



2016 – 2017 Vaccines For Children (VFC) Program Protocol

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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
	Recommendation which will transition to a 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.

2016 - 2017 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 (SCI PAS)* 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.

All **NEW** VFC providers (*defined as has never enrolled in the VFC program OR a **returning** VFC provider- a provider who exited the program for greater than 15 months and is rejoining) are welcome to complete a VFC enrollment application during annual re-enrollment through January 31st. They 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 **60 days (2 months)** prior to the launch of the next year's annual re-enrollment cycle.



REQUIREMENT: Annual re-enrollment is required to continue in the program after initial enrollment.

Annual re-enrollment will occur in late March/ early April annually with an email notification to all VFC providers. The enrollment forms must be completed and submitted in SCIAPPS VFC Enrollment System within 45 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 by May 17th will be contacted by the Immunization Division to schedule a time to retrieve all 2015-2016 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 and email notification from the Immunization Division about their new account status.
3. Certificates of completion for the Annual Provider Training **must be uploaded** in the 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 Provider Training via CDC Training Modules.
 - a. Immunization: You Call the Shots Vaccines For Children Program WB2597.

- b. Immunization: You Call the Shots- Storage and Handling WB2596.
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 [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 thermometer(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 be sent to the practice once site is approved to receive publicly funded vaccine(s).

ANNUAL RE-ENROLLMENT: All VFC providers who were enrolled during the 2015-2016 VFC re-enrollment cycle.

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

*Each provider site **must complete** the following forms in 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)
 - South Carolina Vaccine Transfer Form (DHEC 1208)
 - South Carolina Vaccine Wastage and Return Form (DHEC 1209)
 - South Carolina Refrigerator/Freezer Temperature Log Form (DHEC 1627)
 - South Carolina Vaccine Program(s) Disenrollment Form (VFC or SC State) DHEC 1984
 - Vaccines For Children (VFC) Program Suspected Fraud and /or Abuse Referral Sheet Form (DHEC 1997)
 - Immunization Information Form (DHEC 1103V)
 - Pediatric Vaccine Doses Administered Worksheet (DHEC 1150)
 - SC Vaccine Inventory Log (DHEC 1131)
2. Annual VFC enrollment/re-enrollment requires the signature of the Medical Director or Equivalent who is the Electronic Signature Authority (ESA) on all forms. 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).

The Federal VFC Program Provider Agreement form (DHEC 1144) represents the provider's agreement to comply with all the conditions of the VFC program. The individual signing must have authority to ensure that the practice/ clinic/facility and all providers listed on the agreement will adhere to the requirements of the program.

3. ESA should log in to SCIAPPS using their current individual email address 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 thermometers
 - 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 annual 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 the Immunization Division notifying them of their approved enrollment status. Vaccine Order Forms will be attached to the email only if the provider's vaccine order forms are different from the 2015-2016 VFC enrollment cycle.

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 Vaccine Coordinator and Back up Vaccine Coordinator). 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 all changes and updates should be made ***IMMEDIATELY*** on the VFC Enrollment forms when:
- Office hours for receiving vaccine shipments
 - Change of address (shipping/mailing)
 - 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, and *Registered Pharmacist) who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The ESA agrees to comply with all VFC Program Protocols, including:

1. Annual submission of a provider profile representing populations served by the practice(s)/facility(s) or more frequently if the number of children served changes or the status of the facility changes during the calendar year;
2. Screening and documenting eligibility status at each immunization encounter/visit for VFC eligibility (i.e., federally or state vaccine-eligible) prior to administering immunization(s) by such category only to children who are 18 years of age or younger who meet one or the following categories:

VFC Eligible children:

- A. Medicaid-Enrolled
- B. No Health Insurance
- C. American Indian/Alaska Native
- D. Underinsured, [served by Federally Qualified Health Center (FQHC)/Rural Health Clinic (RHC)]

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/origihanlaw.aspx>;

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

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

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

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

1. **Eligibility Criteria and Categories:**

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

VFC Eligible children

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

Non-VFC Eligible Children

- e) Insured – children whose health insurance covers the cost of vaccinations;
- f) SC State Underinsured, served by Non-FQHC/RHC-must be enrolled in the South Carolina State Vaccine Program

SC State Vaccine Program Underinsured: These children are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not an FQHC/RHC or a deputized provider.

