



2015 – 2016 Vaccines For Children (VFC) Program Protocol

Table of Contents

SECTION A. VFC Program-Federal Vaccines for Children Overview 1

SECTION B. Requirements for Initial Enrollment and Annual Re-Enrollment..... 1

 New Provider Enrollment (New Enrollees) 2

 Annual Re-Enrollment (Returning Providers) 3

SECTION C. Requirements to Participate in the VFC Program 5

 New 2015 VFC Program Requirements 8

SECTION D. VFC Eligibility 9

 Eligibility Criteria and Categories 9

 VFC Screening and Documentation 10

 Medicaid and Secondary Insurance or Medicaid HMO 11

 Children who qualify for more than one VFC eligibility criteria 12

 Border States to South Carolina 12

SECTION E. Vaccine Inventory Management..... 12

 Vaccine Ordering 12

 Vaccine Transfers 13

 Vaccine Borrowing 14

 Vaccine Wastage 15

 Vaccine Stock Supply 16

SECTION F. Vaccine Storage Equipment..... 16

 Vaccine Storage Units..... 16

 Documentation Requirements for Acceptable (New and Existing) Vaccine Storage Units 17

 Thermometers 18

 Thermometer Requirements 18

 CDC strongly recommends thermometer with the following characteristics 18

 Calibration Testing and Traceability Requirements 19

 Thermometer placement 20

 Temperature Monitoring Requirements 20

 Storage Temperatures 21

SECTION G. Vaccine Management Storage and Handling Plans 21

 Routine Storage and Handling 22

2015-2016 VFC Program Protocols
DHEC Immunization Division

Disaster Recover (emergency plan)	22
Roles of the primary/back-up vaccine coordinator(s).....	22
<u>SECTION H. Vaccine Adverse Event Reporting System (VAERS)</u>	23
<u>SECTION I. VFC Program Site Visits</u>	23
VFC Enrollment Visit	24
VFC Compliance Site Visit	24
Assessment Feedback Incentive eXchange (AFIX) Site Visit.....	24
Unannounced Site Visit.....	24
Annual Provider Training	24
<u>SECTION J. VFC Provider Education Training Requirement(s)</u>	25
CDC Web-based Training Courses	25
Immunization: You Call the Shots Vaccines For Children	25
Immunization: You Call the Shots – Storage and Handling	25
VFC Program Provider Presentation	25
VFC Compliance Site Visit.....	25
<u>SECTION K. Non-Compliance with VFC Program Protocols</u>	26
Purpose.....	26
Definitions.....	26
Notification	27
Intervention	27
<u>SECTION L. Disenrollment in the VFC Program</u>	29

2015 - 2016 Vaccines For Children (VFC) Program Protocol

SECTION A. VFC Program-Federal Vaccines for Children Overview

The Federal Vaccines for Children (VFC) Program was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program (Title XIX Medicaid program) to be a required part of each state's Medicaid plan. The VFC program was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative. The VFC program is a unique component of each state's medical assistance plan and is considered a Title XIX Medicaid program. Funding for the VFC program is approved by the Office of Management and Budget and is allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). CDC purchases vaccines at a federally contracted rate and distributes them to the nation for VFC eligible children. In South Carolina these vaccines are distributed, without charge, to provider sites that enroll in the Federal Vaccines For Children (VFC) Program in annually. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP) through passage of VFC resolutions.

Effective 06/15/2012, the Department of Health and Environmental Control (DHEC) immunization program began using an online system, called the *South Carolina Immunization Provider Access System (SCI PAS)* for initial enrollment and annual re-enrollment. This online system allows VFC providers to update information and receive timely communications from the Immunization Division.

SECTION B. Requirements for Initial Enrollment and Annual Re-Enrollment

All providers must complete an initial enrollment to participate in the VFC program.

Initial enrollment into the VFC program can be initiated at any point in time by a SC licensed practitioner authorized to administer pediatric vaccines under state law as defined by the VFC program.

Annual re-enrollment is required to continue in the program after *initial* enrollment. Annual re-enrollment will occur in March/April annually with an email notification to all VFC providers. **The enrollment forms must be completed and submitted in SCI PAS VFC Enrollment System within 45 days after the enrollment period begins each year to avoid any interruption in the receipt of vaccine. The Vaccine Coordinator and Electronic Signature Authority (ESA) may complete the VFC enrollment documents, however; only the ESA can submit the VFC enrollment application. The ESA must log into the SCI PAS VFC Enrollment System and submit the enrollment application.** The provider site should print a copy of all enrollment forms

from SCI PAS VFC Enrollment System and retain a *signed (electronic signature) copy* of the completed enrollment/re-enrollment for future reference. As the provider site updates information in SCI PAS VFC Enrollment System it is important for the provider site to keep the updated copies of enrollment forms for the VFC Compliance Site Visit.

All VFC providers that have not successfully re-enrolled into the VFC Program by May 31st will be contacted by the Immunization Division to schedule a time to retrieve all 2014-2015 VFC vaccines.

NEW PROVIDER ENROLLMENT:

All new enrollees and re-enrollees (providers who were enrolled in or prior to the 2013-2014 enrollment cycles) must complete and submit VFC enrollment forms via SCI PAS VFC Enrollment System. For New enrollees the enrollment process at a minimum takes a month to complete. All enrollees are encouraged to contact the Immunization Division with any questions or concerns about enrolling in the VFC Program at 803-898-0460. The Steps below will guide enrollees in this process. Click on this link [Annual VFC and State Enrollment/Re-Enrollment Quick Reference Guide](#) to begin.

Steps to begin VFC Enrollment forms for New Enrollees:

1. Review all supporting documents for VFC Program participation. All form are located here [VFC and SC State Vaccine Program Information and Resources](#)
2. New Enrollees **only** must Establish a NEW ACCOUNT in SCI PAS click here for instructions on [Establishing a New Account Quick Reference Guide](#). The enrollee will receive and email notification from the Immunization Division about their new account status.
3. Certificates of completion for the Annual Provider Training **must be uploaded** in the SCI PAS VFC Enrollment System prior to beginning the VFC enrollment forms. After viewing the modules, participants can go to [CDC's online learning system](#) to register for and obtain CE credit. General instructions are available in the [CE How-to Guide](#). Persons who are designated by the enrollees practice as the **Primary** and **Back-Up Vaccine Coordinators** **must** complete this Annual Provider Training via CDC Training Modules.
 - a. Immunization: You Call the Shots Vaccines For Children Program WB 2486
 - b. Immunization: You Call the Shots- Storage and Handling WB 2485.
See the VFC Training Resources and Annual Provider Training. Click here <https://www.scdhec.gov/scipas/VFCInformation.aspx>
 - c. Complete VFC Enrollment forms via SCI PAS VFC Enrollment System.
 - d. Properly set up vaccine storage unit(s) in preparation to received vaccine. See Section F. Vaccine Storage Equipment and the [Vaccine Storage and Handling Toolkit](#) for more information regarding vaccine storage units.
 - e. Upload all required documents for vaccine storage unit(s) to the South Carolina Vaccine Management and Disaster Recovery Plan (DHEC 1225) as instructed in the SCI PAS VFC Enrollment System.
 - a. Floor diagram of site where vaccines are stored

b. Certificate(s) of Calibration

- f. Local Immunization Division program field representative will conduct an enrollment visit to educate staff on VFC program requirements and inspect the vaccine storage equipment at the enrollees practice.
- g. Approval to become a provider in the VFC Program is dependent upon the new enrollee's ability to meet all VFC program requirements. Upon review of information submitted in the VFC enrollment system and completion of the enrollment visit, the enrollee will receive an email communication informing them of their status of enrollment in the vaccine programs. Vaccine order forms will be sent to the practice once site is approved to receive publicly funded vaccine(s).

