



2016 Vaccines For Children Enrollment Guidance Document For Providers

OVERVIEW

The VFC Enrollment Guidance Document for Providers (Guide) serves as a companion to the Federal VFC Enrollment Forms online via SCI APPS, go to <https://www.scdhec.gov/Apps/Health>. This guide is a resource for the provider to gather information to assist in completing the Federal VFC enrollment forms. All Federal VFC Enrollment forms must contain the **most current** information about the practice (i.e. Facility Name, Name of Vaccine Coordinators, Health Care Providers, and Delivery Dates & Times, etc.).

This document should be used to systematically prepare and review the following forms: (1) CDC Training Upload; (2) Federal VFC Provider Agreement (DHEC 1144); (3) Federal VFC Provider Profile (DHEC 1145); (4) South Carolina Vaccine Management and Disaster Recovery Plan (DHEC 1225); (5) Federal VFC Patient Eligibility Screening Record (DHEC 1146) and (6) SC State Vaccine Program Provider Agreement (DHEC 1230).

The Primary and Backup Vaccine Coordinators or the Electronic Signature Authority (ESA) using this guidance document should be able to determine if the following actions are in place. All forms are to be submitted in SCI APPS by the ESA, a Medical Doctor (MD), Doctor of Osteopathy (DO), Advance Practice Registered Nurse, or Registered Pharmacist. *☞ A Doctor of Medicine or Doctor of Osteopathy **must co-sign** the VFC agreement (DHEC 144) for a Registered Pharmacist.*

Approval Process

All Annual VFC Enrollment/Re Enrollment forms must be completed and have an “**Approved**” status in SCI APPS.

☞ It is important to complete VFC Enrollment/Re Enrollment forms As Soon as Possible. All enrollment forms must be completed and submitted online by May 16, 2016 to prevent any delays in placing vaccine orders.

Steps for “Approved” Status

STEP 1 Submit the completed enrollment application in SCI APPS by *May 16, 2016*.

STEP 2 Once “Approved”, the ESA, Primary & Back-up Vaccine Coordinators receives an email, including an attached vaccine order form from the Immunization Division.

- a. If the application is returned due to errors, the application must be corrected and resubmitted.
- b. The ESA, Primary & Back-up Vaccine Coordinators receives a “[No Reply@dhec.sc.gov](mailto:No_Reply@dhec.sc.gov)” email about their current enrollment status.

☞ Submitted VFC Enrollment Applications Are Not Automatically “Approved” Applications!

CDC Training Upload

At a minimum, the VFC Primary & Back-up Vaccine Coordinators are required to complete the VFC Provider Education Training prior to enrollment into the VFC program each year. In order to satisfy the requirement, please complete the following two trainings in the [CDC public health training website](#). Print the continuing education guide or watch a video in the Continuing Education Online Education System. The certificates from the completed courses must be uploaded in SCIAPPS.

In the CDC Online Education System (CE) trainings, there are three parts to each training module ***Course Activity**, ***Course Evaluation**, and ***Course Post-Test**. All three parts must be completed in order to print a certificate. Follow the steps from the CE Step-By-Step Guide: <http://www.cdc.gov/vaccines/ed/ce-credit-how-to.htm>

Steps to Completing the Training Requirement:

- Complete the course activity - This portion of training which prepares the user(s) to take the post-test.
- Evaluations of the course activity - User(s) are surveyed on the CDC course activity.
- Post-Test of course activity – Test the user’s knowledge of the course’s subject matter.
- After the post-test you must go to the transcript. (Print your certificate!!)
- Convert into a pdf and upload in SCIAPPS.

STEP 1 Immunization: You Call the Shots-MODULE SIXTEEN-Vaccines for Children Program-2016 WB2597

STEP 2 Immunization: You Call the Shots-MODULE Ten-Storage and Handling-2016 WB2596

Roles and Responsibilities of a Primary or Back-Up Vaccine Coordinator

VFC program requires providers to have both a Primary and a Back-up Vaccine Coordinator who must be responsible for vaccine management in the provider practice. The ESA should select persons who are best suited to manage these activities in the provider practice office.

