

Vaccines For Children (VFC) Program Protocols




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VFC Program Protocol Guide Icon Key

This protocol uses icons and bullets for easier reference and readability. The icon legend below contains each icon used in this program protocol and accompanying description.

ICON	Description
	VFC Program Requirement
	VFC Program Recommendation
	Prohibited for use in the VFC program

Requirement and Recommendation Definitions

Each section contains recommendations and requirements. It is important to understand the intent of each term and how they are used consistently throughout the VFC Program Protocol.

- **Requirement:** All VFC providers must comply with specific guidelines.
- **Recommendation:** A best practice recommended by CDC. It is not required, but providers should be aware that a recommendation often precedes a requirement. It is important to note that:
 - The immunization program will communicate recommendations to providers to allow ample time for implementation in the event that a recommendation becomes a requirement.
 - While not required, providers should implement recommended practices whenever possible.

2019 - 2020 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 12/01/2015, the Department of Health and Environmental Control (DHEC) immunization program upgraded the online system, called the *South Carolina Immunization Provider Access System (SCIPAS)* to *SCIAPPS* 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 application to participate in the VFC program.

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

Initial enrollment providers are defined as:

- **NEW** provider - *"first time participating" in the VFC program*
- **Returning** provider - *exited the VFC program for greater than 12 months and is rejoining*

These providers must receive a VFC enrollment site visit prior to being approved in the VFC program.

The VFC program will not accept any VFC enrollment applications **2 months** prior to the launch of the annual re-enrollment cycle.



REQUIREMENT: *VFC re-enrollment (provider agreement valid for 24 months) is required to continue in the program after initial enrollment. VFC providers must update training and provider profiles every year.*

VFC re-enrollment will occur in early to mid-March annually with an email notification to all VFC providers. The enrollment forms must be completed and submitted in SCIAPPS VFC Enrollment System within 75 days after the enrollment period begins each year to avoid any interruption in the receipt of vaccine. The **VFC Coordinator (authorized role by ESA in SCIAPPS to update VFC enrollment forms) for the site and Electronic Signature Authority (ESA) may complete the VFC enrollment documents, however; only the ESA can sign the provider agreements (DHEC 1144 and DHEC 1230, if applicable) and submit the entire VFC enrollment application.** The provider site should print a copy of all enrollment forms from SCIAPPS 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 SCIAPPS VFC Enrollment System it is important for the provider site to keep updated copies of enrollment forms for the VFC Compliance Site Visit.

All VFC providers who have not successfully submitted a re-enrollment application will be contacted by the Immunization Division to schedule a time to retrieve provider's current inventory of publicly funded vaccines.

NEW PROVIDER ENROLLMENT:

All NEW enrollees (to include previous providers) must complete and submit VFC enrollment forms via SCIAPPS VFC Enrollment System. For new enrollees the enrollment process at a minimum will take a month to complete. All new 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 forms are located here [VFC and SC State Vaccine Program Information and Resources](#)
2. New Enrollees only must establish a NEW ACCOUNT in SCIAPPS. Click here for instructions on [Establishing a New Account Quick Reference Guide.](#) The enrollee will receive an email notification from the Immunization Division about their new account status.
3. Certificates of completion for the Annual VFC Provider Training **must be uploaded** in the SCIAPPS 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 VFC Provider Training via CDC Training Modules.

- a. [Immunization: You Call the Shots Vaccines For Children Program.](#)
- b. [Immunization: You Call the Shots- Storage and Handling.](#)
See the VFC Training Resources and Annual Provider Training. Click here <https://www.scdhec.gov/Apps/Health/SCIAPPS/Public/VFCInfo>
- c. Complete VFC Enrollment forms via SCIAPPS VFC Enrollment System.
- d. Properly set up vaccine storage unit(s) in preparation to receive vaccine. See Section F. Vaccine Storage Equipment and the current [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 SCIAPPS VFC Enrollment System.
 - a. Floor diagram of site where vaccines are stored
 - b. Certificate(s) of Calibration for continuous temperature monitoring devices also known as digital data logger(s) placed in each vaccine storage unit
- 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 become available in SCIAPPS once site is approved to receive publicly funded vaccine(s).

VFC RE-ENROLLMENT: All VFC providers are required to re-enroll (*resign the provider agreement*) every 24 months to continue in the VFC program.

