect to the jurisdiction. The goals of these visits are to:

- Identify areas where providers are doing well, areas needing improvement, and to provide 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.

## **Enrollment Visit/Orientation Site Review**

This visit is required prior to enrolling new providers into the Florida VFC Program. The purpose of this visit is to ensure that providers and staff receive education and appropriate resources to successfully implement program requirements.

## **Compliance Site Visit**

A compliance site visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state guidelines. It involves the administration of a questionnaire, evaluating compliance with requirements, and providing education and technical assistance. 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 non-compliance in need of correction. All enrolled and active VFC Providers must receive a VFC Compliance Site Visit every 24 months. A corrective action plan will be provided at the end of the visit. Providers must complete the action items by the due date indicated on the plan.

Non-compliant issues found during VFC Compliance and Unannounced Storage and Handling Site Visits are handled in the following manner:

- At the end of the site visit, each on-site correction and non-compliant issue found during the visit is discussed with the VFC Provider or the VFC Coordinator(s).
- If possible, on-site corrections are made; if not possible, a Provider Follow-up Plan is discussed with the VFC Provider (or designee) and Coordinator(s) indicating non-compliant issues and time frames in which corrective actions need to be completed.
- The provider or designee is given a copy of the Provider Follow-up Plan and required to sign an Acknowledgement of Receipt Form at the end of the site visit.

## **Unannounced Storage and Handling Visit**

The Florida VFC Program is required to perform Unannounced Storage and Handling Site Visits to serve as “spot checks” on provider vaccine management practices. These visits will evaluate the storage and handling compliance factors at the designated facility. When Unannounced Storage and Handling Visits are completed, providers will receive a report outlining visit findings, and, if applicable, identifying areas of non-compliance in need of correction. Corrective actions with due dates for non-compliant practices will be provided at the time of visit completion. Providers are required to address and correct non-compliant practices to continue VFC Program participation.

## **Immunization Quality Improvement for Providers Site Visit**

Effective July 1, 2019, Immunization Quality Improvement for Providers, an approach to quality improvement replaced the Assessment, Feedback, Incentives, eXchange, or the AFIX approach to quality improvement. IQIP’s purpose is to promote and support immunization quality improvement activities at the provider level to increase vaccine uptake among children and adolescent patients in adherence to ACIP guidelines.

IQIP focuses on a smaller number of quality improvement strategies, compared to AFIX, and is designed to be flexible and responsive. Emphasis is placed on technical assistance, demonstration, review, and practice of strategies. New strategies can replace existing strategies from year to year, allowing the program to stay focused while reflecting evolving federal and state priorities.

## **Clinical Quality Improvement Site Visit**

Clinical Quality Improvement Site Visits are conducted only with county health departments and will include the completion of a Quality Improvement Questionnaire. Other aspects involving immunization services will be reviewed and evaluated in this visit to include the County Health Department Administrator and



supporting staff.

## **Annual Provider Staff Training Requirement**

The VFC enrollees, primary coordinators, and back-up coordinators are required to complete the Annual Provider Staff Training webinars to meet the annual education requirements. Through blast communications, the VFC Program informs enrolled providers of the webinars' availability.

## **Standards for Pediatric Immunization Practices**

The U.S. Department of Health and Human Services Public Health Service along with a diverse group of medical and public health experts developed the Standards for Child and Adolescent Immunization Practices. These Standards represent the consensus of the National Vaccine Advisory Committee and the working groups 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 Advisory Committee on Immunization Practices, as well as the Committee on Infectious Diseases of the American Academy of Pediatrics, accompanies 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 more detailed information, please visit [www.HHS.gov/nvpo/nvac/reports-and-recommendations/the-standards-for-pediatric-immunization-practice/index.html](http://www.HHS.gov/nvpo/nvac/reports-and-recommendations/the-standards-for-pediatric-immunization-practice/index.html).

# **Staff and Responsibilities**

## **VFC Provider**

A VFC Provider represents a clinical facility with key staff identified below who order, maintain, manage, and administer federal vaccine to eligible clients.

## **Medical Director/Enrollee**

The official licensed health care practitioner who signs the VFC agreement and is authorized to administer pediatric vaccines under state law. This individual will be held accountable for the compliance of the entire organization and responsible to the Florida VFC Program for the conditions outlined in the VFC Program Agreement.

## **Vaccine Coordinator**

One staff member is to be the designated Primary Vaccine Coordinator, and, at minimum, 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 Back-up Vaccine 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:

- Conducts a monthly vaccine inventory and documents vaccine usage daily.
- Ensures that refrigerator temperatures are kept between 36°F and 46°F (2°C and 8°C).
- Keeps the freezer temperatures between -58°F and +5°F (-50°C and -15°C).
- Adjusts the temperature of the vaccine storage unit as needed.
- Reports temperature excursions to the VFC Program.

## **Back-up Vaccine Coordinator**

The back-up coordinator is responsible for fulfilling all duties if the Primary Vaccine Coordinator is unavailable.

## **VFC Area Immunization Consultant (Field Staff)**

The VFC Area Immunization Consultant is the point of contact for their geographical area. The VFC Area Immunization Consultant will conduct the VFC Compliance, IQIP, and Unannounced Storage and Handling Site Visits. They are responsible for conducting the Orientation Site Review Visit or Provider Enrollment Site Visit and will serve as a resource in the event there are any technical issues regarding the VFC Program.

# **Vaccine Management**

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## Vaccine Management

Proper vaccine inventory management is essential to the VFC Program. Providers must submit electronic vaccine order requests through Florida SHOTS according to their assigned Economic Order Quality ordering tier as determined by CDC's criteria. The provider enters the number of vaccine doses administered for the previous usage period (from the provider's last submitted order) and enters the current vaccine inventory by lot number. Florida SHOTS will display any discrepancies based on past inventory, transfers since the last order, adjustments since the last order, and current inventory. Providers are required to address and reconcile any inventory discrepancies prior to placing an order. VFC staff check inventory orders submitted into Florida SHOTS for approval to ensure that inventory is reconciled and that requests meet projection amounts. VFC Program staff will note in the VFC Order Request within Florida SHOTS instructing the provider to review, acknowledge, and address any actions needed for the provider to reconcile inventory or to document reasons for orders that exceed projected estimates before the order is processed. Once such actions have been taken, the VFC Program Staff will perform a final review, ensuring inventory reconciliation is complete, and approve the order.