☞ The person(s) designated as vaccine coordinator(s) are not required to be a nurse in order to fulfill these roles and responsibilities! This selection is at the discretion of the ESA.

Roles and Responsibilities:

- **Receive Vaccines**
 - Be present when vaccines are delivered and inspect and store in the vaccine storage unit.
 - Ensure that acceptable temperature ranges have been maintained.
- **Store Vaccines**
 - Rotate the vaccine inventory so that vaccines with shorter expiration dates are used first.
 - Ensure that there are no expired vaccines in the refrigerator or freezer.
 - Keep VFC vaccine separate from private vaccine stock.
 - Perform routine cleaning on vaccine storage units.
- **Monitor Vaccine Temperatures**
 - Use a certified calibrated thermometer to review refrigerator and freezer temperatures.
 - Record at least twice a day the temperatures on the required temperature log for each vaccine storage unit.
 - Take immediate action if temperatures are outside acceptable ranges.
 - Implement the emergency vaccine management plan, if necessary.
 - Review vaccine temperature logs weekly.
 - Retain temperature logs for three years.
- **Order Vaccines**
 - Perform physical inventory of all vaccine stock.
 - Account for doses returned or transferred vaccines since the last order.
 - Complete and submit the vaccine order based on the provider profile population

Federal VFC Provider Agreement (DHEC 1144)

The Federal VFC Provider Agreement (DHEC 1144) represents the provider's agreement to comply with All Conditions of the VFC program. The ESA, as described above must ensure that the practice/clinic/facility and all providers listed on the agreement will adhere to the VFC program requirements.

The VFC Program requires the ESA to list each licensed health care provider with prescribing authority (MD, DO, NP, PA, Pharmacist) and those who administer vaccines (i.e. RN, CMA, CNA, MA) in the practice in this section of the Federal VFC Provider Agreement.

New Feature  You are now able to upload the medical licensure from the [South Carolina Labor Licensing and Regulation Board](#). The medical licensure must be converted into a Portable Document Format (PDF) or a similar formatted file to upload document into the SCI APPS VFC Enrollment application.

New Feature  The person who has a security role of VFC Coordinator in SCI APPS can now complete all VFC enrollment documents on behalf of the ESA. *The ESA must provide their electronic signature before submitting All VFC forms needed for VFC Enrollment.*

How Does This Work?

STEP 1 The VFC Coordinator will simply log into SCI APPS.

STEP 2 Choose the VFC Enrollment option from the Dashboard

STEP 3 Complete each enrollment form and Save.

STEP 4 The ESA *must* log into SCI APPS to sign each provider agreement (VFC and/or SC State, if applicable) and Submit the enrollment application.

☞ If the ESA's email address needed for a electronic signature does not belong to the actual ESA, please call the Help Desk 1-866-439-4082 to make the correction!

VFC Provider Facility Information	What is an FEIN or Federal Identification Number, commonly known as Tax ID Number? It is a nine digit number that the IRS assigns in the following format XX-XXX-XXXX.
	What is a National Provider Identifier or NPI number? A unique 10-digit identification number issued to health care providers in the United States by the Centers for Medicare and Medicaid Services (CMS).

Federal VFC Provider Profile (DHEC 1145)

The Provider Profile captures both the number of VFC-Eligible and Non-VFC Eligible children served by VFC providers. It also captures when and where vaccines will be shipped, as well as how the practice represents itself (the type of facility, *Public* versus *Private*). This data is used to evaluate the providers' vaccine orders. Therefore, the accuracy of data is very important. Data compiled in the provider profile helps the Immunization Division determine the amount of VFC-funded vaccine to appropriate for the number of VFC-eligible children per VFC provider. *☞ Be sure to include your Non-VFC categories!*

The provider profile must be updated annually, during annual re-enrollment, or more frequently if (1) *the number of children served changes* (2) *the status of the facility changes during the calendar year and the changes impact vaccine need* or (3) *the hours for receiving vaccine shipments change.*