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

*Each provider site **must complete** the following forms in SCIAPPS 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)
 - Vaccines For Children (VFC) Seasonal Influenza Vaccine Borrowing Report (DHEC 3226)
 - South Carolina Vaccine Transfer Form (DHEC 1208)
 - South Carolina Vaccine Wastage and Return Form (DHEC 1209)
 - South Carolina Freezer Temperature Log (DHEC 3265)
 - South Carolina Refrigerator Temperature Log (DHEC 3266)
 - 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)
 - VFC Program Family Planning Clinic Log (DHEC 1227) *upon request- contact the VFC program at scvfc@dhec.sc.gov*
2. VFC enrollment/re-enrollment requires the signature of the Medical Director or Equivalent who is the Electronic Signature Authority (ESA) on all forms every 24 months. If the ESA desires to designate users in SCIAPPS to complete VFC Enrollment forms, please call the Help Desk at 866-439-4082 for assistance.
- ❖ The ESA must be a Medical Doctor (MD), Doctor of Osteopathy (DO), Advanced Practice Registered Nurse (APRN) who is required to complete all the VFC enrollment forms.
 - A Registered Pharmacist (RPh) can also be an ESA, but **must** have a Doctor of Medicine (MD) OR Doctor of Osteopathy (DO) **to co-sign** the VFC Program Provider Agreement as the Medical Director or Equivalent on the DHEC 1144.



REQUIREMENT:

All licensed healthcare providers in the enrolled practice and their corresponding professional license numbers must be listed on the Federal VFC Program Provider Agreement form (DHEC 1144). Provider agreements are valid for 24 months.

- 3. ESA should log in to SCIAPPS using their current individual email address (username) and password. If the ESA has forgotten their password, they will need to contact the Immunization Division's Help Desk at 866-439-4082.
- 4. All documentation **must be uploaded** in SCIAPPS VFC Enrollment System:
 - a. CDC Training Certificates for Primary and Backup Vaccine Coordinator;
 - b. Medical license for all health care providers who have prescribing authority
 - c. Certificates of Traceability and Calibration for continuous temperature monitoring devices also known as digital data loggers

- d. Vaccine Storage Facility Floor Plans (floor diagram).

DO NOT FAX OR EMAIL ANY DOCUMENTS TO THE IMMUNIZATION DIVISION.

5. Immunization Division staff will review the application for accuracy of information. If there are errors, it will be returned to the provider through SCIAPPS for correction and resubmission for review.
6. Providers are to log into SCIAPPS VFC Enrollment system periodically during the VFC re-enrollment timeframe 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. ***A submitted application is not an approved application.***
7. VFC Providers will receive an email from "NoReply@dhec.sc.gov" notifying them of their approved enrollment status. Vaccine order forms can be accessed from SCIAPPS. See Section E. Vaccine Inventory-Vaccine Ordering.

Additionally All Providers Must:



REQUIREMENTS:

- ☐ Each facility must designate one staff member to be the primary vaccine coordinator. This person is responsible for providing oversight for all vaccine management within the office and ensuring all vaccines are stored and handled correctly.
 - ☐ Each facility must also designate at least one back-up or alternate vaccine coordinator who can assume oversight responsibilities in the absence of the primary vaccine coordinator.
 - ☐ VFC providers are required to notify the immunization program when there are changes in key vaccine staff (e.g., the vaccine coordinator or back-up vaccine coordinator).
- A. Provide the VFC Program with email address (es) through SCIAPPS 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 and/or Back up Vaccine Coordinator and the additional contact). It is the ESA's responsibility to ensure that all ***email contact information is current in SCIAPPS VFC Enrollment System. This information will ensure appropriate communications from the Immunization Division Program to identified users of SCIAPPS VFC Enrollment system.***
- B. Please note that all [changes and updates](#) should be made **IMMEDIATELY** on the VFC Enrollment forms when:
- Office hours for receiving vaccine shipments
 - Change of address (shipping/mailling)
 - Primary, Back-Up or ESA Email Address Change

- Telephone Number or Fax Number Change
- Facility Status (Private vs. Public)
- Additions or Deletions of Practicing Staff with Prescribing Authority (MD, DO, NP, PA, RPh.)

VFC Providers must contact the Immunization Division **one (1) month** prior to moving, closing, or dis-enrolling in the VFC Program.

SECTION C. Provider Agreement 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) 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. A Registered Pharmacist (RPh) can also be an ESA, but **must** have a Doctor of Medicine (MD) OR Doctor of Osteopathy (DO) **to co-sign** the VFC Program Provider Agreement as the Medical Director or Equivalent on the DHEC 1144. 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)]

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 provider's 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 exceed 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 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/orighanlaw.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. All enrolled VFC Providers must report 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.

SECTION D. VFC Eligibility



REQUIREMENT: Providers must properly screen patients for VFC eligibility and document the resulting eligibility status at each immunization encounter. Based on the eligibility determined from the screening, the appropriate stock of vaccine (VFC/Non-VFC) will be administered to the child.

