SOUTH CAROLINA
DEPARTMENT OF
PUBLIC HEALTH

2024-2025

VFC Provider Handbook

South Carolina Immunization Operations
Section Vaccines For Children (VFC) Program

1994-2024 30TH ANNIVERSARY Vaccines for children

Helping families protect their children since 1994!

BCDPC | SCIOS | SCVFC Rev. JULY 2024

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Introduction

The South Carolina Immunization Operations Section (SCIOS) is within the South Carolina Department of Public Health (DPH) Bureau of Communicable Disease Prevention and Control (BCDPC).

Agency Mission:
To protect, promote, and improve the health and well-being of everyone in South Carolina.

Agency Vision:
Healthy people living in health communities.

Agency Core Values:

- Embracing Service – Reliably serves our communities and customers.
- Inspiring Innovation Encourage our teams to find creative solutions.
- Promoting Teamwork – Fostering an inclusive and collaborative environment.
- Pursuing Excellence - Steadfast in achieving the highest standards of quality.
- Advancing Equity- Attaining optimal health outcomes by fostering a culture of fairness, equity and inclusion for every

The Vaccines for Children Program (VFC) is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated due to inability to pay. SCIOS provides federally purchased and state purchased vaccine to eligible healthcare providers enrolled in the VFC/SC State Vaccine Program. Children who are eligible for the VFC/SC State Vaccine program are entitled to receive vaccines that are routinely or permissively recommended by the Advisory Committee on Immunization Practices (ACIP), as published in the Centers for Disease Control and Prevention's (CDC) "Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger(https://www.cdc.gov/vaccines/schedules/hcp/child- adolescent.html).

VFC Program Benefits:

- Provides cost-savings to states and territories through bulk purchase of vaccine at lower prices using CDC's contracts and eliminates state-to-state differences in price.
- Reduces referrals of children from private providers to local health departments (LHDs) for vaccination.
- Saves VFC-enrolled providers out-of-pocket expenses for vaccine.
- Eliminates or reduces vaccine cost as a barrier to immunizing eligible children.

Acronyms

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
DDL	Digital Data Logger
DHHS	Department of Health and Human Services
FQHC	Federally Qualified Health Center
EHR	Electronic Health Record
ETP	Electronic Trading Partner
HL7	Health-Level 7 (standards for electronic transmission of health data)
HRSA	Health Resources and Services Administration
IQIP	Immunization Quality Improvement for Providers
LHD	Local Health Department
MU	Meaningful Use
PA	Provider Agreement
PIN	Provider Identification Number
QA	Quality Assurance
RHC	Rural Health Center
RIR	Regional Immunization Representative (Field Representative)
TE	Temperature Excursion
SIGNATORY	Signatory (Certifying Provider, Provider of Record)
SCREVMP	South Carolina Routine and Emergency Vaccine Management Plan
SIMON	Statewide Immunization Online Network
SCIOS	South Carolina Immunization Operations Section
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
VIS	Vaccine Information Statement

Contact Information

Vaccine Operations Unit	
This SCIOS section handles the following: • Enrollments (New &Returning) • Vaccine storage & handling issues • Temperature excursions, • Vaccine ordering, • Inventory, reconciliation & returns, • Vaccine supply issues, • VFC compliance questions or concerns, • IQIP site visits, • VFC Facility changes, • Updating Primary/Back Up Coordinators, • VFC Agreement Signatory, • Training (Webinars).	**Phone:** (803) 898-0460 Select Option 2 **Fax:** (803) 898-0318 **Email:** scvfc@dph.sc.gov **Helpdesk: SIMON Helpdesk Request** **Available:** Monday – Friday 8:30am to 5:00pm EST
SIMON Help Desk	
This SCIOS Section handles the following: • SIMON assistance, • register a facility in SIMON, • to add or inactivate users, • or to apply SIMON user permissions, • Establishing an interface between your Electronic Health Record (EHR) and SIMON.	**Phone:** (803) 898-0460 Select Option 3 **Fax:** (803) 898-0326 **Email:** SIMON@dph.sc.gov (IIS Questions) **Available:** Monday – Friday 8:30am to 5:00pm EST
SCIOS Clinical Education Unit	
This SCIOS Section handles the following: • Training opportunities, • SIMON patient management, • Clinical and immunization questions, • Vaccine Approval for TD, and PPSV23.	**Phone:** (803) 898-0460 Select Option 4 **Email:** Immunize@dph.sc.gov **Available:** Monday – Friday 8:30am to 5:00pm EST
UPSTATE VFC Quality Assurance Team—Dana Gurley, Imz. Compliance Unit Mgr.	
• Regional VFC/IQIP Site Visits, • School/Childcare Audits, • Immunization Certificates • SLVC's	**Phone:** (864) 276-1272 **Email:** ***gurleydm@dph.sc.gov*** **Counties: Abbeville, Anderson, Cherokee, Greenville, Greenwood, McCormick, Laurens, Oconee, Pickens, Spartanburg, and Union**
LOWCOUNTRY VFC Quality Assurance Team—Bethany Deford, Imz. Compliance Unit Mgr.	
• Regional VFC/IQIP Site Visits, • School/Childcare Audits, • Immunization Certificates • SLVC's	**Phone:** (803) 318-0788 **Email:** ***lowcountryimz@dph.sc.gov*** **Counties: Allendale, Bamberg, Berkeley, Beaufort, Calhoun, Charleston, Colleton, Dorchester, Hampton, Jasper, Orangeburg**
PEEDEE VFC Quality Assurance Team—Dara Johnson, Regional Imz. Compliance Mgr.	
• Regional VFC/IQIP Site Visits, • School/Childcare Audits, • Immunization Certificates • SLVC's	**Phone:** (843) 250-0211 **Email:** ***johnsodb@dph.sc.gov*** **Counties: Clarendon, Chesterfield, Darlington, Dillon, Florence, Georgetown, Horry, Lee, Marion, Marlboro, Sumter, and Williamsburg**