## Vaccine Order Request

Required documents for processing a vaccine order request:

- Ten consecutive days of compliant temperature readings are required to be documented in Florida SHOTS (within 10 days of the order request creation date) for all VFC Provider storage units storing VFC vaccine. The provider can upload their data logger temperature readings into Florida SHOTS.
- Florida SHOTS orders must include the current number of vaccines in inventory and the number of vaccine doses administered since the last order. In addition, any adjustments made, such as vaccine transfers removed from inventory and sent to other VFC Providers, must be included in the current order request.

**For more detailed information regarding VFC Vaccine ordering, visit <http://flshotsusers.com/training/training-guides>.**

## **Non-Routine Vaccines**

VFC Providers must ensure access to all non-routine vaccines. The vaccines must be in stock or on hand, or the provider must have an alternate plan noted in their vaccine management plan that ensures access to those non-routine vaccines.

It is acceptable for the provider to have a plan for referring the child. However, the plan must be documented, and the provider must do their research. The provider should know that the CHD they have noted in their plan has the needed vaccine available.

## **Vaccine Utilization Reporting**

VFC Providers are required to enter their vaccine administration data directly into Florida SHOTS. Undocumented use may result in a delay of vaccine orders being approved. 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 vaccine 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, and expiration date, and enables providers to easily track administrations.

# Recording Dose Administrations

## For County Health Departments

- A. Select the appropriate patient record within Florida SHOTS.
- B. Add the vaccination which requires the following data:
  - i. Vaccine type
  - ii. Date given
  - iii. Vaccine Information Statement (VIS) Publication Date
  - iv. Date VIS provided to patient, parent or guardian
  - v. Injection site
  - vi. Injection route
  - vii. Name and Title of the individual administering the vaccine
  - viii. VFC eligibility criteria

Select the lot number (which includes the expiration date and vaccine manufacturer) within the VFC inventory to attach to the patient record. Once selected, the dose will be subtracted from the inventory record.

## For Private Providers

- A. Select the appropriate patient record in Florida SHOTS.
- B. Add the following vaccination data:
  - i. Vaccine type
  - ii. Date given
  - iii. Vaccine Information Statement publication date
  - iv. Date VIS provided to patient, parent or guardian
  - v. Injection site
  - vi. Injection route
  - vii. Individual administering the vaccine
  - viii. Enter the lot number
  - ix. Enter the expiration date of the lot administered
  - x. Select the vaccine manufacturer
  - xi. VFC eligibility criteria



Private Providers can upload their VFC vaccine administration data from their Electronic Medical Record (EMR) into Florida SHOTS. Providers that make this choice must ensure that the EMR data uploaded includes the information documented above (i.–xi.). The Vaccine Usage Worksheet Form allows the provider to track each dose of VFC vaccine administered by the practice and assists the VFC Program in determining the amount of replacement vaccine needed by the provider. VFC Providers must record each VFC vaccine administered. Undocumented use may result in a delay of the order being approved or suspension of ordering rights.

**Submission of the Vaccine Usage Worksheet Form to the VFC Program is no longer required.** However, as a best practice, providers should use and retain the Vaccine Usage Worksheet Form for internal use only. Providers should not send copies of the Vaccine Usage Worksheet Form to the VFC Program unless otherwise instructed. These forms may be reviewed, however, by the VFC Area Immunization Consultant during routine site visits.

## **Vaccine Borrowing**

The VFC Program discourages enrolled VFC Providers from borrowing VFC-supplied vaccine for privately insured patients or to use privately purchased vaccine for VFC-eligible patients. However, the VFC Program may allow providers to use privately purchased vaccine to immunize VFC-eligible patients due to documented order delays or shipping blackouts imposed by McKesson.

Under this circumstance, providers will need to adjust their VFC vaccine inventory within Florida SHOTS. VFC Providers can document any borrowing transaction through inventory management in Florida SHOTS by adjusting their inventory up or down as needed and must include the appropriate reason. Florida SHOTS captures all the elements required in the CDC borrowing form. The Florida Immunization Section does not authorize borrowing of publicly funded vaccines. VFC Providers must notify VFC Program staff of any appropriate borrowing activities within 24 hours.

## Vaccine Transferring

All vaccine should be transferred either by a staff member of a VFC-enrolled provider or by a VFC Area Immunization Consultant. All vaccine should be transported in a vehicle; transfers should never occur by mail. Providers are instructed to take precautions when transporting vaccine to maintain the cold chain. 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 VFC Program will consider approving a vaccine transfer for the following situations:

- Provider has excess or inadequate vaccine inventory.
- On-hand inventory will expire within three months, and provider will not be able to use it all.

### **The following are general guidelines for packing vaccine when transporting to off-site activities (i.e. health fairs and immunization clinics):**

- Use properly insulated containers to transport vaccine. The individual responsible to transport the vaccine should ensure these containers are capable of maintaining the vaccine at the correct temperatures. The provider may use the shipping containers the vaccine arrived in from McKesson Specialty. Alternatively, the provider may use hard plastic insulated containers or Styrofoam™ coolers with at least 2-inch thick walls. Thin-walled Styrofoam™ coolers, such as those purchased to hold beverages, are not acceptable.
- Pack enough refrigerated or frozen packs to maintain the cold chain. Do not use loose or bagged ice. The number and placement of refrigerated or frozen packs inside the container will depend on container size and outside temperature.
- Pack vaccines in their original packaging. Do not remove vaccine vials from boxes. Do not transfer opened vials, and do not draw up vaccine in advance.
- Keep a digital data logger near the vaccine, but away from frozen packs.
- 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.

A VFC Provider may transfer a vaccine to another VFC Provider within three months of the expiration date. It is the provider's responsibility to transfer the vaccine safely and correctly. If the cold chain is broken and the vaccine becomes unserviceable, the VFC Program may require the provider to replace the lost doses on a dose-for-dose accountability at the private purchase cost.