1. Eligibility Criteria and Categories:

Children through 18 years of age (under 19 years of age) who meet at least one or more of the following criteria are eligible to receive VFC vaccine:

VFC Eligible children

- a) Medicaid-Enrolled
- b) Uninsured- A child who has 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) ***only***].
 - ❖ A child who has health insurance, but the coverage does not include vaccines, or
 - ❖ A child whose insurance does not cover all Advisory Committee on Immunization Practice (ACIP)-recommended vaccines. The child would be eligible to receive those vaccines not covered by the insurance.
 - ❖ Children who have health insurance, but there is a fixed dollar limit or cap for vaccines

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)."

The Meningococcal B vaccines are 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 (under 19) 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 SCIAPPS 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 in one of following options below to the Immunization Division Program Staff conducting the 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. VFC Provider can complete the paper screening record form:

- a) Private Providers complete the Vaccines For Children (VFC) Program 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. VFC Provider can complete screening and documentation with their Electronic Medical Records (EMR's) or Electronic Health Records (EHR's) as long as the EMR/EHR can:

- Document all the elements present on the current Vaccines For Children (VFC) Program Patient Eligibility Screening Record Form (DHEC 1146 or 1146S). VFC Providers must use screening results to ensure that only VFC-eligible children receive VFC vaccine.

Option 3. Screen and Document VFC eligibility status (es) for all children in the South Carolina Immunization Registry, as required by South Carolina State Law (refer to VFC provider agreement number 14). Contact the Immunization Division by email at sciregistry@dhec.sc.gov for instructions on how to enroll as a Direct Data Entry Only providers in the South Carolina Immunization Registry.

Please note: *VFC eligibility is not populated to the registry for those VFC providers who report information via HL7 messaging.*

Important Note:

VFC providers will notate the Vaccines For Children (VFC) Program 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 (State Medicaid) 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 (Vaccines are inventoried monthly. Order and stock vaccines to ensure there is an adequate supply to meet patient needs.) An adequate supply for most facilities would normally be enough vaccines to last 60 days, with reordering threshold of 30 days. 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.

Accessing Vaccine Order Forms

Enrolled providers may now access blank vaccine order forms via SCIAPPS. To access vaccine order forms:

1. Log in to [SCIAPPS](#).
2. Under Enrollments & Applications, click on **VFC Enrollment**.
3. Under Documents, click on **Generate Order Forms**.
4. Click **Open** to view vaccine order forms in pdf.
5. Click **Printer Icon** (or **File, Print**)
6. Close forms and exit [SCIAPPS](#).
7. Review vaccine order forms to ensure correct forms printed.

If you have any questions, please call the Immunization Division at 800-277-4687 or scvfc@dhec.sc.gov.



REQUIREMENT: 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.

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. Sites that do not work down the old brand of vaccine before expiration/moving to new brand will be in violation of the VFC program.

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 scvfc@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.

Vaccine Inventory Accountability: 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. Vaccine that is ordered and shipped to the provider site is to be used at the site to which the vaccine is shipped.

Vaccine Stock Supply:



REQUIREMENT: Providers serving both VFC and non-VFC eligible children must store VFC stock separately from other public and private vaccine stock types

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.*

2. Vaccine Transfers



REQUIREMENT: Vaccine transfers between providers can only occur after receiving approval from the Immunization Division.

Routine transfer of vaccines is NOT recommended by CDC. ALL VFC VACCINE TRANSFERS MUST BE APPROVED BY THE VFC PROGRAM PRIOR TO TRANSFER. Contact the VFC Program by 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 scvfc@dhec.sc.gov or fax to the VFC Program at 803-898-0318.

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:



REQUIREMENT: CDC's expectation is that VFC-enrolled providers maintain adequate inventories of vaccine to administer to both privately insured and VFC-eligible children that they serve. Borrowing vaccine should be rare and must be due to unforeseen delays or circumstances surrounding the vaccine that was ordered. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory.

Vaccine borrowing is approved only for the following instances:

- There is a lack of vaccine stock because of delayed or spoiled shipments. This bidirectional borrowing does not apply to influenza vaccine.
- Vaccine will expire soon and will be lost if not used. Providers with a small privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated, VFC dose.

- New staff calculated ordering intervals incorrectly, leading to a lack of either private or public vaccine stock.
- VFC seasonal influenza vaccine stock is not yet available. Providers may use private stock, seasonal influenza vaccine for VFC-eligible children and replace it when VFC vaccine becomes available. This one-directional borrowing is unique to seasonal influenza vaccine.

PRIOR APPROVAL IS REQUIRED

Borrowing of vaccines requires approval by the VFC program. For approval call the Immunization Division at 803-898-0460 or email the VFC Program at scvfc@dhec.sc.gov.