VFC- Eligible Categories <ul style="list-style-type: none"> ✓ Enrolled In Medicaid ✓ No Health Insurance ✓ American Indian/Alaska Native ✓ Underinsured in Federally Qualified Health Center/Rural Health Center (FQHC/RHC) or Deputized Facility 	Non-VFC Eligible Categories <ul style="list-style-type: none"> ✓ Insured (private pay/health insurance covers vaccines) ✓ Other Underinsured (SC State Program, Non-FQHC/Non RHC) ✓ *SC State Insured <p><i>*All private providers see DHEC 1146 and Health Departments see DHEC 1146D</i></p>
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Selecting a Facility Type

While there are many facility types to select from the drop down menu on this form, select the type that is the closest representation of your provider practice. There are two main designations of facility types **Public** *OR* **Private**.

Key Points...	<p>Public Facilities: Public Health Department Clinic as agent for FQHC/RHC – deputized; Public Hospital; FQHC/RHC (Community/Migrant/Rural); Community Health Center; Tribal/Indian Health Services Clinic; Woman, Infants and Children; STD/HIV; Family Planning; Juvenile Detention Center; Correctional Facility; Drug Treatment Facility; Migrant Health Facility; Refugee Health Facility; School-Based Clinic; Teen Health Center, Adolescent Only Provider.</p>
	<p>Private Facilities: Private Hospital; Private Practice (solo/group/HMO); Private Practice (solo/groups as agent for FQHC/RHC – deputized); Community Health Center; Pharmacy; Birthing Hospital; School-Based Clinic; Adolescent Only Provider.</p>
	<p>What is a Federally Qualified Health Center (FQHC)? An health center that is designated by the Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide healthcare to a medically underserved population. FQHCs include community and migrant health centers, special health facilities such as those for the homeless and persons with acquired immunodeficiency syndrome (AIDS) that receive grants under the Public Health Service (PHS) Act, as well as “look-alikes,” which meet the qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian Health Service centers.</p>
	<p>What is a Rural Health Clinic (RHC)? An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time that the clinic is open.</p>

Types of Vaccines Offered

VFC Providers must offer vaccines for the population they serve. These vaccines are identified and agreed upon during the new enrollment and annual re-enrollment process. Non-specialty providers are to offer **all** ACIP-approved vaccines. Specialty providers offer Select Vaccines from the DHEC 1145.

All ACIP Recommended Vaccines (0-18)

The vaccines identified and agreed upon in the Provider Profile must comply with immunization schedules, dosages, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) <http://www.cdc.gov/vaccines/acip/index.html> and included in the VFC program unless:

- 1.) 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:
- 2.) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

OR

Offering Selected ACIP Recommended Vaccines

The provider is certifying that they will order vaccines only of the age-appropriate ACIP recommended vaccines for their VFC eligible patient population. These providers are considered a Specialty provider.

What is a Specialty Provider?

A “Specialty Provider” is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g., OB/GYN; STD clinic; family planning) or (2) a specific age group within the general population of children ages 0 –18. **Local Health Departments and pediatricians are not considered specialty providers.** The VFC Program has the authority to designate VFC providers as specialty providers. At the discretion of the VFC Program, enrolled providers such as pharmacies and mass vaccinators may offer only influenza vaccine.

Vaccine Shipping Dates and Times

Providers must be on site with appropriate staff available to receive vaccine at least 1 day a week other than Monday and for at least 4 consecutive hours during that day Tuesday through Friday.

1. Example: Tuesday 10:00am to 12:00pm and **1:00pm to 5:00pm** ← Acceptable Afternoon time

4 Consecutive Hours

2. Example: Tuesday **8:00am to 12:00pm** and 2:00pm to 5:00pm ← Acceptable Morning time

4 Consecutive Hours

New Feature – Special Delivery Instructions



Providers are responsible for updating any special delivery instructions as often as needed. If the provider practice has specified holidays or office closings, update it in the Special Delivery Instructions box. This will alert the Immunization Division to make the appropriate changes to the vaccine ordering system.

Provider Population

You must enter a number as these are required fields. If not serving a population, enter 0. If you are enrolled or will enroll in the South Carolina State Vaccine program, remember to enter your profile for that population here.