ANNUAL RE-ENROLLMENT (RETURNING PROVIDERS): VFC providers who were enrolled during the 2014-2015 VFC re-enrollment cycle.

- 1. Review all supporting documents for VFC Program participation. All forms located on the [VFC and SC State Vaccine Program Information link](#).

*Each provider site must **complete** the following forms in SCI PAS VFC Enrollment System:*

- A. Vaccines For Children Program Provider Agreement (DHEC 1144)
PRACTICES WITH MULTIPLE SITES MUST ENROLL EACH SITE AS A SEPARATE VFC PROGRAM PROVIDER SITE.
- B. Vaccines For Children Provider Profile Form (DHEC 1145)
- C. South Carolina Vaccine Management and Disaster Recovery Plan (DHEC 1225)
- D. Review and accept the terms for the Vaccines For Children (VFC) Program Patient Eligibility Screening Record Form (DHEC 1146 or DHEC 1146D)

Additionally, each provider must **review** the following link [VFC and SC State Vaccine Program Information](#):

- A. Vaccines For Children Program Protocols
- B. All other Vaccine Forms:
 - Vaccines For Children (VFC) Program Vaccine Borrowing Report (DHEC 1167)
 - South Carolina Vaccine Transfer Form (DHEC 1208)
 - South Carolina Vaccine Wastage and Return Form(DHEC 1209)
 - South Carolina Refrigerator/Freezer Temperature Log Form (DHEC 1627)
 - South Carolina Vaccine Program(s) Disenrollment Form (VFC or SC State) DHEC 1984

- Vaccines For Children (VFC) Program Suspected Fraud and /or Abuse Referral Sheet Form (DHEC 1997)
 - Immunization Information Form (DHEC 1103V)
 - Pediatric Vaccine Doses Administered Worksheet (DHEC 1150)
 - SC Vaccine Inventory Log (DHEC 1131)
2. Annual VFC enrollment/re-enrollment requires the signature of the Medical Director or Equivalent who is the Electronic Signature Authority (ESA) on all forms. The ESA may designate users in the SCI PAS VFC Enrollment system that may access VFC enrollment forms.
- ❖ The ESA must be a Medical Doctor (MD), Doctor of Osteopathy (DO), Advanced Practice Registered Nurse (APRN), or *Registered Pharmacist (RPh) who is required to complete all the VFC enrollment forms.
 - Doctor of Medicine (MD) or Doctor of Osteopathy (DO) **must** co-sign the VFC Program Provider Agreement as the Medical Director or Equivalent on the DHEC 1144.
3. ESA should log in to SCI PAS using their current individual email address and password. If the ESA has forgotten their password, they will need to contact the Division of Immunization's Help Desk at 866-439-4082 and choose option 2.
4. All documentation **must be uploaded** in the SCI PAS VFC Enrollment System:
- a. CDC Training Certificates for Primary and Backup Vaccine Coordinator;
 - b. Certificates of Traceability and Calibration for certified calibrated thermometers;
 - c. Vaccine Storage Facility Floor Plans (floor diagram).
- DO NOT FAX OR EMAIL ANY DOCUMENTS TO THE IMMUNIZATION DIVISION.**
5. Log into SCI PAS VFC Enrollment system periodically to check the provider's VFC enrollment status. The Immunization Division will contact the ESA by email if VFC enrollment documents are considered incomplete and cannot be processed.
6. VFC Providers will receive an email from the Immunization Division notifying them of their approved enrollment status. Vaccine Order Forms will be attached to the email only if the provider's vaccine order forms are different from the 2014-2015 VFC enrollment cycle.

Additionally All Providers Must:

- A. Provide the VFC Program with email address (es) through SCI PAS VFC Enrollment System of: (1) Medical Director or Equivalent who is responsible for signing the Provider agreement for the practice (*ESA*) and (2) person(s) who should receive email communications regarding vaccine management and VFC Program updates (Primary Vaccine Coordinator and Back up Vaccine Coordinator). It is the ESA's responsibility to ensure that all *email contact information is current in*

SCI PAS VFC Enrollment System. This information will ensure appropriate communications from the Immunization Division Program to identified users of SCI PAS VFC Enrollment. [Note: all email addresses will be captured in SCI PAS VFC Enrollment System during annual enrollment/ re-enrollment].

- B. Please note all changes and updates immediately in SCI PAS VFC Enrollment System as they occur Including, but not limited to, the following: office hours for receiving vaccine shipments, change of address (shipping/ mailing), VFC Vaccine Coordinators and their email addresses, telephone number, fax number, facility status, number of VFC and Non VFC eligible children, and additions/deletions of providers practicing at the facility who have prescribing authority (MD, DO, NP, Physician Assistants, Pharmacist), or SCI PAS Users to the provider site. VFC Providers must contact the Immunization Division one (1) month prior to moving, closing, or dis-enrolling in the VFC Program.

SECTION C. Requirements to Participate in the VFC Program

By enrolling in the VFC Program, the official VFC health care provider (Medical Director or Equivalent) signing the provider enrollment agreement must be a practitioner authorized to administer pediatric vaccines under state law (MD, DO, APRN, and Registered Pharmacist) who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The ESA agrees to comply with all VFC Program Protocols, including:

1. Annual submission of a provider profile representing populations served by the practice(s)/facility(s) or more frequently if the number of children served changes or the status of the facility changes during the calendar year;
2. Screening and documenting eligibility status at each immunization encounter/visit for VFC eligibility (i.e., federally or state vaccine-eligible) prior to administering immunization(s) by such category only to children who are 18 years of age or younger who meet one or the following categories:
VFC Eligible children:
 - A. Medicaid-Enrolled
 - B. No Health Insurance
 - C. American Indian/Alaska Native
 - D. Underinsured, (served by Federally Qualified Health Center(FQHC)/Rural Health Clinic (RHC) or deputized provider)

Non-VFC Eligible Children:

- E. Insured, (private pay/health insurance covers vaccines)
- F. SC State Underinsured, (served by Non-FQHC, and Non-RHC)

G. SC State Insured (Insured Hardship and Vaccine Caps)

Refer to the VFC Patient Eligibility Screening Record Forms (DHEC 1146, DHEC 1146D, DHEC 1146S, and DHEC 1146SD) for eligibility documentation;

3. For the vaccines identified and agreed upon in the provider profile, comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) recommendations and included in the VFC program unless:
 - a) In the providers medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
 - b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

Adhering to the current Recommended Childhood Immunization Schedule as approved by the Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP) and American Academy of Family Practice Physicians (AAFP);

4. Maintaining all records related to the VFC program for a minimum of three years and upon request makes these records available for review. VFC records include, but are not limited to: VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records(temperature logs, wastage reports, transfer and borrowing forms);
5. Immunizing eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6. VFC Vaccine Eligible Children
Not charging a vaccine administration fee to **non-Medicaid** federal-eligible children that exceeds the administration fee cap of **\$20.16** per vaccine dose.
For Medicaid children, the provider **must accept** the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
State Vaccine Eligible Children
Not charging a vaccine administration fee to **non-Medicaid** state vaccine-eligible children that exceeds the administration fee cap of **\$20.16** per vaccine dose;
7. To not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee;
8. Distributing a current Vaccine Information Statements (VIS) each time a vaccine is administered and maintains records in accordance with the National Childhood

Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

The VIS should be provided to the patient, parents(s) or legal representative of any child prior to administration of any vaccine, as required by federal law (42 US Code 300aa-25) (Note: VISs may be downloaded from the CDC at <http://www.cdc.gov/vaccines/Pubs/vis> or the Immunization Action Coalition at <http://www.immunize.org>);