Vaccine Borrowing Documentation:

The Vaccines For Children (VFC) Borrowing Report (DHEC 1167) must be completed when either: Non-VFC purchased (Private stock/SC State stock) vaccine is administered to a VFC-eligible child, or VFC vaccine is administered to a Non-VFC eligible child (private or SC State). 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.

Vaccine Borrowing Report:

A Vaccine Borrowing Report must be completed when either:

- Non-VFC (Private stock/SC State stock) vaccine is administered to a VFC-eligible child, or
- VFC vaccine is administered to a Non-VFC (private or SC State) insured child

Vaccine Invoices: 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. Failure to replace any borrowed publicly funded vaccine is fraud of the VFC program.

SEASONAL INFLUENZA VACCINE BORROWING REPORT (DHEC 3226)

For seasonal influenza vaccine, providers may use PRIVATE-STOCK seasonal influenza vaccine to vaccinate VFC/STATE eligible children **IF** VFC seasonal influenza stock is not yet AVAILABLE. Those PRIVATE STOCK doses used on VFC/STATE eligible children can later be replaced when VFC/STATE influenza stock becomes available. *This ONE-DIRECTIONAL (private to VFC/STATE) borrowing exception is unique to seasonal influenza vaccine only.*

- VFC providers who borrow seasonal influenza vaccine must accept the VFC presentation allocated for replacement of private stock vaccines.

4. Vaccine Storage and Handling, Wastage, and Expiration



REQUIREMENT:

Upon receipt of a VFC vaccine shipment, VFC providers must:

- ☐ Open vaccine packages immediately
- ☐ Inspect the vaccine and packaging for damage
- ☐ Compare the vaccine received with the vaccine products that appear on the packing list
- ☐ Immediately store at appropriate temperatures
- ☐ Check the temperature monitor readings (shipments from CDC's centralized distributor (McKesson) only)
- ☐ Determine length of time the vaccine was in transit (shipments of frozen vaccine only). It is important to check the shipper insert supplied in the box. This insert will let the provider know the acceptable transit time based on the shipment date shown on their packing list.

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:

1. VFC program at 800-277-4687 – do not leave voice messages -- and a copy of the packing slip faxed to 803-898-0326;
2. Then to the Centralized Distributor (McKesson) 1-877-836-7123. The distributor cannot be held accountable for replacement of damaged shipments if reports of problems are not immediately made to the program.



REQUIREMENT:

If the provider believes that a vaccine shipment from the Centralized Distributor (McKesson) is compromised or there is a problem with the temperature monitors, the provider must contact the customer service center for centralized distribution immediately using the telephone number dedicated to receiving provider calls about vaccine viability: 1-877-TEMP123 (1-877-836-7123) or their immunization program.



REQUIREMENT: *Providers must notify the immunization program of any vaccine doses that will expire before they can be administered.*

Vaccine Wastage and Expiration:

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>)



REQUIREMENTS: VFC provider requirements for the management of expired, spoiled and wasted vaccine:

- ☐ Remove wasted/expired/spoiled vaccine from storage units with viable vaccine to prevent inadvertent administration (this includes wasted/expired/spoiled diluents).
- ☐ Label all expired/spoiled/wasted vaccine: “DO NOT USE”
- ☐ Report vaccine storage and handling incidents that result in vaccine loss, reasons for loss, and the number of doses involved in loss, as instructed by awardee.
- ☐ Spoiled/expired vaccines should be returned to the centralized distributor within 6 months after their spoilage or expiration date. This should result in frequent, timely returns. Providers should not wait to make returns. However, vaccines that have expired more than 6 months previously will still be accepted. Providers must properly dispose of all vaccine designated as waste.

SECTION F. Vaccine Storage Equipment

Vaccine Storage Units- See charts below for Acceptable Vaccines Storage Units

Acceptable Vaccine Storage Units- Refrigerators

Not all refrigerators are designed to maintain proper temperatures that protect vaccine viability. When evaluating existing or shopping for new vaccine refrigerators, select the required grade and type by practice volume.

Grade/Type Rating	Comments	Practice Volume
Pharmacy-or biologic <i>Best</i>	Purposely built to maintain consistent temperatures for storage of vaccines or biologics. Come in stand-alone and combination units.	Very High
Compact Pharmacy or biologic (Stand-alone) <i>Best</i>	These under-the-counter units are suitable for smaller practices with limited space.	Low, Medium, High, Very High
Commercial units* (stand-alone) <i>Good</i>	Intended to store food and beverages in commercial settings. Are often larger and more powerful than household units but not designed to store biologics and experience some temperature fluctuations.	Low, Medium, High
Household* (stand-alone) <i>Ok</i>	Intended for use in homes and offices, typically for food storage. Like commercial units, are not designed to store biologics and experience frequent temperature fluctuations.	Low, Medium, High
Household* Combination <i>Very Poor</i>	Household combination units have one compressor with poor temperature control. May pose a risk to refrigerated vaccines because cold air from the freezer is vented into the refrigerator and can freeze vaccines. Freezer portions of many combination units are not capable of maintaining the consistent temperature for frozen vaccines.	Low, Medium

*NIST and CDC has shown that these units may require additional water bottles to maintain stable temperatures.