However, these children may be served with state vaccine program vaccine to cover these non-VFC eligible children. Only providers enrolled in the SC State Vaccine Program are eligible to serve this population. You must have SC State Vaccine program vaccine stock prior to seeing this patient population.

- g) SC State Insured- provider must be enrolled in the South Carolina State Vaccine Program

SC State Vaccine Program - Insured Hardship and Vaccine Caps: These children are considered insured and are not eligible for vaccines through the VFC program.

However, these children may be served state vaccine program vaccine to cover these non-VFC eligible children.

Insured Hardship is defined as “Health Insurance deductible is greater than \$500.00 per child or \$1,000.00 per family (Eligible for state vaccine only if the deductible has not been met and the family cannot afford to pay for vaccine).”

Vaccine Caps is defined as “Insured but coverage capped at certain amount and cap has been exceeded.”

The 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 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:

- a) 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. Eligibility status must be readily available to staff administering vaccine prior to selecting which vaccine stock to use **OR**;
- b) Scan the current version of the Vaccines For Children (VFC) Program Patient Eligibility Screening Record Form into the provider sites EMR or EHR system if the above cannot be documented in the provider EMR/EHR.

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 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.

Provider specific vaccine order forms can be obtained by email request at immunize@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 immunize@dhec.sc.gov to check the status of the order.

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

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

for Merck frozen vaccines to reach provider offices once the order has been placed.

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

2. **Vaccine Transfers:**

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

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

3. **Vaccine Borrowing:**

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

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

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

Short-dated vaccine exchange:

The expectation for VFC enrolled providers regarding the exchange of short-dated vaccines is that a two way exchange can be used by a VFC– enrolled provider with a

patient population that is mostly VFC-eligible. This means the provider has a small number of state eligible and/or privately insured children.

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

Unintentional Retrieval of Vaccine:

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

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

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

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

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

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

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



REQUIREMENT: CDC's expectation is that VFC-enrolled providers maintain adequate inventories of vaccine to administer to both privately insured and VFC-eligible children. Borrowing vaccine must be due to unforeseen delays or circumstances surrounding the vaccine that was ordered.

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.

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



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

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.

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.

SECTION F. Vaccine Storage Equipment

 **Recommendation that will transition to a program requirement: Beginning January 1, 2019 VFC Providers must have one of the following vaccine storage unit(s) in place in order to re-enroll in the 2019-2020 VFC enrollment year.**

Beginning January 2019 Acceptable Vaccine Storage Units

Grade/Type	Comments	Rating
Pharmaceutical grade/ purpose-built units (stand-alone)	Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices.	Best
Pharmaceutical grade/ purpose-built units (combination)	Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices.	Best
Commercial units* (stand-alone)	Specifically engineered to maintain consistent temperatures throughout the unit. Purpose-built or pharmacy-grade refrigerators can be compact, making them ideal for small offices.	Good

Household* (stand-alone)	Usually smaller than commercial units and are intended for use in small offices and in homes, typically for food storage. Like commercial units, they are not designed to store biological materials.	OK
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1. Vaccine Storage Units

⊘ 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.

! **Recommendation that will transition to a Requirement beginning January 1, 2019.

Beginning January 1, 2019 Unacceptable Vaccine Storage units

Dormitory-style and bar-style combined refrigerator/freezers <i>(Current VFC requirement)</i> ⊘	These units pose a significant risk of freezing even when used for temporary storage.
**Manual defrost (cyclic defrost) units	These models have an exposed vertical cooling plate at the back of the refrigerator. They have significant temperature variation and risk freezing vaccines.
**Convertible refrigerator-only units	These units have an internal switch that converts an “all-refrigerator unit” to an “all freezer” unit.
**Cryogenic Freezers	These freezers reach temperature well below -58.0°F (-50.0°C), too cold for frozen vaccines is between -58°F and 5.0°F (-50.0°C and -15.0°C).
**House Combination Units	These units have a refrigerator and a freezer with separate exterior doors. These units have one compressor with poor temperature controls. They may pose a risk to refrigerated vaccines because cold air from the freezer is vented into the refrigerator and can freeze vaccines. The freezer portions of many combination units are not capable of maintaining the correct temperature for frozen vaccines.