The VFC Program does not recommend transferring varicella-containing vaccines to another provider or location because of storage temperature requirements. Keep some of the original shipping coolers or cold packs for vaccine transfers or returns. The provider must complete a Vaccine Transfer Form in Florida SHOTS. All vaccines being transferred must be properly packed by the VFC Provider making the transfer. Vaccine transfers must be documented in Florida SHOTS to maintain accurate electronic vaccine accountability.

### **Vaccine Transferring Instructions:**

- A. The following documentation (using the Florida SHOTS Transfer Form) must be provided on a Florida Vaccines for Children Program Vaccine Transfer Form and accompany all transferred vaccine:
  - i. Provide the name of the person who is preparing and transporting the vaccine, the telephone number, and the Provider Identification Number (PIN).
  - ii. Provide the same information for the recipient receiving the vaccine (name of coordinator receiving it, PIN, and phone number).
  - iii. On separate lines, list each vaccine being transferred. Include the name of the vaccine, the temperature of the refrigerator, the temperature in the transporting cooler before and after arrival, the number of doses being transferred, the lot number, and the expiration date(s).
  - iv. At the bottom of the document, below the documentation for the vaccine being transferred, include the signatures of the person receiving and the person transferring the vaccine and the date.
- B. The transferring and receiving party should each keep a copy of the documentation for their records.

- C. A provider transferring out vaccine should enter the transfer into Florida SHOTS as an inventory transfer on the day of transfer. The inventory will not be reduced until the receiving PIN accepts the transfer in Florida SHOTS.
- D. A provider receiving vaccine into their inventory should accept the transferred vaccine as vaccine “received” in Florida SHOTS immediately upon receipt.

## Vaccine Inventory Tracking System

For providers with more than one standalone refrigerator and more than one standalone freezer storage unit, it is recommended that a vaccine inventory tracking system be implemented. This will help with identifying which unit VFC vaccines are stored in the event a temperature incident occurs.

## Emergency Vaccine Plan

In the event of an emergency situation such as a mechanical or power supply failure affecting the vaccine storage unit, the vaccine coordinator is responsible for implementing their emergency vaccine plan. The emergency vaccine plan should be completed by the provider’s Primary and Back-up Vaccine Coordinators in case of a mechanical or power outage of the vaccine storage unit and include vaccine transportation details to a back-up storage site. If the site doesn't have an emergency transport plan, the VFC Area Immunization Consultant can give the vaccine coordinator a vaccine emergency plan template to review and complete with site-specific information. A magnetized transparent document holder is given to the provider to display the emergency plan prominently on the storage unit. During subsequent VFC site visits, the VFC Area Immunization Consultant (Field Staff) reviews the written vaccine emergency plan with the provider’s vaccine coordinator and asks if the plan has been updated within the last year or sooner, if the provider has had turnover of staff, or if the back-up location to store vaccine has changed. This plan is to be implemented as outlined in an emergency. **For providers who plan to store vaccine at an off-site location during an emergency, it is highly recommended that contact is made with the storage site at least twice per year to verify the agreement is still in place.**

**For more detailed information on managing your VFC Vaccine Inventory, visit [http://flshotsusers.com/sites/default/files/uploads/2013/07/Managing-Your-VFC- Vaccine-Inventory\\_12.09.15.pdf](http://flshotsusers.com/sites/default/files/uploads/2013/07/Managing-Your-VFC-Vaccine-Inventory_12.09.15.pdf).**

# Storage and Handling

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## Storage and Handling Requirements

Providers must have appropriate vaccine storage equipment that can maintain proper temperature conditions. Refrigerators or freezers used for vaccine storage must comply with the following requirements:

1. The provider must have temperature-monitored, alarm-equipped, standalone refrigerator and freezer units. The refrigerator units should maintain the required temperature ranges between 36°F to 46°F (2°C to 8°C). The freezer units should maintain temperatures between -58°F and +5°F (-50°C and -15°C). A National Institute of Standards and Technology study conducted in 2009 demonstrated that these units maintain the required temperatures better than household combination refrigerator/freezer units.
2. Both the refrigerator and freezer units must be large enough to hold the year's largest supply of vaccine without storing vaccine in the door. The year's largest inventory of vaccine is during flu season.

**Please Note:** The VFC Program does not approve dormitory-style refrigerators for VFC vaccine storage. A dormitory-style refrigerator is defined as a small combination refrigerator/freezer unit that is outfitted with one external door.

## Equipment Maintenance

If a provider uses a manual defrost, he or she should have another storage unit with appropriate monitoring equipment for temporary storage that is capable of maintaining correct temperatures to place the vaccine in while defrosting the main unit. It is normal for ice and frost to accumulate inside the freezer. A thin layer of frost does not affect the cooling performance, but a thick layer will affect the unit's ability to maintain temperature efficiently and will eventually cause unit failure. Providers should service refrigerators and freezers properly and defrost as necessary. See unit manufacturer's recommendations for frequency. If defrosting is necessary every month or more frequently, check the seals on the doors or call a technician for necessary maintenance. The proper steps for defrosting a freezer unit vary by manufacturer. Consult manufacturer guidelines on proper defrosting procedures.

## **General maintenance consists of the following actions:**

1. Check the inside walls of the freezer weekly.
  - a. When frost has accumulated to a thickness of approximately 1 cm, the unit requires defrosting.
  - b. The more the unit is opened and closed, the more quickly frost will build.
  - c. Follow the manufacturer's specific recommendations for defrosting a freezer.
2. Remove all vaccine.
3. Place all vaccine in an alternate storage unit(s) that will maintain correct temperatures.
4. Turn off the power to the unit you are defrosting and unplug the unit.
5. Remove all frozen packs (keep frozen if possible).
6. Keeping the freezer door open, allow the frost to melt.
7. Remove loose ice by hand to speed up the process, but do not use sharp tools.
8. Defrosting time can be reduced by placing a container of warm water (not boiling hot) inside the compartment.
9. Once the frost is melted completely, clean the freezer compartment thoroughly and wipe dry.
10. Connect the power; ensure that the thermostat is turned on and set correctly.
11. Wait for the temperature to stabilize within the proper range before returning vaccine to defrosted unit. This may take hours or even a day depending on the unit, so monitor with a calibrated data logger.
12. Monitor and record the temperature frequently (every hour for several hours).
13. Re-stock the unit with vaccine once the temperature is stabilized. Return to monitoring the temperature twice a day after the vaccine is returned to the unit.