*To ensure that publicly funded vaccines are being stored properly, **household (domestic) combination units** are not recommended for use of both the refrigerator and freezer portions. Studies conducted by NIST and the CDC have shown these types of units do not maintain appropriate temperatures for vaccine storage. If a VFC provider has 3 or more excursions with a combination unit; it will be recommended by the VFC program that the provider purchase a stand-alone unit.

*All providers enrolling into the VFC program for the 1st time must purchase a stand-alone unit for vaccine storage.

Acceptable Vaccine Storage Units - Freezers

Not all freezers are designed to maintain proper temperatures that protect vaccine viability. When evaluating existing or shopping for new vaccine freezers, select the required grade and type by practice volume.


Grade (Type) Rating	Comments	Practice Volume
Pharmacy or Biologic (stand-alone) Best	Specifically designed to maintain consistent temperatures for storage of vaccines or biologics.	Any Practice
Pharmacy or Biologic (Combination) Best	Have more than one compressor allowing for better and separate temperature control of the refrigerator and freezer compartments.	Any Practice
*Commercial units (Stand-alone) Good	Intended to store food and beverages in commercial settings. Are often larger and more powerful than household units but not designed to store biologics and experience some temperature fluctuations.	Any Practice
*Household (Stand-alone/Freezer portion only) Poor	Intended for use in homes and offices, typically for food storage. Like commercial units, are not designed to store biologics and experience frequent temperature fluctuations.	Any Practice
*Manual defrost units Very Poor	These models have an exposed vertical cooling plate at the back of the refrigerator. They have significant temperature variation and risk freezing vaccines.	Any Practice

*NIST and CDC has shown that these units may require additional frozen cold packs to maintain stable temperatures.


*To ensure that publicly funded vaccines are being stored properly, **household (domestic) combination units** are not recommended for use of both the refrigerator and freezer portions. Studies conducted by NIST and the CDC have shown these types of units do not maintain appropriate temperatures for vaccine storage. If a VFC provider has 3 or more excursions with a combination unit; it will be recommended by the VFC program that the provider purchase a stand-alone unit.

*All providers enrolling into the VFC program for the 1st time must purchase a stand-alone unit for vaccine storage.

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 range.**

Unacceptable Vaccine Storage units

Dormitory-style and bar-style combined refrigerator/freezers (Current VFC requirement) 	Have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing even when used for temporary storage.
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Provider 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 standalone 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) In vaccine units that are not pharmaceutical/medical-grade, have enough room to store water bottles (in the refrigerator) and frozen water bottles

(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 continuous temperature monitoring devices also known as a digital data loggers (DDL's) centrally located 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.
- 7) Have protection for the power source of all vaccine storage equipment by means of warning labels such as "Do Not Disconnect" posted at the electrical outlet and the circuit breaker, back-up generators.



- b) **CDC recommended vaccine storage units:** CDC recommends purpose built designed to either refrigerate or freeze. These units can vary in size, from compact, under-the-counter style to large. If you must use a household grade, combination refrigerator/freezer unit, only use the refrigerator compartment only for storing vaccines. Stand-alone, pharmaceutical grade units.
- 1). A separate stand-alone refrigerator should be used for refrigerated vaccines that require storage temperatures between 36°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 frost-free or has an automatic defrost cycle is preferred.

2. **Compliance with Acceptable (New and Existing) Vaccine Storage Units: Documentation Requirements**

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

***In range temperature for refrigerator must be between 36°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). An acceptable vaccine storage unit must be able to maintain proper storage temperatures for the vaccines that are stored in that unit. If the discovery of an un-acceptable storage unit (s) is made during a VFC program site visit, report of a storage and handling incident, 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 three to five days with a certified calibrated DDL. The VFC provider will submit a copy of the receipt of purchase and the temperatures recorded from the new acceptable vaccine storage unit on the appropriate DHEC temperature log to the Immunization Division by fax 803-898-0326 or email scvfc@dhec.sc.gov:

- DHEC 3265 SC Freezer Temperature Log-Celsius for Vaccine Storage Units
- DHEC 3266 SC Refrigerator Temperature Log- Celsius for Vaccine Storage Units

The ESA or assigned user will update the Vaccine Management and Disaster Recovery Plan (DHEC 1225) in SCIAPPS with the location of the new acceptable vaccine storage unit, date the DDL was placed in the acceptable vaccine storage unit, and date of expiration of the DDL, new vaccine storage unit location, and upload a copy of the new *Certificate of Traceability and Calibration (also known as the Report of Calibration Test)* to the SCIAPPS.