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 stand alone refrigerator and freezer;
- 2) Have enough room to store the year’s largest inventory without crowding (this includes flu season and back to school times)
- 3) Have enough room to store water bottles (in the refrigerator)

and frozen coolant packs 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 thermometer **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 Stand-alone units suitable for vaccine storage. Stand-alone units are self-contained units that only refrigerate or freeze. These units can vary in size, from compact, under-the-counter style to large, stand-alone, pharmaceutical grade units.

- 1) CDC recommends purpose built or pharmaceutical/medical grade units.
- 2) Stand alone units for vaccine storage. Stand-alone unit are self-contained units that only refrigerate or freeze. These units that only refrigerate or freeze. These units can vary in size, from compact, under the counter style to large, stand-alone, pharmaceutical grade units.
- 3). 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).
- 4) 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.

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

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

VFC Providers must have five 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.

***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). If the discovery of an un-acceptable storage unit(s) is made during a VFC program site visit or at any other communication; the Immunization Division will suspend vaccine ordering privileges of the provider's site.

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

The ESA or assigned user will update the Vaccine Management and Disaster Recovery Plan (DHEC 1225) in SCIAPPS with the location of the new acceptable vaccine storage unit, date the certified calibrated thermometer was placed in the acceptable vaccine storage unit, and date of expiration of the certified calibrated thermometer, new vaccine storage unit location, and 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:**

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



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



When implementing the above requirement, the following recommendation should be considered:

- CDC recommends that the backup thermometer be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion.

- The backup thermometer should have a different calibration retesting date. If both thermometers 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 thermometer available for use.

4. **Thermometer Requirements:**

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

For information on accredited laboratories:

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



REQUIREMENT: VFC providers must have a working calibrated thermometer with a current and valid certificate of calibration testing in each vaccine storage unit.



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

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

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



Beginning January 1, 2018, all VFC providers storing vaccine must use a continuous temperature monitoring device with active temperature display, with continuous monitoring and recording capabilities where the data can be routinely downloaded. Additional recommended continuous temperature monitoring device characteristics include:

- A detachable, buffered probe
- Alarm for out of range temperatures
- Current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings
- User programmable logging interval(or reading rate)

6. **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.

For listings of accredited laboratories:

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

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

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

IAS: http://www.iasonline.org/Calibration_Laboratories/CL.html

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

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

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

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



This logo may appear on the certificate. It represents a group of accreditation organizations such as the ones whose logos appear above.

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 +/- 1F (+/-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 +/- 1F (+/-0.5C)]

7. **Thermometer placement:**

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



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 Requirements**

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



REQUIREMENT: VFC providers must follow the set forth established protocol for reviewing and recording temperature readings twice daily when the office is open.

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

9. **Storage Temperatures**

The temperature of all refrigerated vaccine must stay between 2° and 8° C (between 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 ice packs should be stored along the walls, back, and door of the freezer to help maintain temperatures in case of a power outage.
- b) Vaccines must not be stored in the doors or floor of refrigerators or freezers, or on the top shelf of a refrigerator that is part of a combination refrigerator/freezer unit.
- c) 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:*
 - Store vaccine under correct temperature storage conditions.
 - Quarantine the vaccine. Label the vaccine “DO NOT USE” 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 your VFC program on how to document and report the incident.
 - Do not discard any vaccine unless directed to do so by the VFC program.

Do not presume that the vaccine has been compromised. These corrective action steps must be documented on the Vaccine Storage Action Plan for Temperature Excursions on the DHEC 1627.