## **Temperature Monitoring Equipment**

Providers are required to have a working and up-to-date temperature monitoring digital data logger (DDL) with a Certification of Calibration (certified in accordance with the American Society for Testing and Materials [ASTM] standards) in each of their refrigerator and freezer units used for vaccine storage. Providers should follow the manufacturer's recommended schedule for recalibration of the certified DDL.

In the absence of manufacturer recommended timeline, calibration testing must be performed at least every 24 months. All VFC Providers are required to upload their data logger temperature recordings every seven days into Florida SHOTS.

Providers are also required to have, on hand, at least one working and up-to-date back up digital data logger with a Certification of Calibration (certified in accordance with ASTM standards).

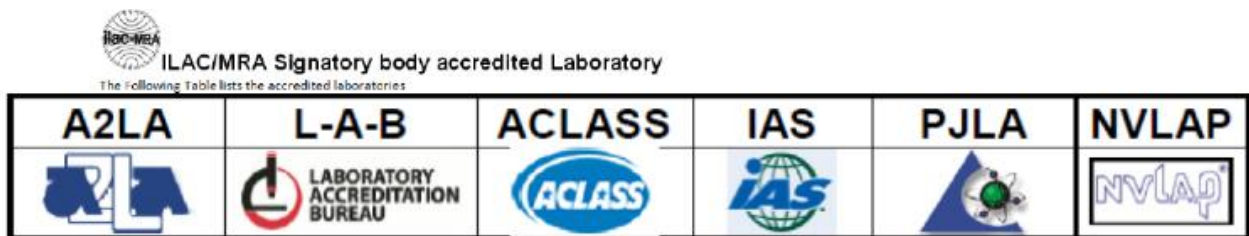
The back-up digital data logger must have a Certification of Calibration expiration date that should be 60 days greater than the expiration of the one currently being used in the vaccine storage units.

## **Certification of Calibration**

Providers are required to use a certified calibrated DDL 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.

## Temperature Monitoring Equipment Acceptable for VFC

### Program Participation:

- Provides continuous monitoring information with an active display.
- Displays current temperatures 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/Low 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 digitally).
- User programmable logging interval (or sampling rate) of 15 minutes (Florida SHOTS will only log readings every 15 minutes).
- Accuracy of +/- 0.5 degree Celsius or +/- 1 degree Fahrenheit as certified by a current Certificate of Traceability and Calibration.

**Requirement:** Providers must use a continuous temperature monitoring device or DDL with a probe in a buffered material in all of their VFC vaccine storage units. The temperature readings are required to be uploaded into Florida SHOTS.

## Temperature Monitoring Equipment 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 bio-safe 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 Bio-Safe Liquid**

## Probe Placement Requirements

- Place the probe 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 probe on the middle shelf, adjacent to the vaccine, or hanging down from the upper shelf.
- In the freezer, suspend the probe 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 shelf or bottom of the unit.
- If temperatures read out of range, ensure that the probe is appropriately located.



**Placement of Probe**

## **Thermometer Recalibration**

Certified-calibrated digital data loggers require periodic recertification and recalibration in order to remain accurate. Contact the manufacturer for instructions regarding recalibration procedures. When choosing a certified calibrated DDL, consider the cost and frequency of required recalibration. Recalibration costs will vary by manufacturer, model, and type of data logger. 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 Digital Data Logger**

VFC Providers are required to have at least one back-up DDL with a current certificate of calibration on hand. Back-up digital data loggers should not be stored in the storage units with the primary device. This allows the back-up temperature monitoring device to be used in the event that something happens to the primary DDL or if it needs to be sent out for recalibration.

### **The back-up temperature monitoring device or digital data logger 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

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 response procedures, equipment failures, and improper maintenance have all been implicated in vaccine mishandling incidents.



Continuous monitoring temperature alarm/notification systems

# **Temperature Incidents**

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## Temperature Incidents

Due to continuous monitoring devices, more information is made available surrounding the details of a temperature incident. A temperature excursion is defined as a storage unit reaching out of VFC required temperature ranges. A temperature incident is a series of temperature excursions within established parameters. **TEMPERATURE EXCURSIONS SHOULD BE REPORTED TO THE FLORIDA VFC PROGRAM IMMEDIATELY UPON DISCOVERY.**

The Florida VFC Program has developed a process that addresses, investigates, and resolves temperature incidents reported by our providers. Providers are required to follow this process in order to avoid being penalized by the restitution policy.

## Temperature Monitoring Resolution Process

1. Report temperature incident to VFC Program immediately, preferably through FloridaVFC@flhealth.gov. Provider storage unit temperatures will be reviewed before VFC vaccine orders are processed. If there has been a recent temperature excursion within the past seven days, the provider's VFC order will be suspended.
2. Communications will be sent to the Medical Director, VFC Primary Coordinator, and the Back-up Coordinator, including information with parameters, checklist, and vaccine inventory impacted. Documents that include a summary of the event, a copy of the vaccine management plan, on hand vaccine inventory, and manufacturer viability letters should be kept and made available to the VFC Program as needed
3. Providers will be instructed to contact the manufacturers of the vaccine impacted in the incident and report the parameters provided to them by the VFC Program for stability information within 24–72 hours.
4. Once documents are returned and reviewed by the VFC Program, vaccine viability will be communicated to the VFC Providers including further instructions.

# Restitution Policy

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## Restitution Policy

The following vaccine management situations **WILL** require a VFC Program Provider to replace vaccine:

- The VFC Provider does not properly store the VFC vaccine.
- The VFC Provider administers vaccine that was involved in a temperature excursion.
- The VFC Provider administers potentially compromised vaccine, where stability data from the vaccine manufacturer was not obtained and provided to the VFC Program Office so that a determination can be made on whether the vaccine is viable.
- The VFC Provider has not documented 14 or more days of temperatures for their VFC vaccine storage units within Florida SHOTS. These required missing data prevent the VFC Program Office and the vaccine manufacturers from determining vaccine viability for administering to patients.
- Does not have a current emergency vaccine management plan in place upon any VFC Program Office request.
- The VFC Provider did not contact the VFC Program or their VFC Area Immunization Consultant for assistance with expiring vaccine.