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 VFC program requirements.

3. **Thermometers (Continuous Temperature Monitoring Device (DDL)):**

As of January 1, 2018, VFC providers must use a continuous temperature monitoring device known as a digital data logger (DDL) to monitor all publicly funded vaccines. 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 temperature monitoring device known as a digital data logger (DDL) with a current certificate of calibration on hand (the DDL is not stored in a unit but is a backup thermometer). Providers will upload the certificate of calibration and update the DHEC 1225 in SCIAPPS VFC Enrollment System only when the backup thermometer is placed in service for monitoring a vaccine storage unit for publicly funded vaccine.

4. **Continuous Temperature Monitoring Device (DDL) Requirements:**



Continuous Temperature Monitoring Device also known as a digital data logger (DDL) Requirements:

As of January 1, 2018, all VFC providers must use a continuous temperature monitoring device also known as a digital data logger device. To meet VC program requirements, the device must also be equipped with:

- a) Temperature probe
- b) Active temperature display (easily read from outside of the vaccine storage unit)
- c) Ability to continuously monitor temperatures and record when data is routinely downloaded

Additional recommended features include: audible alarm for out of range temperatures, current, minimum, maximum temperature indicator, low battery indicator, accuracy of $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$), memory storage of a minimum of 4,000 readings, logging interval at maximum of every 30 minutes.

6. Certificate of Calibration Testing (also known as Report of Calibration)

Requirements:



- a) *Providers enrolled in the VFC Program are required to have certified calibrated continuous temperature monitoring device(data loggers) 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 DDL used to monitor publicly purchased (VFC and State) vaccine.
- c) A copy of the current DDL certificate must be maintained at the provider office as well as provided to the Immunization Division for each DDL 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 DDL 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.
- f) The DDL are to be placed in the center of each vaccine storage unit.
- g) A supply of extra batteries is maintained for DDL, if applicable.



Backup Continuous Temperature Monitoring Requirement:

REQUIREMENT: VFC providers must have at least one backup DDL with a valid and current certificate of calibration readily available to ensure that temperature assessment and recordings can be performed.

When implementing the above requirement, the following must happen:

- ☐ The backup DDL be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.
- ☐ The backup DDL should have a different calibration retesting date. If both DDL's have the same calibration date, they will need to be sent out for re-calibration at the same time. By having different calibration dates there will always be one DDL available for use.

Calibration Traceability and Testing Requirements:

Calibration traceability and testing (also known as a Report of Calibration) must include key pieces of information. Information required on the certificate depends on whether the laboratory performing calibration testing is an accredited or non-accredited laboratory. Before sending your thermometer(s) for calibration, check with the calibration company to verify required information will be included on your certificate.

Accredited Laboratory

If an accredited laboratory is performing calibration testing, one of these logos will be on the certificates of calibration:

A2LA



L-A-B



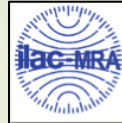
ACLASS



IAS



PJLA



These logos may appear on the certificate. They represent a group of accreditation organizations.

In addition, the following information must be included on the certificate:

- ☐ Name and address of laboratory conducting the test
- ☐ Name of device (optional)
- ☐ Model number (enables product identification)
- ☐ Serial number (enables product identification)
- ☐ Date of calibration (report or issue date)
- ☐ Measurement results for the device
 - ☐ Instrument pass or in tolerance testing result
 - ☐ Document uncertainty [must be within $\pm 1F$ ($\pm 0.5C$)]

Non-accredited Laboratory

If a non-accredited laboratory is performing calibration testing, the following information must be included on the certificate:

- ☐ Statement that calibration testing conforms to ISO IEC 17025 standards
- ☐ Name and address of laboratory conducting the test
- ☐ Name of device (optional)
- ☐ Model number (enables product identification)
- ☐ Serial number (enables product identification)
- ☐ Date of calibration (report or issue date)
- ☐ Measurement results for the device
 - ☐ Instrument pass or in tolerance testing result
 - ☐ Document uncertainty [must be within $\pm 1F$ ($\pm 0.5C$)]

7. **DDL Probe 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.



REQUIREMENT: In a household combination unit or commercial units, thermometer must be placed in a central area or middle of the unit directly with vaccines. Thermometers must not be placed in the doors, near or against walls, close to vents, or on the floor of the vaccine storage unit.