Type of Data Used to Determine Provider Population

Providers may select multiple types of data to determine the profile.

Benchmarking – New Providers Only

New VFC Enrollee’s must select *Benchmarking* as the type of data used to determine eligibility. The provider can still select other data sets in conjunction with benchmarking. The provider must update this provider profile in SCI APPS as soon as (1) *the number of children served changes* or (2) *the status of the facility changes during the calendar year and the changes impact vaccine needed for VFC and Non-VFC eligible children.*

Sources for benchmarking data may come from a variety of sources such as: United States Census Bureau and Business Plans.

Contact information for Vaccine Coordinators

- Please ensure you include a number where you can be reached in case of an emergency such as a Home Phone. You may use a cell phone number in this slot.

Vaccine Manufacturers and National Weather Service Contact Information

- When reporting a storage and handling incident to the Immunization Division please note that all vaccine manufacturers telephone numbers are listed here.

Part A: Routine Storage and Handling

I. Vaccine Storage

- A. Types of Vaccine Storage Units – The link to the Storage and Handling toolkit are available for accessing information regarding your vaccine storage units. [Vaccine Storage & Handling Toolkit](#)
- C. Certificates of Calibration – Links to accredited laboratories are listed here. Here you may research if your thermometer has been calibrated by one of these laboratories.
- I. Appropriate Diluent Storage Conditions (6) List the location that diluent is stored? – Ensure that you update this field.

Indicate The Following For Thermometers At Your Site

- If you are re-enrolling, check all uploaded certificates of calibration for each thermometer used to monitor VFC/State Vaccine. If you have additional thermometers or you are replacing thermometers, upload them here.

How Does This Work?

STEP 1 Write the VFC PIN on each certificate

STEP 2 Add the VFC PIN when naming the file

STEP 3 Click *Upload* to SCI APPS VFC Enrollment form, 4) SC Vaccine Management and Disaster Recovery Plan (DHEC 1225)

- **Date Thermometer Certification Expires:** - See the certificate for this date. If there is no date given by the manufacturer, the thermometer must be recalibrated one year from the date of placement in the vaccine storage unit. *Example: Date placed in unit 2.16.2016. Manufacturer gives no date on certificate, so it expires 2.16.2017*
- **Stored in Refrigerator or Freezer?** - Select where the device is stored. Only if the thermometer has two probes, then you may choose “Both”.
- **Date Thermometer was Initially Placed in Unit:** - This is the date that the thermometer was initially placed or replaced if the provider had the thermometer recalibrated. The back-up thermometer should be placed in the unit when a thermometer is being recalibrated. Back-up thermometers must have a valid and current certificate of calibration.
- **Location/Description/Manufacturer** - All three of these should be given. *Example: Lab 1/Side wall/Control Solutions*
- **Serial Number or Model Number** - Either of these are fine unless the thermometers have the same serial number or model number. You should use the number that specifically identifies the thermometer.
- **Certificate of Calibration** - Upload the most current certificate. If the certificate is expired or will expire before the end of the open enroll/re-enroll period of May 16, 2016, you must upload a new certificate.

Part B: Disaster Recovery Plan

II. Content

A. The Disaster Recovery Plan for this practice contains the following:

- Name of person(s) responsible for preparing and transporting vaccine in the event of an emergency: Give the name and their contact information.
- Location that will receive the vaccine: This should be one of your alternate storage facilities.
- How the receiving location will be notified of transport: Enter the telephone numbers here and use more than one contact number for the facility.
- Sources for packing materials and certified, calibrated thermometers: Know the location of these items to be readily available.
- How to pack vaccine for transport: See Part B, section III Vaccine Packing for Emergency Transport below for proper instructions.
- How to document the steps taken when vaccine is involved in a power or equipment failure: See Part A, section VI. Inappropriate Vaccine Storage Conditions/Storage and Handling Events.