## Temperature Excursions

In these scenarios, the VFC Program Provider **DID NOT** perform one or more of the following activities and may have been required to replace vaccine:

- **Immediately contact** Area Immunization Consultant or the VFC Program Office when documented temperatures, through manual entry or data file upload into Florida SHOTS, were outside of the required temperatures ranges.
- **Implement** emergency vaccine storage management plan.
- **Contact** vaccine manufacturers or provide the Vaccine Manufacturer information to the VFC Program Office so that vaccine viability could be determined.
- **Quarantine** potentially compromised vaccine where stability data from the vaccine manufacturer was not obtained or did not support continued use.

**The following vaccine management situations WILL NOT require a VFC Program Provider to replace vaccine:**

**Natural Disasters:**

A Florida VFC Program Provider with a current emergency vaccine management plan will not be asked to replace vaccines that were lost due to a natural disaster, such as a hurricane, impacting their ability to maintain VFC vaccine storage and handling temperature requirements. The provider took the following steps to address an excursion in which the provider was NOT negligent regarding the management of the vaccine (i.e. a power outage or similar incident):

1. Contacted the VFC Program Office upon their knowledge of the excursion.
2. Implemented their emergency vaccine storage management plan.
3. Quarantined the vaccine related to the excursion, marked “Do Not Use/Administer” and did not administer the vaccine.
4. Contacted the vaccine manufacturers to assist the VFC Program Office to determine the stability of the vaccines once parameters were provided by the VFC Program.
5. The VFC Program shipped the provider vaccine that expires within the next 60 days.
6. The VFC Provider contacted the VFC Program upon receipt of shipment for assistance to manage vaccine no less than 60 days before it expired. This allows time to find a provider that can use the vaccine.

**Vaccine Accountability**

VFC Providers need to prioritize inventory accountability. Just like in the hospital setting, there should be two people counting and verifying the vaccine doses/counts (medication dose counts). There should never be doses unaccounted for. To avoid wasting doses, CHD staff need to run the “Aging Vaccine Report” in FL SHOTS and rotate or move vaccine up front for immediate use or transfer it out within 90 days of expiration. It is understandable that sometimes vaccine doses might get wasted. However, we should be diligent in not allowing vaccine to expire.

# **Fraud and Abuse**

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## Fraud and Abuse

As the cost of childhood vaccines increases and the complexity of immunization programs grow, the federally funded Vaccines for Children Program, administered by the Immunization Section, becomes more vulnerable to fraud and abuse. 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 the 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-eligible patients and 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, or consumer protection or medical licensure laws may also apply.

### Definitions:

- **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.
- **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.
- **Oversight:** A mistake due to someone forgetting or failing to notice something.
- **Enforcement:** The act of carrying out requirements and policies effectively.

- **Wasted:** Any vaccine that a provider cannot use. This includes expired, non-viable, and lost vaccines.
- **Expired:** Any vaccine with an expiration date that has passed.
- **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 the vaccine is non-viable.
- **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.

## **Identification (Suspicion) of Fraud and Abuse**

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

## **Fraud and Abuse Reporting**

Contact the Florida VFC Program Fraud and Abuse Hotline (toll-free) at 1-877-888-7468. Complete the Florida VFC Program Suspected Fraud and Abuse Report Form located at FloridaHealth.gov, then fax it to 850-922-4195 or mail it to:

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

## **VFC Program Authority**

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:

- Extenuating circumstances
- 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 10 working days from the assessment and determination of fraud or abuse.**



## **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 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 and may be terminated from the VFC Program. The provider's name may be added to the excluded provider list, and 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 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.
- G. The Immunization Section will make this determination on a case-by-case basis, depending on such factors as:
  - i. The amount of money lost by the VFC Program
  - ii. How the VFC Program identified the incident
  - iii. Duration time of the incident

- iv. 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.

# VIS and VAERS

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## What is a Vaccine Information Statement (VIS)?

Vaccine Information Statements are information sheets produced by the Centers for Disease Control and Prevention 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. A VIS may be provided by paper copy, reviewing a permanent office copy, reviewing on a computer monitor, or downloading to an electronic device.

### Provider responsibilities

- A. Offer 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 a video version, provide additional printed material, or provide additional information 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 [www.CDC.gov/vaccines/hcp/vis/index.html](http://www.CDC.gov/vaccines/hcp/vis/index.html). We encourage all providers to sign up to receive CDC updates regarding VIS statements through the website.

**CDC's Contact Center: 1-800-CDC-INFO** (or 1-800-232-4636)

**Immunization Action Coalition website: <http://immunize.org/vis>**

## Vaccine Adverse Event Reporting Systems (VAERS)

VAERS is a national vaccine safety surveillance program co-sponsored by the CDC and the Food and Drug Administration for collection of information about adverse events (possible side effects) following immunization with U.S.-licensed vaccines. By monitoring such events, 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/index.jsp](http://www.VAERS.hhs.gov/esub/index.jsp).

**Mail:** Print form at [www.VAERS.hhs.gov/uploadFile/index.jsp](http://www.VAERS.hhs.gov/uploadFile/index.jsp) and mail it to:

**VAERS**

**P.O. Box 1100**

**Rockville, Maryland 20849-1100**

**FAX:** Print form (from above link) and FAX it to 1-877-721-0366 (toll-free)

**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:

**ATTN: VAERS Coordinator**

**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.

# Resources

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## **Training Resources**

Whether you have a new Florida SHOTS account or just need refresher training to stay up-to-date on the latest registry tools, training tools are available 24/7. Save time and download training guides at <http://flshotsusers.com/training/training-guides/>. Guides are available in English and Spanish.

## **Live Trainings**

Live trainings are offered in English and Spanish and include easy to follow step-by-step instructions about using Florida SHOTS and all of its tools and reports. Begin by selecting the appropriate office type: private provider or county health department.

## **Recorded Trainings**

Recorded versions (English and Spanish) of various training webinars are available as a supplement or a refresher.

## **Training Guides**

Save time and download one of our quick tips training guides—abbreviated Florida SHOTS user’s manuals. Begin by selecting the appropriate office type: private provider or county health department. Guides are available in English and Spanish.