Documenting vaccination in records as required by the National Childhood Vaccine Injury Act (42 US Code 300aa-25): (1) the name of the vaccine, (2) date the vaccine was given, (3) name of the vaccine manufacturer, (4) lot number, (5) signature and title of person who gave the vaccine, (6) address of clinic where vaccine was given, (7) date of VIS given to the parent/guardian/individual of record (8) date printed on the VIS, (9) and any other identifying information on the vaccine required by this regulation. This law applies to all health care providers that administer vaccines regardless of the age of the individual or the source of funding for the vaccine. <http://www.nvic.org/injury-compensation/origihanlaw.aspx>;

9. Complying with the requirements for vaccine management including:
 - a) Ordering vaccine and maintaining appropriate vaccine inventories;
 - b) Not storing vaccine in dormitory-style units at any time;
 - c) Storing vaccine under proper storage and handling conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet DHEC Immunization Division storage and handling requirements;
 - d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration;
10. Operating within the VFC program in a manner to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR§ 455.2, and for the purposes of the VFC program:

Fraud: is 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, (and/or 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;

11. Participating in VFC Program compliance site visits including unannounced visits (storage and handling) and other educational opportunities associated with the VFC program requirements;
12. Providing a signed deputization Memorandum of Understanding (**if applicable**) between a FQHC or RHC and Immunization Division to serve underinsured VFC eligible children, agree to:
 - a) Included “underinsured “as a VFC eligibility category during screening for VFC eligibility at every visit;
 - b) Vaccinate “walk-in” VFC-eligible underinsured children; and
 - c) Report required usage data

Note: “Walk-in” in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a provider must serve underinsured patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well;
13. Complying pharmacies, urgent cares, or school located vaccine clinics agree to:
 - a) Vaccinate all “walk-in” VFC-eligible children and;
 - b) Will not refuse to vaccinate VFC-eligible children based on a parent’s inability to pay the administration fee;

Note: “Walk-in” refers to any VFC eligible child who presents requesting a vaccine; not just established patients. “Walk-in” does not mean that a provider must serve VFC patients without an appointment. If a provider’s office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well;
14. Reporting to the South Carolina Immunization Registry as required by S.C. Code Ann. § 44-29-40 and South Carolina Immunization Registry Regulation, S.C. Ann. Regs. 61-120 (Supp. 2013);
15. Understanding and agreeing that the Immunization Division or the practice/facility may terminate this agreement at any time. If the practice/facility chooses to terminate this agreement it will properly return any unused publicly purchased vaccine as directed by the Immunization Division.

NEW 2015 VFC Program Requirements:

VFC Providers enrolled in the VFC program must meet these requirements. All of these requirements were currently implemented in South Carolina with exception of **number 4** and **number 6**.

1. VFC Providers must now include on document signature, name, and title of the person who prepares your Vaccine Storage and Handling Plans. This is the DHEC 1225 Form that is completed for VFC enrollments.
2. VFC Providers must separate VFC stock from all *other public stocks if serving both VFC and Non-VFC Eligible Children.

3. VFC Providers must in addition to recording twice a day temperatures, NOW record the time of the reading, and the name (or initials) of person who assessed and recorded the reading.
4. **VFC Providers must have a back up thermometer (only one per office) with a current certificate of calibration**
5. VFC Providers must place thermometer probes in a central area of the vaccine storage unit with the vaccines.
6. **VFC Providers must have appropriate staff on site to receive vaccines at least one day a week other than Monday for at least four consecutive hours on that day.**

SECTION D. VFC Eligibility

1. **Eligibility Criteria and Categories:**

Children from birth through 18 years of age who meet one or more of the following categories:

VFC Eligible children

- a) Medicaid-Enrolled
- b) No Health Insurance
- c) American Indian/Alaska Native (as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603) ;
- d) Underinsured, (served by Federally Qualified Health Center (FQHC)/Rural Health Clinic (RHC) or deputized provider).
 - ❖ A child who has health insurance, but the coverage does not include vaccines;
 - ❖ A child whose insurance does not cover all Advisory Committee on Immunization Practice (ACIP)-recommended vaccines. The child would be eligible to receive those vaccines not covered by the insurance.

Non-VFC Eligible Children

- e) Insured – children whose health insurance covers the cost of vaccinations;
- f) SC State Underinsured, served by Non-FQHC/RHC-must be enrolled in the South Carolina State Vaccine Program
SC State Vaccine Program Underinsured: These children are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not an FQHC/RHC or a deputized provider. However, these children may be served with state vaccine program vaccine to cover these non-VFC eligible children. Only providers enrolled in the SC State Vaccine Program are eligible to serve this population. You must have SC State Vaccine program vaccine stock prior to seeing this patient population.
- g) SC State Insured- provider must be enrolled in the South Carolina State Vaccine Program
SC State Vaccine Program - Insured Hardship and Vaccine Caps: These children are considered insured and are not eligible for vaccines through the VFC program. However, these children may be served state vaccine program vaccine to cover these non-VFC eligible children. Insured Hardship is defined as "Health Insurance deductible is greater than \$500.00 per child or \$1,000.00 per family (Eligible for state vaccine only if the deductible has not been met and the family cannot afford to pay for vaccine)." Vaccine Caps is defined as "Insured but coverage capped at certain amount and cap has been exceeded." The Human Papillomavirus Vaccine is

excluded from the SC State Vaccine Program. Only providers enrolled in the SC State Vaccine Program are eligible to serve this population. You must have SC State Vaccine program vaccine stock prior to seeing this patient population.

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

Family Planning Clinics:

Family Planning Clinics (FPC): Minors under 19 years of age who do not know their insurance status and who present at family planning clinics for contraceptive services or STD treatment can be considered uninsured for the purpose of the VFC program. CDC defines FPC as a clinic or provider whose main purpose is to prescribe contraceptives and/or treat sexually transmitted diseases. ***School-based clinics or any VFC-enrolled provider whose main services are primary or acute care services do not meet CDC's definition of a FPC and cannot use this VFC eligibility category.*** The Family Planning Clinic Log (DHEC 1227) is used for unaccompanied minors without insurance information. This form must be completed and submitted to the VFC Program monthly, as applicable.

2. **VFC Screening and Documentation:**

A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office for 3 years. The record may be completed by the parent, guardian, individual of record, or by the health care provider. Patient eligibility screening and documentation must be performed at each immunization encounter to ensure the child's eligibility status has not changed from a previous immunization encounter. While verification of responses is not required, it is necessary to retain this or a similar record for EACH child receiving vaccine(s).

Providers **MUST** document their provider population on the VFC Program Provider Profile (DHEC 1145) in SCI PAS VFC Enrollment System annually or more frequently if the number of children served changed or the status of the facility changes during the calendar year. The provider population is an **ACCURATE reflection of how many children received VFC vaccine, by category, and how many received Non-VFC vaccine.** The VFC program patient eligibility screening record form, (DHEC 1146) is the tool that is used by the VFC enrolled provider in order to record this information as children are receiving immunizations throughout the year.

The VFC provider must be able to provide this documentation to Immunization Division Program Staff during a site visit for the timeframe requested as evidence of how they are conducting VFC eligibility screening procedures. Failure to screen and document correctly is Non-Compliance with the VFC program.