8. **Temperature Monitoring Requirement**

VFC providers must monitor publicly funded vaccines using the appropriate temperature logs and document in the following manner:

- a) Record minimum and maximum temperatures at the start of each clinic day.
- b) Review the current temperature prior to accessing and administering vaccines
- c) Record the time and date of each reading
- d) Record the name (or initials) of person who assessed the temperature reading
- e) Download data (reports) from the DDL device and reviewed weekly; preferably every **Monday** morning.
 - If the provider office is closed or it's a holiday then the data is to be downloaded on the next business day.
 - Data logger files do not need to be printed. The files need to be **saved** electronically in a location that can be accessed at any time
- f) All temperature logs and downloaded data reports must be kept on file for 3 years. Temperature logs can be printed from SCIAPPS.
- g) If out-of-range temperatures are found, immediate corrective action will take place.
- h) Action taken will be documented on the “**Vaccine Storage Troubleshooting Record**” section of the appropriate temperature log (DHEC 3265 or DHEC 3266).



REQUIREMENT: VFC providers must follow the set forth established protocol for reviewing and recording Min/Max temperature readings at the start of the clinic day.

Send a copy of the appropriate temperature Log (DHEC 3265 or DHEC 3266) for each vaccine storage unit **if** requested by the VFC Program. Copies may be submitted to Immunization Division by email to scvfc@dhec.sc.gov or fax: at 803-898-0326.

9. Vaccine Storage Temperatures

The temperature of all refrigerated vaccine must stay between 2°C and 8°C (between 36°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 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) To allow for cold air circulation around the vaccines, there should be space between the vaccines and the storage unit walls and between each large package, block, tray, or bin of vaccines. Adequate cold air circulation helps each vaccine reach a consistent temperature throughout its mass, and is necessary for the storage unit to maintain a consistent temperature. Packing any vaccine storage unit too tightly can negatively affect the temperature.



REQUIREMENT: Refrigerated vaccines must be maintained between 2°C and 8°C [36°F and 46°F] and frozen vaccines between -50°C and -15°C [-58°F and +5°F] at all times.

10. Reporting Improper Storage Temperatures



REQUIREMENT: If a cold chain failure is suspected or there is evidence vaccine has been exposed to temperatures outside the recommended temperature range, providers must:

- ☐ Notify the primary or backup vaccine coordinator immediately or report to a supervisor.
- ☐ Quarantine the vaccine. Label the vaccine “DO NOT USE” (place in separate container within storage unit) so the vaccine is not administered until a response indicating the vaccine is acceptable for use has been received.
- ☐ Notify your VFC program immediately after discovery of the incident.
 - ***Call 803-898-0460 or 800-277-4687, please make sure that you speak (do not leave a voicemail message) to a Division staff member***
- ☐ Follow the guidance of the Immunization Division’s VFC program on how to document and report the incident.

- At the direction of the Immunization Move and store vaccine under correct temperature storage conditions.

- Do not discard any vaccine unless directed to do so by the Immunization Division's VFC program.

Do not presume that the vaccine has been compromised. These corrective action steps must be documented on the Vaccine Storage Troubleshooting Record on the appropriate temperature log DHEC 3265 or DHEC 3266.

If the Immunization Division 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



REQUIREMENT: Immunization Division VFC Program must develop and implement a routine and emergency vaccine management plan. This template plan must include guidance on routine and emergency vaccine management processes/practice and requirements.

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 SCIAPPS 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. The DHEC 1225 must have the signature, name, and title of the preparer of the document. 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 SCIAPPS on the Federal 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)**



REQUIREMENT: VFC Providers are also responsible for training their staff.

VFC Providers 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) Record Min/Max temperatures at the start of the clinic day and monitor and document the temperatures on the appropriate temperature log (DHEC 3265 or DHEC 3266) 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;
- h) Train all staff (annually and new hires) at provider site on the vaccine management and disaster recovery plan.

If the Min/Max temperature readings are being conducted by a backup person to ensure proper temperature recording at the start of the clinic day, the primary vaccine coordinator should review temperature logs weekly and DDL reports. The primary/backup vaccine coordinator must ensure that they download DDL reports every Monday.



REQUIREMENT: Providers must be on site with appropriate staff available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during that day.

Recommended Trainings for VFC providers is available on the CDC website:

<http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>

- ☐ Vaccines For Children
- ☐ Vaccine Storage and Handling

[WD2215: Keys to Storing and Handling Your Vaccine Supply](#)

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 Med Watch, 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 provider 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. The goals of these visits are to: identify areas where providers are doing well and areas needing additional follow-up; identify the educational needs of VFC providers in order to support them with meeting program requirements; ensure that VFC-eligible children received properly managed and viable vaccine. Site visits are critical opportunities to engage provider staff and develop and strengthen ongoing relationships. The Immunization Division program field representatives will 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 for the new provider 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) New enrollees in the program, 2) provider has moved into a new facility or another county, or 3) are delinquent in re-enrolling during the annual re-enrollment process and 4) requested to be re-activated in the program. 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).