# Training Resources for County Health Departments

## General Florida SHOTS Resources

- DH680 Form Creation Changes
- DH680 Changes FAQs
- List of Vaccine Types
- Private Providers' FAQs
- Quick Tips for Full-Access Accounts
- Quick Tips for View-Only Accounts
- Current VIS Dates
- Inactive Status Guide
- Adding Shots with CPT Codes
- Download Tips

## Tools in Florida SHOTS

- Setting Up Patient Shot Record Retrieval
- Reminder/Recall Guide
- Assessing Immunization Levels for 1-Year-Olds
- Assessing Immunization Levels for 2-Year-Olds
- Vaccine Accountability
- Vaccine Utilization Report

## VFC Resources

- VFC Flu Order Request
- VFC Annual Enrollment in Florida SHOTS Quick Tips
- Setting Up and Using the Log Tag TRED 30-7
- Log Tag Recalibration
- VFC Recalibration Guide
- VFC LogTag Recalibration FAQs
- Accepting Pending Receipts
- VFC Waste/Return Guide
- VFC Temperature Logs Quick Tips

# Training Resources for Private Providers

## General Florida SHOTS Resources

- DH680 Form Creation Changes
- DH680 Changes FAQs
- List of Vaccine Types
- Private Providers' FAQs
- Current VIS Dates
- Quick Tips Guide for Full-Access Accounts
- Quick Tips for View-Only Accounts
- Download Tips

## Tools in Florida SHOTS

- Setting Up Patient Shot Record Retrieval
- Reminder/Recall Guide
- Assessing Immunization Coverage Levels
- Vaccine Utilization Report

## VFC Resources

- Adding VFC Vaccines
- VFC Flu Order Request
- VFC Annual Enrollment in Florida SHOTS Quick Tips
- VFC Temperature Logs Quick Tips
- Setting Up and Using the LogTag
- Log Tag Recalibration
- Log Tag Recalibration FAQs
- VFC Vaccine Ordering
- How to Manage VFC Vaccine for Your Site
- How to Determine Your VFC Ordering Cycle
- Private Providers' FAQs—VFC Vaccine Ordering and Inventory
- Private Providers' FAQs—VFC Temperature Monitoring

## Additional Resources

- **Florida Department of Health Immunization Section**  
[FloridaHealth.gov/programs-and-services/immunization/](http://FloridaHealth.gov/programs-and-services/immunization/)
- **CDC Immunization Website**  
[www.CDC.gov/vaccines/index.html](http://www.CDC.gov/vaccines/index.html)
- **CDC Immunization Schedules**  
[www.CDC.gov/vaccines/schedules/index.html](http://www.CDC.gov/vaccines/schedules/index.html)
- **CDC Vaccines for Children (VFC) Website**  
[www.CDC.gov/vaccines/programs/vfc/index.html](http://www.CDC.gov/vaccines/programs/vfc/index.html)
- **CDC Vaccine Storage and Handling Toolkit**  
[www.CDC.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf](http://www.CDC.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf)
- **CDC “You Call the Shots” Training**  
[www.CDC.gov/vaccines/ed/youcalltheshots.html](http://www.CDC.gov/vaccines/ed/youcalltheshots.html)
- **Florida SHOTS**  
<http://FLSHOTSusers.com/>
- **Immunization Action Coalition**  
<http://immunize.org/>
- **Standards for Adult Immunization Practice**  
[www.CDC.gov/vaccines/hcp/adults/for-practice/standards/index.html](http://www.CDC.gov/vaccines/hcp/adults/for-practice/standards/index.html)

# Vaccine Management Plan Template

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## Vaccines for Children (VFC) Program Vaccine Management Plan

Practice Name: \_\_\_\_\_ PIN: \_\_\_\_\_

Primary Vaccine Coordinator: \_\_\_\_\_

Back-Up Vaccine Coordinator: \_\_\_\_\_

### Vaccine Management Personnel

This section highlights key duties of designated vaccine management staff. However, all personnel working with vaccines should be familiar with VFC Program requirements and guidelines.

#### Provider of Record (Enrollee)

- Complies with all federal vaccine management requirements, including key areas outlined in this plan.
- Designates one employee as the practice's Primary Vaccine Coordinator, responsible for vaccine management.
- Designates one employee as the Back-up Vaccine Coordinator responsible for vaccine management when the primary Vaccine Coordinator is not available.
- Reports staffing changes regarding the Vaccine Coordinators, and enrollee to the VFC Program.
- Meets and documents required orientation and annual training for the practice's vaccine management personnel.
- Ensures that vaccine management personnel are skilled and knowledgeable regarding VFC Program requirements for temperature monitoring and storage equipment.
- Ensures that the practice's vaccine inventory management is consistent with VFC Program requirements.
- Ensures that the practice's vaccine storage units meet VFC Program requirements.
- Updates and revises vaccine management plans at least annually and when necessary.
- Reviews VFC Program requirements and management plans with staff at least annually and when necessary.

#### Primary Vaccine Coordinator

The Primary Vaccine Coordinator's responsibilities vary depending on the amount of vaccine the practice gives and practice protocols. The Primary Vaccine Coordinator is responsible for all vaccine management activities, completing required VFC Program trainings, including training other (especially new) staff. In other practices, a different person may have one or more vaccine management responsibilities, such as ordering vaccines. Below is a list of essential responsibilities.

##### Receiving vaccines

- Be present when vaccine is delivered and immediately process it into inventory.
- Ensures acceptable temperature ranges have been maintained.





## Vaccines for Children (VFC) Program Vaccine Management Plan

### Storing vaccines

- Rotates the vaccine inventory so that vaccines with shorter expiration dates are used first.
- Ensures there are no expired vaccines in the refrigerator or freezer.
- Keep VFC Program vaccine separate from private vaccine stock.
- Perform routine cleaning on vaccine storage units.

### Monitoring vaccine temperatures

- Use a certified calibrated thermometer to review refrigerator and freezer temperatures.
- Record current temperatures on a VFC Program supplied temperature log twice a day. If available, record minimum and maximum temperatures once a day, preferably in the morning.
- Take immediate action if temperatures are outside acceptable ranges.
- Implement the Emergency Vaccine Management Plan, if necessary.
- Review vaccine temperature logs weekly.
- Retain temperature logs for three years.