This screening MUST be documented with one of the following options below:

Option 1. Complete the paper form:

- a) Private Providers complete the Vaccines For Children (VFC) Patient Eligibility Screening Record Form, DHEC 1146 or DHEC 1146S (Spanish version);
- b) DHEC Health Departments complete the Vaccines For Children (VFC) Patient Eligibility Screening Record Form for Health Departments, DHEC 1146D or DHEC 1146DS (Spanish version) located on RIMS;

Option 2. Provider sites with Electronic Medical Records (EMR's) or Electronic Health Records (EHR's):

- a) Scan the current version of the Patient Eligibility Screening Record Form into the provider sites EMR or EHR system or;
- b) The provider must demonstrate to the Immunization Division that the EMR or EHR system can capture all reporting elements listed on the current version of the Patient Eligibility Screening Record Form (DHEC 1146 or 1146S) to ensure standardization regardless of the type of health record used or;
- c) The provider must submit a request to the Immunization Division by email at immunize@dhec.sc.gov to obtain the current portable document format (pdf) version of the Patient Eligibility Screening Record Form to be used in their EMR or EHR system.

Option 3. Screen and Document VFC eligibility status(es) for all children in the South Carolina Immunization Registry, (SCI Registry) for **Direct Data Entry Only**. Contact the Immunization Division by email sciregistry@dhec.sc.gov for instructions on how to enroll as a Direct Data Entry provider in the South Carolina Immunization Registry (SCI Registry).

Important Note:

VFC providers will notate the Vaccines For Children (VFC) Patient Eligibility Screening Record Form whenever the provider refers a child to another VFC provider to receive immunizations.

3. **Medicaid as Secondary Insurance:**

A child with Medicaid as a secondary insurance is always entitled to VFC vaccine, regardless of the fact that the child has primary insurance as well. In such a case, the provider has several options: administer VFC vaccine and then bill the vaccine administration fee to the Medicaid agency or administer private stock vaccine and bill the primary insurance the usual and customary charge for both the vaccine and the vaccine administration fee.

Providers are *strongly* encouraged to contact the South Carolina Department of Health and Human Services for more information on how to receive reimbursement of vaccine administration fees for children enrolled in Medicaid <https://www.scdhhs.gov/>.

4. **Children who qualify for more than one VFC eligibility category**
Occasionally, children may be VFC-eligible for more than one eligibility category. A provider must select the eligibility category that will require the least amount of out-of-pocket expenses to the parent/guardian for the child to receive necessary immunizations.

5. **Border States to South Carolina**
If you are a provider who may service children from a border state of South Carolina with Medicaid from that border state, please call the Immunization Division at 803-898-0460 or 800-277-4687 for assistance.

SECTION E. Vaccine Inventory Management

1. **Vaccine Ordering**
VFC Providers are to order vaccine based upon actual need of eligible children served by the practice. The VFC Program fills provider vaccine requests from the vaccine order forms. These forms should be completed monthly as needed (generally there should be a 6 week supply in inventory). DHEC clinics use the Federal Vaccines For Children (VFC) Order Form (DHEC 1130) and non-DHEC providers use the SC DHEC Immunization Program Vaccine Order Form Childhood Vaccine Programs: VFC (DHEC 1117). Providers enrolled in the State Vaccine Program order State Vaccine Program Vaccine on the State Childhood Vaccine Program Order Form (DHEC 0713) for non- DHEC Sites and DHEC sites order State Vaccine Program vaccine on the SC DHEC Immunization Program Vaccine Order Form Childhood Vaccine Programs: State and 317 (DHEC 0711). Each of these forms requires the reporting of current vaccine inventory and vaccine doses used since the last report.

Provider specific vaccine order forms can be obtained by email request at immunize@dhec.sc.gov.

When completing the Vaccine Order Form (DHEC 1130, DHEC 1117, DHEC 0711 or DHEC 0713), providers *must always show the number of doses used since the last report and give a complete report of current VFC and State inventory (if applicable) including lot numbers and expiration dates.* If additional space is needed for inventory reporting, a duplicate order form can be submitted with the additional inventory documented. Partially completed report forms may be returned, which could delay shipping of vaccines. Vaccine doses used will not be automatically replaced in the next order; the provider must enter the number of doses desired.

The VFC Program *may* modify the provider's vaccine order, as needed to manage vaccine supply.

If a provider wishes to switch from one brand of vaccine to another, they must submit the request in writing. A signed statement on the letterhead of the facility indicating which brand of vaccine the site would like to begin ordering is to be submitted along

with the order requesting the new brand. Failure to submit the request with the signed statement may result in the request not being honored. Sites are required to deplete the old brand of vaccine before using the new brand.

To submit an order, fax the form to the VFC Program at 803-898-0318. An email notification that the vaccine order has been submitted to CDC (including any modifications), will be sent to the provider within 72 hours (3 business days). If email notification is not received within 72 hours after faxing the order, the provider should send an email to immunize@dhec.sc.gov to check the status of the order.

Providers must allow up to 14 days for processing and shipment for vaccine to reach their site from the time they submit their vaccine order. Not reporting all required information on the order form, not using current order forms, and/or not submitting supplemental documentation (as applicable) will delay vaccine order processing time.

Note: Frozen vaccines are always shipped by the manufacturer directly to the VFC provider site. The shipping invoice will state that the vaccine has been paid for by CDC in Atlanta, GA for VFC vaccine or by DHEC in Columbia, SC for State Vaccine Program vaccine. In rare cases it may take up to 15 business days for Merck frozen vaccines to reach provider offices once the order has been placed.

DT vaccine will always be listed as “STATE” on your pack list. Please refer to your order form to determine from which program the vaccine has been ordered.

2. **Vaccine Transfers:**

ALL VFC VACCINE TRANSFERS MUST BE APPROVED BY THE VFC PROGRAM PRIOR TO TRANSFER. Contact the VFC Program for transfer authorizations of VFC vaccine. The SC Vaccine Transfer Form (DHEC 1208) must be used for all approved VFC vaccine transfers. All vaccines must be labeled by the appropriate vaccine stock type as VFC or State vaccine during the transfer and placed in the appropriate vaccine stock at the receiving provider’s office. Any unauthorized transfers are subject to fraud and abuse of the VFC Program. To submit the completed form, email to immunize@dhec.sc.gov or fax to the VFC Program at 803-898-0326.

Important Note: If a provider is moving office locations, they MUST contact the VFC program at least 4 weeks prior to the move to have the transfer approved. Failure to notify the VFC Program and obtain approval in this type of event will place the providers ordering status in a suspended status and is considered an unauthorized transfer.

3. **Vaccine Borrowing:**

The Borrowing Report must be completed when either: Privately/SC State purchased vaccine is administered to a VFC-eligible child, or VFC vaccine is administered to a non VFC eligible child (private or SC State).

Borrowing would occur **only** when there is lack of appropriate stock vaccine (VFC, SC State, or provider-purchased) due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff that calculated ordering time(s) incorrectly.

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.** VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date. **The reason cannot be that a provider planned vaccine borrowing from either the private stock, or the VFC and SC State stock**

Short-dated vaccine exchange:

The expectation for VFC enrolled providers regarding the exchange of short-dated vaccines is that a two way exchange can be used by a VFC– enrolled provider with a patient population that is mostly VFC-eligible. The means the provider has a small number of state eligible and/or privately insured children.

- a) SC State vaccine and privately purchased vaccine that is short-dated may be exchanged for a VFC eligible child or vice versa, and the dose exchanged with a longer-dated SC state vaccine or privately purchased vaccine.
- b) Providers must document this short-dated exchange on the borrowing form regardless of inventory origin and include date borrowed, vaccine borrowed, vaccine stock (VFC vs. private), and date returned.
- c) Must keep the invoice (shipping labels) for review by Immunization Division field representatives to verify exchange. This will ensure that the inventory is made whole.

Unintentional Retrieval of Vaccine:

Provider staff who unintentionally retrieved the wrong vaccine stock type to administer to a patient must report it on the VFC Vaccine Borrowing report (DHEC 1167) using the appropriate code as indicated on the form.

NOTE: Inventory must be rotated to ensure that the shortest dated vaccine is used first. VFC or SC State vaccine with short expiration dates (expiring within 3 months) should be reported to the VFC program, if the provider site does not anticipate using these short-dated vaccines before they expire.