If the 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. As of January 1, 2015 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)**

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

 - a) Ordering vaccines;
 - b) Overseeing proper receipt and storage of vaccine shipments;

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

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

 **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.*

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

1. *Train any provider staff involved in receipt of vaccine deliveries to immediately open, inspect and store vaccines upon delivery. Provider staff will alert primary and/or back up Vaccine Coordinator of vaccine delivery.*
2. *Ensure all staff with vaccine management responsibilities are trained on proper vaccine storage and handling procedures.*
3. *Train other staff who are responsible for administering vaccines or who may be required to transport vaccine in an emergency situation on proper vaccine storage and handling procedures.*
4. *Train responsible staff on all elements of the routine and emergency vaccine management storage and handling plans.*
5. *Document completed staff training in SCIAPPS on form #4 SC Vaccine Management and Disaster Recovery Plan. Include the staff member's name and date of training.*

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 MedWatch, the FDA's drug safety surveillance system. To obtain additional information about the VAERS program:

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

SECTION I. VFC Program Site Visits

All VFC 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. Providers must complete and submit the CDC online training (You Call the Shots: Vaccines For Children AND Vaccine Storage and Handling); or through the VFC Compliance Site Visit conducted during the current calendar year. The provider must meet the training requirement as outlined in SECTION J.

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

VFC Provider Education Training Requirement (Annually within the current calendar year) – This training will assist the practice in an area of improvement to become proficient in managing the VFC program within the provider’s office. Providers must receive annual training on all VFC requirements on focused areas that CDC requires for providers. All enrolled VFC providers must meet the annual training requirement during the current calendar year. ***At a minimum, the 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 must be uploaded to the VFC Enrollment System under CDC Upload Training)

1. **Immunization: You Call the Shots – Vaccine For Children** – This course provides key training on immunization knowledge on the VFC program requirements. The training is great for VFC Coordinators, office managers, billing personnel and new office staff. The training is capable of printing a certificate of completion for the course and provides accreditation for CME, CNE, CEU and CECH credits. Please print a copy of your score and the certificate and keep on file to get credit for the training.

<http://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp>



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*

uploaded in SCIAPPS and names changed on the appropriate enrollment forms.

3. **VFC Program Provider Presentation (optional):** This presentation may be emailed to all enrolled VFC providers after annual re-enrollment that covers all of the current VFC requirements. Providers will be educated through this presentation on current VFC requirements. There will be any credit given to VFC Providers for this presentation as it is only for education purposes only.

4. **VFC Compliance Site Visit (received within the current calendar year):** Providers who receive a scheduled VFC compliance site visit during the calendar year will meet the annual training education requirement. The VFC compliance site has a formal educational component and counts as meeting training requirement from the Immunization Division program field representative conducting the site visit. It is at the discretion of the Immunization Division program field representative, depending on site visit findings to request the specific provider staff to take the CDC online training as a part of the site visit follow-up process.

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** – ie. a report to the VFC Program from a concerned patient or provider staff member; or
- b) **Vaccine orders** – ie. a provider is ordering vaccine inconsistent with usual ordering patterns and/or reported patient population in Provider Profile; or
- c) **Routine VFC Site Visits** - ie. 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.
- b) ***Repeated Violations (violations of the same VFC requirement category that have been identified in previous two site visits):*** Failure to adequately correct serious deficiencies will result in corrective action will be referred to Immunization Division Central Office for further action. The decision to place a provider in a formal education process will be made at the Immunization Division Central Office level.

Failure to adequately correct serious deficiencies will result in termination of the provider's participation in the VFC program. Referral to appropriate State or Federal agencies will 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 disenrolled in the VFC program at any time. The VFC provider must submit the South Carolina Vaccine Program(s) Disenrollment Form (VFC or State) DHEC 1984. The form must be signed by the Medical Director or Equivalent (ESA) who has signed the current VFC Program Provider Agreement DHEC 1144.

Additionally the VFC provider must submit:

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

All submission for disenrollment request must include the above information for processing by the Immunization Division. Upon receipt of this documentation, the VFC Program will disenroll the provider as requested from 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 disenrolled 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: immunize@dhec.sc.gov