### Ordering vaccines

- Perform a physical inventory monthly of all vaccines in stock.
- Account for doses of returned or transferred vaccines since the last order.
- Complete and submit the VFC Program vaccine order in the Florida State Health Online Tracking System (SHOTS).

### Back-Up Vaccine Coordinator

- Complete required VFC Program trainings.
- Meet responsibilities described above when the primary Vaccine Coordinator is not available.

### **Vaccine Storage and Handling**

Vaccine storage and handling plans follow the "Vaccine Management Guidelines" found in the *VFC Program Manual* and the Centers for Disease Control and Prevention's (CDC) *Vaccine Storage and Handling Toolkit* found at [cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf](http://cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf).

### Vaccine Storage Units

#### Equipment

- The practice uses VFC Program compliant vaccine storage refrigerator(s) and freezer(s) and maintains required temperature ranges:
  - Refrigerator: between 36°F and 46°F (between 2°C and 8°C).
  - Freezer: between -58°F and +5°F (between -50°C and -15°C).
- Storage units have adequate capacity to store vaccine supply at all times, including during peak back-to-school and flu season.
- Storage units are routinely cleaned inside, kept dust-free outside, and doors have proper seals.





## Vaccines for Children (VFC) Program Vaccine Management Plan

- Keep maintenance and repair records on file and make them available to review upon request.

### Power Supply

- Each unit is plugged directly into a wall outlet and is not controlled by a light switch, power strips, or surge protectors with an on/off switch.
- Extension cords are never used to connect storage units to an outlet. "DO NOT UNPLUG" signs are posted at each outlet and circuit breakers.

### Set-up

- Storage units are set up according to VFC Program requirements.
- Units are kept away from direct sunlight and away from walls to allow air circulation.
- Vaccine is never stored in the door, drawers, or bins. Unit drawers/deli crispers are removed.
- To stabilize temperatures, water bottles are kept in the refrigerator where vaccines cannot be stored. Frozen cold packs are kept in the freezer for similar purpose.
- VFC Program and private vaccine storage areas/shelves are marked "VFC" and "Private" to clearly identify vaccine supplies.
- Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine.
- The glycol-encased thermometer probe is placed in the center of the unit, near the vaccines.
- The thermometer's display is securely attached to the outside of the storage unit.
- Vaccines are stored in their original packaging until administered; vaccine supply is 2-3 inches away from walls, air vents, and floor to allow space for air circulation.
- Food, beverages, and laboratory specimens are not stored in the units at any time.
- When medications or biologic media (not inoculated) are stored in the unit, they are placed on the shelves below vaccines.

### Temperature Monitoring

#### Thermometers

- Each storage unit has a VFC Program compliant thermometer accurate within  $\pm 1^{\circ}\text{F}$  ( $\pm 0.5^{\circ}\text{C}$ ).
- Each thermometer has a current and valid Certificate of Calibration (also known as a Report of Calibration).
- Each thermometer has a biosafe glycol-encased probe placed in the center of the storage unit in close proximity to the vaccine.
- Each thermometer has a digital display of current, minimum, and maximum temperatures.
- The practice has a minimum of one back-up thermometer, meeting VFC Program requirements, for use when primary thermometers fail or are being recalibrated.
- Probes are NEVER placed in the unit's doors, near or against unit's walls, underneath air vents, or on the unit floor.
- Thermometer batteries are replaced every six months.

#### Thermometer Calibration

- Primary and back-up thermometers are calibrated annually (or according to the manufacturer's recommendation).





## Vaccines for Children (VFC) Program Vaccine Management Plan

- Thermometer calibration is done by a laboratory with accreditation from an ILAC/MRA signatory body.
- Valid certificates not issued by an accredited lab must include: date of testing, thermometer model/serial number, measurement results, uncertainties, pass/fail statements, and statement that testing meets ISO 17025 Standard.
- Certificates of Calibration are filed in a readily accessible area, kept for three years, and are presented to VFC Program and Immunization Section staff for review upon request.
- Thermometers are replaced when no longer accurate within  $\pm 1^{\circ}\text{F}$  ( $\pm 0.5^{\circ}\text{C}$ ) based on calibration results.

### Safeguarding Vaccines, Handling and Reporting Out-of-Range Temperatures

- When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage.
- The VFC Program is contacted to report the incident and to file a storage and handling incident report.
- Label vaccine "DO NOT USE." Keep vaccine stored in the recommended temperature range, if possible.
- The practice has an Emergency Vaccine Management Plan to follow in the case of power outage, appliance malfunction, weather conditions, or human error that may affect vaccine viability.
- When necessary to transport vaccine to another storage unit or to a predetermined site, the practice always follows VFC Program guidelines.
- Actions are documented on the VFC Program temperature log and other VFC Program forms, as appropriate.

### Temperature Monitoring and Documentation

- Read and record refrigerator and freezer temperatures twice a day, when the clinic opens and before it closes.
  - Record current temperatures on a VFC Program supplied temperature log twice a day. If available, record minimum and maximum temperatures once a day, preferably in the morning.
  - Record a.m. temperatures before opening storage units.
  - Record p.m. temperatures at the end of the day.
  - Reset MIN and MAX after each reading by pressing the memory clear button (in most thermometers).
- The person documenting the storage unit temperature initials the temperature log.
- Document temperatures on VFC Program temperature log even if the practice uses a continuously recording/graphing thermometer, data logger, or remote monitoring system.
- Temperature logs are posted on the storage unit door or nearby in an accessible location.
- The practice maintains completed temperature logs for three years and makes them available for review upon request to VFC Program representatives.

### Inventory Management

#### Vaccine Stock

- The practice conducts a physical vaccine inventory at least once a month and before ordering vaccine.







## Vaccines for Children (VFC) Program Vaccine Management Plan

- The practice has enough vaccine supply to meet the needs of its VFC Program eligible patients.
- The practice must keep up to four weeks' additional supply to mitigate shortages in the event of shipment delays.
- The practice uses an inventory control system, i.e., usage log, which documents each patient, vaccine type, lot number, and date of administration.
- The practice maintains accurate records, including purchase invoices, for privately purchased vaccines and makes them available upon request to VFC Program representatives.
- Vaccine drawn up and not used is disposed of and accounted for properly in Florida SHOTS.
- When diluent is packaged with vaccine, the practice stores them together. When diluent is not packaged with its vaccine, the diluent is clearly labeled and stored where it can be easily identified.