Providers may not use VFC influenza vaccine stock to vaccinate non - VFC eligible children.

ALL vaccine stock types (VFC, STATE*, and PRIVATELY PURCHASED) must be labeled and separated within the vaccine storage unit for easy identification by provider staff member, as well as Immunization Division field representatives.

*State Vaccine is only supplied to sites enrolled in the SC State Vaccine Program.

The Immunization Division may ask for a copy of the invoice validating that the privately purchased vaccine was used to replenish the borrowed VFC vaccine. The invoice date must correspond with the replacement date on the borrowing report.

Borrowing and replacement of vaccines requires approval by the VFC program. For approval email the VFC Program at immunize@dhec.sc.gov.

4. **Vaccine Wastage**

Immediately upon receipt of VFC vaccines, the VFC provider must properly store the vaccines and compare the shipping invoice to the actual contents of the shipment. The provider also must check any temperature monitoring device in the shipment to determine if the device is signaling that shipping temperatures were acceptable or out of range (delays in checking a monitor can result in false alarms for out of range temperatures). Any discrepancies concerning shipment contents or temperature problems must be reported immediately to the VFC program at 800-277-4687 – do not leave voice messages -- and a copy of the packing slip faxed to 803-898-0326. The distributor cannot be held accountable for replacement of damaged shipments if reports of problems are not immediately made to the program.

Inventory must be rotated to ensure that the shortest dated vaccine is used first. Vaccine that is ordered and shipped to the provider site is to be used at the site to which the vaccine is shipped. **VFC vaccine with short expiration dates (expiring within 3 months) should be reported to the VFC Program, IF the provider site does not anticipate using these short-dated vaccines before they expire.** Providers should be monitoring vaccine inventories to ensure transfers are rare.

Notify the VFC Program immediately of a vaccine cold chain failure or other wastage incidents involving VFC vaccines after the discovery of the incident. All wasted vaccine (includes expired, spoiled, re-called, doses drawn-up but not administered, dropped/broken vials, and lost vials) must be reported to the VFC Program using the SC Wastage and Return form (DHEC 1209) and returned, as directed, to McKesson (CDC's Central Distributor) for Federal Excise Tax Credit (FETC). Vaccine must be returned to McKesson within 6 months of expiration. **Vaccine wastage cost estimates for the incident will be determined by the VFC program and reported to the provider and CDC.**

VFC providers are strongly urged to have all staff responsible for vaccine storage monitoring or handling review and apply the practices for proper vaccine storage and handling found in the CDC Vaccine Storage and Handling Toolkit (online <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>)

Vaccine Stock Supply:

1. **CDC Requirement:** Providers serving both VFC and non-VFC eligible children must store VFC stock separately from other public and private vaccine stock types or use a CDC-approved method for accounting for VFC vaccines.

SECTION F. Vaccine Storage Equipment

1. **Vaccine Storage Units**

Sites should consider moving away from combination refrigerator and freezer vaccine storage units to store frozen vaccines as they do not maintain frozen vaccine storage temperatures. If a combination storage unit is used, only the refrigerated portion of a combination refrigerator and freezer storage unit is recommended to be used. For recommended vaccine storage units, please review the **CDC recommended vaccine storage units** section below and reference the [Vaccine Storage & Handling Toolkit](#) provided by CDC.

- a) **Vaccine Storage Units (CDC required)-** must meet the following requirements:
 - 1) Have a separate freezer compartment with separate exterior door or stand alone refrigerator and freezer;
 - 2) Have enough room to store the year's largest inventory without crowding (this includes flu season and back to school times)
 - 3) Have enough room to store water bottles (in the refrigerator) and frozen coolant packs (in the freezer) to stabilize the temperatures and minimize temperature excursions that can impact vaccine potency. The addition of water bottles in the refrigerator (not coolant packs) reduces the risk of freezing due to the tremendous latent heat released from water prior to freezing;
 - 4) Have a certified calibrated thermometer inside each storage unit;
 - 5) Reliably maintain the appropriate vaccine storage temperatures year-round;
 - 6) Be dedicated to the storage of vaccines. Food and beverages must NOT be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.
- b) **CDC recommended vaccine storage units:** CDC recommends Stand-alone units for vaccine storage. Stand-alone units are self-contained units that only refrigerate or freeze. These units can vary in size, from compact, under-the-counter style to large, stand-alone, pharmaceutical grade units.
 - 1) A separate stand-alone refrigerator should be used for refrigerated vaccines that require storage temperatures between 35°F and 46°F (2°C and 8°C).
 - 2) A separate stand-alone freezer should be used to store frozen vaccines that require storage temperatures between -58°F and +5°F (-50°C and -15°C). A storage unit that is frost-free or has an automatic defrost cycle is preferred.

ALL vaccine stock types (VFC, STATE, and PRIVATELY PURCHASED) must be labeled and separated within the vaccine storage unit for easy identification by staff members.

2. Documentation Requirements for Acceptable (New and Existing) Vaccine Storage Units:

VFC Providers must have five days of *in-range temperatures documented and provided to the VFC program prior to storing vaccines in a new or existing vaccine storage unit.

***In range temperature for refrigerator must be between 35°F and 46°F (2°C and 8°C), for refrigerator with an average temperature of 41°F (5°C).**

***In range temperature for the freezer must be -58°F and +5°F (-50°C and -15°C)**

Providers will not be permitted to enroll or re-enroll in the VFC program without an acceptable vaccine storage unit(s). If the discovery of an un-acceptable storage unit(s) is made during a VFC program site visit or at any other communication, the Immunization Division will suspend vaccine ordering privileges of the provider's site.

The Immunization Division will lift suspension of vaccine ordering once the VFC provider has placed an acceptable vaccine storage unit at the VFC provider site, and has recorded and monitored *in-range temperatures for five days with a certified calibrated thermometer. The VFC provider will submit a copy of the temperatures recorded from the new acceptable vaccine storage unit on the SC Refrigerator/Freezer temperature log (DHEC 1627) to the Immunization Division by fax 803-898-0326 or email immunize@dhec.sc.gov.

The ESA or assigned user will update the Vaccine Management and Disaster Recovery Plan (DHEC 1225) in SCI PAS with the location of the new acceptable vaccine storage unit, date the certified calibrated thermometer was placed in the acceptable vaccine storage unit, and date of expiration of the certified calibrated thermometer, new vaccine storage unit location, and send a copy of the new *Certificate of Traceability and Calibration (also known as the Report of Calibration Test)* to the Immunization Division by fax 803-898-0326 or email immunize@dhec.sc.gov

It will be at the discretion of the Immunization Division to make a determination with each provider regarding proper storage and handling occurrences on best practices of how to stay in compliance with program requirements.

UNACCEPTABLE Vaccine Storage Unit

Dormitory-style refrigerator units are never acceptable for storage of any VFC vaccine due to inability to reliably maintain temperatures needed to store vaccine within required temperature ranges.

3. **Thermometers:**

During site visits, Immunization Division program staff must determine whether the Certificate of Calibration (or Report of Calibration Test) is current and valid. VFC providers must have at least one back up thermometer with a current certificate of calibration on hand (the thermometer is not stored in a unit but is a back up thermometer). Providers will upload the certificate of calibration and update the DHEC 1225 in SCI PAS VFC Enrollment System only when the backup thermometer is placed in service for monitoring a vaccine storage unit for publicly funded vaccine.