IV. Vaccine Storage Facilities

A. Entering Vaccine Storage Facilities:

- Unit # – You may associate a number to the number of vaccine storage units that are located at the facility. This number should correspond with the floor diagram.
- Location and Description – Write the location and give brief description of unit.
- Category (Refrigerator/Freezer) – Indicate the unit here. If you use the refrigerator portion only of a combination unit, then select refrigerator. Same if it is for freezer.
- Grade of Unit (Household, Commercial, Pharmaceutical) and Type (Stand-Alone, Combined) – Important to note the grade of the unit.
- Type (Stand-Alone, Combined)
- Make (GE, Sub-Zero, Amana, etc.) – Enter the manufacturer/brand name here.
- Contains Varicella? (Yes or No) – Answer appropriately as these are frozen vaccines.
- Active/Inactive (Currently Used)? – If the unit is not active, ensure that it is listed and answer appropriately. This is critical if you were to use this unit in the storage and handling incident and need to move vaccines temporarily.

Uploaded Floor Plan

Re-enrolling providers should verify that your floor plan is accurate. If you have moved locations or moved vaccine storage unit(s), update your floor diagram.

How Does This Work?

STEP 1 Write the VFC PIN on the floor diagram

STEP 2 Add the VFC PIN when naming the file

STEP 3 Click *Upload* to SCI APPS VFC Enrollment form, 4) SC Vaccine Management and Disaster Recovery Plan (DHEC 1225)

B. Alternative storage facility(s) with a back-up generator:

Indicate your alternate vaccine storage facilities here. The Immunization Division encourages providers to have more than one Alternate Facility available to receive vaccines in case of an emergency. Remember other providers may be seeking the same location as an alternate facility.

- Alternate Facility Name – List full name of organization. For pharmacy retail stores, include the store number. This will help with location. *Example: Good Health Store # 56, Anytown SC*
- Point of Contact – Ensure that there is a personal contact here. *Example: Jane Doe, Rph* If a corporation, enter the person who handles their disaster preparedness. *Example: John Doe, Good Health Store - Regional Disaster Preparedness Rep.*
- Work Phone – Enter phone number of person to contact here. Always include extensions, whenever possible.
- Emergency Phone – Enter their emergency phone number here. Always include extensions, whenever possible.

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
Household (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.	Poor

Unacceptable Vaccine Storage Units

☞ *These do not meet VFC specifications and may not be used to store vaccines.*

Dormitory-style and bar-style combined refrigerator/freezers	These units pose a significant risk of freezing even when used for temporary storage.
Convertible refrigerator-only units	These units have an internal switch that converts an “all-refrigerator unit” to an “all freezers” 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).

SC State Vaccine Program Provider Agreement (DHEC 1230)

The Department of Health and Environmental Control (DHEC) offers the South Carolina State Vaccine Program (State Program) as a supplement to the Federal VFC Program.

The purpose of the State program is to allow Non-Federally Qualified Health Centers (FQHC)/Non-Rural Health

Clinics (RHC) providers are to serve the "underinsured" child in their medical home. Participation in the State Vaccine Program also allows all VFC enrolled providers to vaccinate certain insured-hardship children.

☞ *Providers must be enrolled in the Federal VFC Program as a prerequisite to enrollment in the SC State Vaccine Program.*

Providers may opt to participate in the VFC Program only or both the VFC and State Vaccine Programs. A separate enrollment agreement is required in SCI APPS for State Vaccine program to ensure accountability.

☞ *The SC State Vaccine Program offers all ACIP recommended vaccines with the **EXCEPTION** of the Human Papillomavirus (HPV) vaccine, which is **ONLY** available through the Federal VFC Program.*

<u>Eligibility Definitions</u> Children from birth to 18 years of age who meet one of more of the following categories are eligible to receive State Vaccine.	1.) <u>SC State Underinsured</u> Health insurance does not pay for vaccines.
	2.) <u>SC State Insured</u> These children are considered insured with a deductible that has not been met and cannot afford to pay for vaccine and are not eligible for vaccines through the VFC Program.
	a.) <u>Insured Hardship</u> “Health Insurance deductible is greater than \$500.00 per child or \$1,000.00 per family.”
	b.) <u>Vaccine Caps</u> “Insured but coverage capped at certain amount and cap has been exceeded.”