REQUIREMENT: Providers must not receive vaccine shipments before:

- ☐ Enrollment visits are successfully completed
- ☐ Provider has been trained on how to successfully perform VFC requirements
- ☐ Provider has the appropriate storage and handling equipment in place to receive and store vaccine.

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 audit is completed and a review is conducted to verify patient eligibility screening and documenting practices of 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. How these visits are conducted is at the discretion of the Immunization Division's Central Office. **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 (January –December). Providers must complete and submit the CDC online

training (You Call the Shots: Vaccines For Children AND Vaccine Storage and Handling) at enrollment and upon hire of a primary/backup vaccine coordinator. This is verified at all program site visits. 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 Primary 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 and/or transcripts 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.



REQUIRED: *Primary and Back-up vaccine coordinators must take the above training. If the primary or back up vaccine coordinator changes the person who assumes the role must take the training prior to carrying out the duties of a vaccine coordinator. The certificates must be uploaded in SCIAPPS and names changed on the appropriate enrollment forms.*

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 providers 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>



REQUIRED: *Primary and Back-up vaccine coordinators must take the above training. If the primary or back up vaccine coordinator changes the person who assumes the role must take the training prior to carrying out the duties of a vaccine coordinator. The certificates must be*

3. VFC Program Provider Presentation (optional):

This presentation may be emailed to all enrolled VFC providers after re-enrollment that covers all of the current VFC requirements from the Provider Agreement and the VFC Operations Guide. Providers will be educated through this presentation on current VFC requirements. This is not a continuing education credit course. VFC Providers will use this presentation as a resource and reference to help them recall VFC requirements.

4. **VFC Compliance Site Visit:** Providers who receive a scheduled VFC compliance site visit during the calendar year may meet the annual training education requirement if the following criteria are met: 1) Training covers all VFC program requirements described in the Provider Agreement and the VFC Operations Guide and 2) At minimum, the provider's VFC Coordinator and back up coordinator have completed You Call The Shots training. It is at the discretion of the Immunization Division field staff to determine if site is eligible for this training.

5. Optional Training:

Keys to Storing and Handling Your Vaccine Supply

This course provides key training on maintaining the vaccine cold chain in a provider facility. The training will address elements of proper vaccine storage and handling, procedures for storage and handling of vaccine, and components of vaccine inventory management. The training is great for Vaccine 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 providers accreditation for CME, CNE, CEU, and CPE credits. Please print a copy of your score and the certificate and keep on file to get credit for the training. [WD2215: Keys to Storing and Handling Your Vaccine Supply](#)

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 the current *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 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 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 healthcare. 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 and any other agencies that must be notified.

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 parents' inability to pay for the administration fee
- **Failing to implement provider enrollment requirements of the VFC program**
- **Failing to screen for and document eligibility status 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** – i.e. a report to the VFC Program from a concerned patient or provider staff member; or
- b) **Vaccine orders** – i.e. a provider is ordering vaccine inconsistent with usual ordering patterns and/or reported patient population in Provider Profile; or
- c) **Routine VFC Site Visits** - i.e. Conducted by VFC Program Staff (regional or central)

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. The VFC Compliance Site Visit Reviewer Guide will serve as a proxy measure for compliance with federal requirements that providers agree to maintain as participants in the VFC program.
- b) ***Repeated Violations (violations of the same VFC requirement category that have been identified in previous two site visits):*** If it appears provider is intentionally failing to adequately comply with previous minimum follow-ups and non-compliance, and the provider has received financial benefits from the behavior, the situation would require an immediate referral to an outside agency for investigation of suspected VFC fraud and abuse. The referral decision will be made at the Immunization Division Central Office level.

Failure to adequately correct serious deficiencies may result in termination of the provider's participation in the VFC program. Referral to appropriate State or Federal agencies will be 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 dis-enrolled 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.
- 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 (DHEC 3265 or DHEC 3266) and DDL reports for Vaccine Storage Units.

All submission(s) for disenrollment request must include the above information for processing by the Immunization Division. Upon receipt of this documentation, the VFC Program will dis-enroll the provider as requested from SCIAPPS 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 dis-enrolled VFC provider may request to be re-activated in the VFC program through SCIAPPS 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 the South Carolina Vaccine Program(s) Disenrollment Form (VFC or State) DHEC 1984 **must occur one (1) month before effective date to the** Immunization Division by one of the following ways:

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