4. **Thermometer Requirements:**

- a) Providers enrolled in the VFC Program are required to have certified calibrated thermometers with valid and up-to-date Certificate of Calibration (or Report of Calibration Testing) to monitor temperatures in all refrigerator and freezer compartments used for VFC vaccine storage.
- b) The documentation of a Certificate of Traceability and Calibration Testing (also known as Report of Calibration Testing) must be provided for each thermometer used to monitor publicly purchased (VFC and State) vaccine.
- c) A copy of the current thermometer certificate must be maintained at the provider office as well as provided to the Immunization Division for each thermometer used in all refrigerator and freezer compartments.
- d) Thermometer calibration must be tested annually, or according to manufacturer recommendations, by a laboratory with accreditation from International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC/MRA) signatory body. Laboratories that have attained this accreditation meet the requirements for traceability;
- e) If there is no calibrated thermometer with valid documentation (e.g., certificate) at the time of the VFC compliance site visit in any of the vaccine storage units, then action will be taken to correct the situation, and the follow-up action will be monitored by the Regional Immunization program.

For information on accredited laboratories:

<http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>

5. **CDC strongly recommends thermometer with the following characteristics:**

- a) Provide continuous monitoring information with an active, digital display of the internal storage unit temperature;
- b) Digital thermometer with a probe in a glycol-filled bottle;
- c) Include an alarm for out- of- range temperatures;
- d) Have a reset button if using a data logger with a min/max display;
- e) Capable of showing current temperature as well as minimum and maximum temperatures;
- f) Within +/- .5°C accuracy (+/- 1°F);
- g) Have a low battery indicator;
- h) Allow for the main device, which is attached to the temperature probe through a narrow cable, to remain outside of the storage unit;
- i) User programmable logging interval (or reading rate);

- j) Memory storage of at least 4000 readings, device will not rewrite over old data and stops recording when memory is full.

6. **Calibration Testing and Traceability Requirements:**

Calibration testing and traceability must be performed by a laboratory accredited by an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body **OR as an alternative** by a laboratory or manufacturer that provides documentation that demonstrates that calibration testing performed meets ISO/IEC 17025 international standards for calibration testing and traceability.

- ILAC/MRA signatory body-accredited laboratory
- Laboratory accreditation should be clearly identifiable (for a list of ILAC-accredited laboratories see box below)
- An ILAC MRA-accredited laboratory is the easiest way to identify that the instrument has been tested correctly according to international standards
- The certificate may have an Accrediting Body Symbol, which is the logo, and a unique laboratory code or certificate number included on the certificate
- ILAC accredited laboratories:
 - Name of Device (optional)
 - Model Number
 - Serial Number
 - Date of Calibration(Report or Issue Date)
 - Whether instrument pass/fail testing- Measurement results indicate unit passed within suitable limits (recommended uncertainty = +/- 1F (+/- 0.5C))
- Non-ILAC accredited laboratories and manufacturers:

These manufacturers or laboratories must provide a Certificate of Traceability or Report of Calibration Test that must include the following elements:

 - Name of device
 - Model number
 - Serial number that matches device reviewed
 - Date of calibration (Report or Issue Date)
 - Whether instrument pass/fail testing -Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty= +/- 1F(+/- 0.5C))
 - Measurements results for the device
 - Information statement that demonstrates that the laboratory performing the testing maintains a measurement assurance program and meets current ISO/IEC 17025 standards for calibration testing and traceability

For listings of accredited laboratories:

A2LA: <http://www.a2la.org/dirsearchnew/newsearch.cfm>

L-A-B: <http://www.l-a-b.com/content/directory-accredited-labs>

ACLASS: <http://www.aiclasscorp.com/search-accredited-companies.aspx>

IAS: [http://www.iasonline.org/Calibration Laboratories/CL.html](http://www.iasonline.org/Calibration_Laboratories/CL.html)

PJLA: <http://www.pjlabs.com/search-accredited-labs>

A listing of signatory bodies outside of the U.S. can be found on the ILAC website:

<https://www.ilac.org/>

7. **Thermometer placement:**

- a) Thermometer placement within the unit is just as important as thermometer selection. The thermometers (probes) are to be placed in the center of each vaccine storage unit, in proximity to the vaccines being stored.
- b) Thermometers should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit. A thermometer can inadvertently be displaced during a busy workday.
- c) Ensure appropriate placement of the thermometer in each unit with daily inspection of each storage unit. Proper placement is very important since it helps the provider to most accurately identify the actual vaccine vial/syringe temperature and to take immediate corrective action if necessary.

8. **Temperature Monitoring Requirements**

- a) Regardless of the type of thermometer used, both refrigerator and freezer temperatures must be checked twice daily in the morning and afternoon, along with the date, exact time and initial's of the person reviewing and documenting the temperature on the graph-style DHEC Refrigerator/ Freezer temperature log (DHEC 1627) provided by the VFC Program.
- b) After the temperatures are checked, check that each unit door is closed.
- c) The current month's log for each unit is posted on each unit's door.
- d) Logs will be retained in a file for 3 years.
- e) If out-of-range temperatures are found, immediate corrective action will take place.
- f) Action taken will be documented on the "**Vaccine Storage Action Plan for Temperature Excursions**" section of the DHEC 1627 (Refrigerator/Freezer Temperature Log).
- g.) The temperature logs are to be kept on file for at least three (3) years. Providers can print the temperature log from SCI PAS: <https://www.scdhec.gov/SCIPAS/>

Send a copy of the SC Refrigerator/Freezer Temperature Log (DHEC 1627) for each vaccine storage unit if requested by the VFC Program. Copies may be submitted to Immunization Division by email to immunize@dhec.sc.gov or fax: at 803-898-0326.

9. **Storage Temperatures**

The temperature of all refrigerated vaccine must stay between 2° and 8° C (between 35°F and 46°F). MMR vaccine may be stored in a refrigerator or freezer. Frozen vaccines are received directly from the manufacturer in a shipping container on frozen gel packs and must be maintained in a freezer at or below –15°C (5°F) until use. In order to maintain temperatures within the required ranges:

- a) Bottles of water should be stored on the floor of the refrigerator, on the top shelf of the refrigerator, and in the door of the refrigerator and ice packs should be stored along the walls, back, and door of the freezer to help maintain temperatures in case of a power outage.
- b) Vaccines must not be stored in the doors or floor of refrigerators or freezers, or on the top shelf of a refrigerator that is part of a combination refrigerator/freezer unit.
- c) Vaccines must be stacked with at least 1 inch of air space between the stacks and 2 inches between side/back of the unit to allow adequate air circulation around the vaccines.

If vaccines have been exposed to improper temperatures, immediately label the affected vaccines as “Do Not Use” and contact the VFC Program at 803-898-0460 or 1-800-277-4687, please make sure that you speak (do not leave a voicemail message) to a Division staff member to assess whether vaccine potency could have been affected. Do not presume that the vaccine has been compromised. *These corrective action steps must be documented on the Vaccine Storage Action Plan for Temperature Excursions on the DHEC 1627.*

If the DHEC Immunization Program determines that vaccines were administered to children after exposure to damaging storage conditions, the VFC Program will recommend that parents/guardians of the recipients be notified by the provider and offered revaccination to ensure they are fully immunized.

SECTION G. Vaccine Management Storage and Handling Plans

The DHEC Immunization Division provides the Vaccine Management and Disaster Recovery Plan (DHEC 1225) **template** for routine and emergency vaccine management to providers and makes it available through SCI PAS VFC Enrollment System for annual enrollment/re-enrollment. CDC requires that VFC enrolled providers review and update the plan annually or more frequently if changes to any information within the plan occur, such as new staff members who have responsibilities specified in the plan.

The review date is required on all plans in order to verify that they are current. *CDC will require all plans have the signature, name, and title of the preparer of the documents beginning January 1, 2015.* The DHEC 1225 is divided into two sections: Part A. Routine Storage and Handling and Part B. Disaster Recovery. This plan must be easily accessible and posted near the vaccine storage units. Lastly the primary and back-up vaccine coordinators as designated in SCI PAS on the Vaccines For Children Program Provider Agreement (DHEC 1144) have specific roles regarding this plan.