### Stock Rotation, Returns, and Transfers

- The practice organizes vaccines so those with the shortest expiration dates are used first.
- The practice returns expired and/or spoiled vaccine to McKesson for excise tax credit within six months of expiration/spoilage.
- If the practice has vaccine due to expire within three months and it will not be used:
  - Notify the VFC Program about the vaccine.
  - Request a transfer approval from the VFC Program.
  - Identify VFC Program providers in the area to contact and inquire if they may be able to use the soon-to-expire vaccines.
- If a practice transfers or transports vaccine, it follows VFC Program guidelines, and completes the appropriate transaction in Florida SHOTS.
- If vaccine becomes spoiled or expires, staff removes it immediately from the storage unit, reports it to the VFC Program, and adjusts it out of their inventory in Florida SHOTS.
- The practice may return unused vials/prefilled syringes to McKesson if unopened and in original packaging.
- The following vaccine supplies should not be returned:
  - Used syringes with or without needles.
  - Syringes with vaccine drawn up and not used.
  - Broken or damaged vaccine vials.
  - Multi-dose vials that have already been withdrawn.
- Vaccine that is spoiled or expired must be reported to the VFC Program before a new order can be submitted.

### Vaccine Ordering

- Orders are submitted in Florida SHOTS and placed according to assigned order frequency, vaccine usage, and take into account the inventory in stock. Orders are placed with sufficient inventory on hand to allow time for order processing and vaccine delivery
- The practice does a physical inventory before placing a vaccine order.
- Providers must document inventory and doses administered since the previous order for each order.





## Vaccines for Children (VFC) Program Vaccine Management Plan

- Every VFC Program vaccine dose is accounted for; vaccine doses not accounted for or lost due to negligence will be replaced at the expense of the provider of record for the facility.
- The practice verifies its hour of operation in the Florida SHOTS before submitting each order.
- Any changes to the practice's hours are reported to the VFC Program to avoid receiving vaccine shipments when the clinic is closed or the staff is not available. The VFC Program is not responsible for wasted vaccine due to incorrect delivery address or provider hours.

### Receiving and Inspecting Vaccine Shipments

- The practice assumes responsibility for all VFC Program vaccine shipped to its site.
- Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, length of time the vaccine was in transit, and that the vaccines being delivered match those listed on the packing slip and order confirmation.
- The practice never rejects vaccine shipments.
- The practice reports shipment discrepancies and vaccine exposed to out-of-range temperatures immediately to the VFC Program.
- Vaccines are immediately stored according to VFC Program requirements.
- The practice accepts the pending receipt in Florida SHOTS to add the vaccine to their inventory.

### Staff Training on Vaccine Management and VFC Program Requirements

All office staff that handle or administer vaccines should receive annual training to ensure they are familiar with the **Vaccine Management Plan** and the VFC Program requirements.

### Signature Log

Staff assigned vaccine management responsibilities are to review and sign the signature page at the end of this document annually and when the plan is updated. This Plan may be reviewed by VFC Program Area Immunization Consultants during routine and drop-in site visits. By signing, I acknowledge I have reviewed and am familiar with the information in this document.

Review Date:	
Provider of Record Name:	Signature:
Primary Coordinator Name:	Signature:
Back-Up Coordinator Name:	Signature:

Review Date:	
Provider of Record Name:	Signature:
Primary Coordinator Name:	Signature:
Back-Up Coordinator Name:	Signature:



# **Emergency Management Plan Template**

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## EMERGENCY VACCINE MANAGEMENT PLAN (Sample)

Post on outside of storage unit for all staff

Phone Number:

Practice Name:	
Primary Person Responsible for Vaccines:	
Secondary Person Responsible for Vaccines:	
Person with 24-hour Access:	
County Health Department:	

### How to Manage Vaccines in the Following Scenarios:

- Power failure
- Vaccine storage unit failure
- Staff left the refrigerator door open
- Temperature was too cold
- Storage unit became unplugged
- Any other improper storage condition

1. Close the door and/or plug in the refrigerator/freezer.
2. Record the current time and temperature of the refrigerator/freezer.
3. Move the vaccines to a refrigerator/freezer that is working properly and document the time of relocation. *Do not throw out the affected vaccine.*
4. Mark and quarantine the potentially compromised vaccines for easy identification.
5. Notify the VFC Program at 1-877-888-7468 Option 1.
6. Adjust thermostat as needed and monitor temperatures frequently.
7. Call manufacturers of all exposed vaccine(s) and submit documents\* to [floridavfc@flhealth.gov](mailto:floridavfc@flhealth.gov).

**In Case of a Power Outage:** If you do not have a generator, identify at least one location with a generator (hospital, 24-hour store, etc.). Before transporting, call the back-up location site to ensure that their generator is working and they have room for the vaccine stock.

1. Location & Contact's Name: \_\_\_\_\_ Telephone #: \_\_\_\_\_
2. Location & Contact's Name: \_\_\_\_\_ Telephone #: \_\_\_\_\_

How will you be notified of an outage? \_\_\_\_\_

\*Completed On-Hand Inventory of Exposed VFC Vaccines form, Vaccine manufacturers' recommendation letters for all vaccines stored in the unit and Written, detailed explanation of the incident, including pertinent times and temperatures especially if vaccines were relocated, and plans to avoid future incidents.

Updated June 2019

## Contact Information

*As a Florida Vaccines for Children (VFC) Provider, we thank you for helping to protect, promote and improve the health of all the people in Florida through integrated state, county, and community efforts.*

<b>Phone</b>	<b>1-877-888-7468</b>
<b>FAX</b>	<b>850-922-4195</b>
<b>Email</b>	<b>Immunization@flhealth.gov</b>
<b>Mailing Address</b>	<b>Florida Department of Health</b> Immunization Section 4052 Bald Cypress Way, Bin A11 Tallahassee, Florida 32399-1719