The provider site must have the following written storage/handling plans:

1. **Routine Storage and Handling**- Includes routine vaccine management, such as:
 - Proper vaccine storage and handling practices;
 - a) Temperature monitoring,
 - b) Vaccine storage (e.g., equipment, placement);
 - Vaccine Shipping and receiving procedures;
 - Vaccine ordering procedures;
 - Inventory Control (e.g., stock rotation);
 - Vaccine expiration, spoilage, and wastage prevention (e.g, protocol for responding to and reporting vaccine loss).

2. **Disaster Recovery (emergency plan)** - Includes emergency vaccine management, such as:
 - Refrigerator or freezer malfunctions;
 - Power failure to vaccine storage units;
 - Natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions;
 - Protocol for maintaining the vaccine cold chain during transport to and while stored in emergency storage locations.

3. **Roles of the primary/back-up vaccine coordinator(s)**

The provider site **must** have a primary vaccine coordinator and at least one back-up vaccine coordinator who are responsible for ensuring that all vaccines are handled appropriately and that procedures are documented. Proper vaccine storage and handling procedures include but are not limited to the following tasks:

 - a) Ordering vaccines;
 - b) Overseeing proper receipt and storage of vaccine shipments;
 - c) At least twice daily monitor and document the temperatures on the SC Refrigerator/ Freezer Temperature Log (DHEC 1627) for each vaccine storage unit;
 - d) Response to storage temperatures outside recommended range;
 - e) Rotation of vaccine stock so that vaccine closer to its expiration date will be used first;
 - f) Monitoring of expiration dates on vaccines and ensuring that expired vaccine is not administered to patients;
 - g) Overseeing proper vaccine transport.

If the twice-daily monitoring is being conducted by a backup person to ensure proper temperature recording, the primary vaccine coordinator should review temperature logs weekly. The backup staff should monitor the temperature logs if the primary coordinator is recording the twice-daily temperatures.

Training for VFC providers is available on the CDC website:
<http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>

The ESA must provide the primary vaccine coordinator and back-up vaccine coordinator updated email contact information on the Vaccines For Children Program Provider Agreement (DHEC 1144).

SECTION H. Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. The online reporting form can be found at <http://vaers.hhs.gov/esub/index>.

VAERS encourages the reporting of any significant adverse event that occurs after the administration of any vaccine licensed in the United States. You should report clinically significant adverse events, even if you are unsure whether a vaccine caused the event. The National Childhood Vaccine Injury Act (NCVIA) requires health care providers to report:

- Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.
- Any event listed in the Reportable Events Table that occurs within the specified time period after vaccination. A copy of the Reportable Events Table is available at the following web address:
http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf.

Both the CDC and FDA review data reported to VAERS. The FDA reviews reports to assess whether a reported event is adequately reflected in product labeling, and closely monitors reporting trends for individual vaccine lots. Reports sent to the VAERS program that also make reference to non-vaccine pharmaceutical products are shared with MedWatch, the FDA's drug safety surveillance system. To obtain additional information about the VAERS program:

- Send e-mail inquiries to info@vaers.org
- Visit the VAERS Website at: <http://vaers.hhs.gov/professionals/index>
- Call the toll-free VAERS information line at (800) 822-7967
- Fax inquiries to the toll-free information fax line at (877) 721-0366

SECTION I. VFC Program Site Visits

All VFC providers' sites must be reviewed periodically as a condition of continued enrollment in the VFC program. Site visits are performed to evaluate provider compliance with VFC program requirements as set forth by CDC and address any deficiencies. Immunization Division program field representatives may contact the providers/clinics for scheduling of the site visits and reviews. The Immunization

Division program field representative may conduct one or more of the following types of visits:

1. **VFC Enrollment Visit** – An enrollment visit includes education (training) about the VFC program requirements, including proper vaccine storage and handling of VFC vaccine and best practices. This visit is also an opportunity to establish a working relationship with the local Immunization Division program field representative. An enrollment site visit will be made to providers/clinics that have: 1) requested to be re-activated in the program, 2) moved into a new facility or another county, or 3) are delinquent in re-enrolling during the annual re-enrollment process. It is at the discretion of the Immunization Division to have the provider take the CDC online training's prior to receiving VFC vaccine (see section H for details about training's).
2. **VFC Compliance Site Visit** – is defined as a formal visit to a VFC-enrolled provider to evaluate the provider's compliance with the VFC program requirements and provide formal training and education related to VFC program requirements and proper storage and handling of vaccine. The VFC questionnaire is completed and a review is conducted of to verify patient eligibility screening and documenting practices VFC and non-VFC eligible children from birth through 18 years of age. The site visit may require additional follow-up. An acknowledgement of receipt is required to be signed by the Medical Director or Equivalent (ESA) or, designee with authorization to act on behalf of the organization. **The ESA is strongly recommended to attend this visit.**
3. **Assessment Feedback Incentive eXchange (AFIX) Site Visit** – A formal review of a provider's continuous quality improvement (CQI) process that is used to help assess and improve the health care provider's immunization practice and immunization coverage rates. AFIX is an assessment of VFC enrolled providers utilizing immunization data reported to the South Carolina Immunization Registry (SCI Registry). The assessment may look at patients from age range 24 – 35 months or 13-18 years old. AFIX site visits can be done in combination with the VFC Compliance Site Visit. **The ESA is strongly recommended to attend this visit.**
4. **Unannounced Site Visit** - is defined as an unannounced, “drop in” visit performed to a provider site to assess current storage and handling practices. An acknowledgement of receipt is required to be signed by the Medical Director or Equivalent (ESA) or, designee with authorization to act on behalf of the organization.
5. **Annual Provider Training** – The training covers all of the VFC program requirements with emphasis on focused areas that CDC requires for providers. Each enrolled and active VFC provider **must** complete training annually each calendar year. Providers must complete and submit the CDC online training (You Call the Shots: Vaccines For Children AND Vaccine Storage and Handling); or through the VFC Compliance Site Visit conducted during the current calendar year. The provider must meet the training requirement as outlined in SECTION J.

SECTION J. VFC Provider Education Training Requirement(s):

VFC Provider Education Training Requirement (Annually within the current calendar year) – This training will assist the practice in an area of improvement to become proficient in managing the VFC program within the provider’s office. Providers must receive annual training on all VFC requirements on focused areas that CDC requires for providers. All enrolled VFC providers must meet the annual training requirement during the current calendar year. At a minimum, the VFC vaccine coordinator and Back-Up vaccine coordinator at each VFC provider office must annually complete the VFC provider educational training requirement prior to enrollment into the VFC program. *Failure to complete the annual training will affect the enrollment status of the VFC provider.*

The trainings featured below will meet the annual requirement for VFC Education Training within the current calendar year:

CDC Web-based Training Courses (Both certificates must be uploaded to the VFC Enrollment System under CDC Upload Training)

1. **Immunization: You Call the Shots – Vaccine For Children** – This course provides key training on immunization knowledge on the VFC program requirements. The training is great for VFC Coordinators, office managers, billing personnel and new office staff. The training is capable of printing a certificate of completion for the course and provides accreditation for CME, CNE, CEU and CECH credits. Please print a copy of your score and the certificate and keep on file to get credit for the training.
<http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp>
2. **Immunization: You Call the Shots - Storage and Handling** - This course provides key training on vaccine storage and handling requirements for vaccines. The training is great for VFC Coordinators, or any personnel in the office setting who handles vaccines. The training is capable of printing a certificate of completion for the course and provides accreditation for CME, CNE, CEU, CECH and CPE credits. Please print a copy of your score and the certificate and keep on file to get credit for the training.
<http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>
3. **VFC Program Provider Presentation:** This presentation will be emailed to all enrolled VFC providers after annual re-enrollment that covers all of the current VFC requirements. Providers will be educated through this presentation on current VFC requirements. There will be any credit given to VFC Providers for this presentation as it is only for education purposes only.
4. **VFC Compliance Site Visit (received within the current calendar year):**
Providers who receive a scheduled VFC compliance site visit during the calendar year will meet the annual training education requirement. The VFC compliance site has a formal educational component and counts as meeting training

requirement from the Immunization Division program field representative conducting the site visit. It is at the discretion of the Immunization Division program field representative, depending on site visit findings to request the specific provider staff to take the CDC online training as a part of the site visit follow-up process.

SECTION K . Non-Compliance with VFC Program Protocols

1. **Purpose**

The CDC mandates that state immunization programs work to prevent fraud and abuse of vaccines purchased with public funds. The VFC Program Fraud and Abuse protocol is based on *CDC VFC Operations Guide – Module 5*. When providers enroll in the VFC Program, they agree to comply with all the requirements of the program. Lack of adherence to the VFC Program requirements by an enrolled provider could lead to fraud and abuse of the VFC program by the provider. The VFC Program will work actively with the VFC Providers for prevention, identification, investigation and resolution of suspected cases of fraud and abuse within the VFC Program.

The VFC Program works with Medicaid and CDC in VFC fraud investigations. Reports are made to Medicaid and CDC, as applicable. *Every effort will be made by the VFC Program to differentiate between intentional fraud and abuse and unintentional abuse or error due to lack of knowledge of the VFC program.*

2. **Definitions**

Federal fraud and abuse laws apply to the entire VFC program. In addition, for those portions of the VFC program involving state funds, state fraud and abuse/consumer protection/medical licensure laws may also apply. Per the *CDC VFC Operations Guide and Medicaid regulations at 42 CFR § 455.2*, the following definitions are used:

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 (and/or including actions that result in 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. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

All suspected fraud and abuse cases that merit further investigation will be referred to the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office.

Fraud and abuse can occur in many ways. Some examples of potential fraud and abuse include:

- Providing VFC vaccine to **Non-VFC eligible children**
- Selling or otherwise **misdirecting VFC vaccine**
- **Billing a patient** or third party for VFC-funded vaccine
- **Charging more than the established maximum regional charge** for administration of a VFC-funded vaccine to a federally vaccine-eligible child
- **Denying VFC-eligible children** VFC-funded vaccine because of the parents' inability to pay for the administration fee
- **Failing to implement provider enrollment requirements of the VFC program**
- **Failing to screen patients for VFC eligibility at every visit**
- Failing to maintain VFC records and comply with other requirements of the VFC program
- **Failing to fully account for VFC-funded vaccine**
- **Failing to properly store and handle VFC vaccine**
- **Ordering VFC vaccine in quantities or patterns that do not match your provider profile or otherwise over-ordering of VFC doses of vaccine**
- **Waste of VFC vaccine**

3. **Notification**

Suspected Fraud and Abuse can be identified by the VFC Program from many sources including but not limited to:

- a) External source – ie. a report to the VFC Program from a concerned patient or provider staff member; or
- b) Vaccine orders – ie. a provider is ordering vaccine inconsistent with usual ordering patterns and/or reported patient population in Provider Profile; or
- c) Routine VFC Site Visits.

To report suspected Fraud and/or Abuse use the Vaccines For Children (VFC) Program Suspected Fraud and/or Abuse Referral Sheet Form (DHEC 1997) available on the [VFC and SC State Vaccine Program Information and Resources](#)

4. **Intervention**

The VFC Program will determine if this is an *initial* or *repeated* violation. Note: All reported allegations related to fraud and abuse of the VFC program requirements, including actions taken to address identified situations, will be maintained in a database in the Immunization Division. This database will be made available to CDC, as requested.

- a) ***Unintentional Initial Violations:*** If the VFC Program staff determines that the discrepancy is originating from lack of program knowledge, *the reasonable*

corrective action plan will be education efforts including a follow-up site visit after the initial site visit and monitoring of records or replacement of vaccine damaged through provider negligence at provider expense, as applicable.

- b) *Repeated Violations (violations of the same VFC requirement category that have been identified in previous two site visits)*: Failure to adequately correct serious deficiencies will result in corrective action will be referred to Immunization Division Central Office for further action. The decision to place a provider in a formal education process will be made at the Immunization Division Central Office level. The agreements to which a provider may be enrolled in to become compliant from serious deficiencies are as follows:
 - c. Secondary Education Process Agreement : This agreement must be signed by the provider and compliance with the conditions will be monitored by the VFC Program. Failure to comply with the corrective action plan will result in enrollment in the “tertiary education process” that is considerably more involved and detailed.
 - d. Tertiary Probation Agreement: This agreement must be signed by the provider and is implemented when there is noted failure to comply with the Secondary Education Process Agreement.

Failure to adequately correct serious deficiencies will result in termination of the provider’s participation in the VFC program. Referral to appropriate State or Federal agencies will made as required.

As required by CDC, any provider or provider site found listed on the “List of Excluded Individuals and Entities” (LEIE) will be immediately terminated from the VFC Program. The “List of Excluded Individuals and Entities” is administered and published by the Department of Health and Human Services (HHS), Office of the Inspector General (OIG) and State Medicaid Agency. The basis of exclusion includes program - related fraud, patient abuse, licensing board actions, and default on Health Education Assistance Loans.

On June 12, 2008, the Centers for Medicare and Medicaid Services (CMS) issued a letter providing guidance to State Medicaid Directors establishing a requirement for screening the LEIE list for ineligible providers prior to and during provider enrollment (monthly) in the Medicaid Program. The VFC Program falls within the auspices of CMS, providers included on this list are not eligible to enroll in the VFC program.

Additionally, excluded providers cannot participate in the program indirectly, such as providing services under a non-excluded VFC provider. A non-excluded VFC provider that employs or contracts with an excluded provider cannot seek payment on behalf of the excluded provider. In such circumstances, the non-excluded provider employing or contracting with the excluded provider is not able to participate in the VFC program.

SECTION L. Disenrollment in the VFC Program

A VFC provider may request to become disenrolled in the VFC program at any time. The VFC provider must submit the South Carolina Vaccine Program(s) Disenrollment Form (VFC or State) DHEC 1984. The form must be signed by the Medical Director or Equivalent (ESA) who has signed the current VFC Program Provider Agreement DHEC 1144.

Additionally the VFC provider must submit:

- An inventory (SC Vaccine Inventory Log, DHEC 1131) of the VFC vaccines on hand by vaccine type, lot number, expiration date, and number of doses.
- Submit the most recent 6 months of temperature logs (SC Refrigerator/Freezer Temperature Log for Vaccine Storage Units, DHEC 1627)

All submission for disenrollment request must include the above information for processing by the Immunization Division. Upon receipt of this documentation, the VFC Program will disenroll the provider as requested from SCI PAS VFC Enrollment System and the Vaccine tracking system. A local Immunization Division field representative staff will transfer any viable VFC vaccines to another VFC provider office.

A disenrolled VFC provider may request to be re-activated in the VFC program through SCI PAS VFC Enrollment System at any time; however, a re-supply order of VFC vaccines will not be shipped to the re-activated/re-enrolled VFC provider until a VFC enrollment/re-enrollment site visit has been conducted and the site is approved as being in compliance with VFC Program Protocols.

Submission of Disenrollment **must be one (1) month before effective date** to the Immunization Division may be done in the following ways:

- By fax to: 803-898-0326
- By email to: immunize@dhec.sc.gov