MIDLANDS VFC Quality Assurance Team—Lynne Foster, Imz. Compliance Mgr.	
• Regional VFC/IQIP Site Visits, • School/Childcare Audits, • Immunization Certificates • SLVC's	**Phone:** (803) 576-2831
	Email: fosterlw@dph.sc.gov
	Counties: Aiken, Barnwell, Chester, Edgefield, Fairfield, Kershaw, Lancaster, Lexington, Newberry, Richland, Saluda, and York
VFC Fraud and Abuse Prevention	
Anyone with concerns about misuse or mishandling of VFC vaccines are to report to SCIOS. Reports may be anonymous; all are confidential.	**Phone:** (800)-277-4687 Select Option 2
	Helpdesk Submission: https://dph.sc.gov/professionals/simon
	Available: Monday – Friday 8:30am to 5:00pm EST

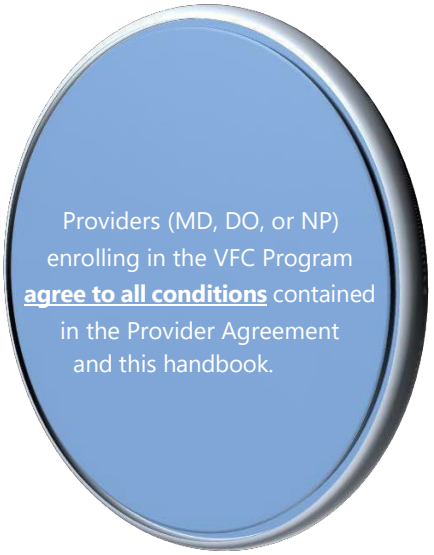
VFC Program Resources for VFC Providers

SCIOS website	General Immunization Information SCIOS website at: https://dph.sc.gov/health-wellness/child-teen-health/vaccine-requirements-info
VFC Provider Map	Looking for access to care regarding vaccines. https://sc-dhec.maps.arcgis.com/apps/instant/nearby/index.html?appid=0e0839a15f114dca89083ba5ac21da51
SIMON Website Homepage	The SIMON homepage has links to SIMON training guides, videos, webinars, and other helpful resources: https://dph.sc.gov/professionals/simon
VFC & Vaccine Management Information	Documents and forms referenced in the VFC Provider Handbook https://dph.sc.gov/professionals/simon/vfc-vaccine-management-information

1. VFC Program

1.1. Who May Enroll?

To participate in the South Carolina VFC Program, a healthcare provider must have an active, unencumbered medical or advanced nursing practice license in the state of South Carolina. In addition, all licensed health care providers (MD, DO, NP, PA, pharmacist) practicing at this facility must be included on the provider agreement, in addition the following must be entered, the physician's full name, medical license number, and Medicaid or NPI number on the online Provider Agreement in SIMON.



1.2 Initial VFC Enrollment Process

A facility may join the VFC Program between March and October. All VFC training is available on SIMON website.

Initial Enrollment Process:

a) Confirm or establish (1) a SIMON facility registration and (2) an active SIMON user account.
   - To register a new facility in SIMON, complete the SIMON Facility Registration application on the public SIMON homepage https://simon-qa.dhec.sc.gov/simon_qa/Login.aspx
   - If the facility is already registered in SIMON, but the user does not have a SIMON user account, contact the SIMON Registration team by email at SIMON@dph.sc.gov to request one.

b) NEW PROVIDERS--To request a New VFC Enrollment:
   - Step 1: Click here to complete VFC pre-enrollment> VFC Pre-Enrollment Form
   - Step 2: Submit SIMON Help desk ticket
     - 2a: Under "Program Area" **Select** "Vaccine Programs"
     - 2b: Under "Category" **Select** "Enrollment"
     - 2c: In Description Box—Enter the Message: **"Requesting New VFC Enrollment"**
     - 2d: Review information entered on form for accuracy then **Click** "**Submit"**
   - Step 7: SCIOS Staff member will contact you with guidance on next steps.
   - Step 8: A VFC Enrollment visit will be scheduled and the RIR will assist provider with final setup during the visit.
   - Step 9: A member of the SCIOS will review and approve/deny enrollment.

Complete Annual VFC Provider Training or Refresher Option:

Both Primary and Back-Up Vaccine Coordinators must complete approved annual training. To meet this requirement, complete the following trainings prior to recertification:

- Both CDC *You Call the Shots* training modules (Vaccine Storage and Handling and Vaccines for Children) for the current calendar year (January-December). The modules can be accessed at: CDC Immunization Education and Training
- SIMON Application Training Course "SIMON Application Training" can be accessed at CDC Train

*NOTE** You Call the Shots (YCTS), now has a Refresher Option. This new Option is a pretest that will be available for providers familiar with VFC and vaccine storage and handling requirements who have completed the full YCTS modules previously. Two refresher options (25 questions each) include content from the original YCTS modules. Providers may choose to complete both Refresher Options or satisfy the provider annual training requirement through a combination of Refresher Option completion and the corresponding YCTS module completion. Providers must score 80% or higher to receive a Statement of Completion for documentation in the PEAR system. Continuing education credit will not be given for completion of either Refresher Option.*

a) Complete a SC Routine and Emergency Vaccine Management Plan (SC**REVMP**)[DPH1225]. A completed copy must be available upon request at the initial enrollment or any type of VFC Site Visit(s).
b) Review the Guidance for Purchasing of New Vaccine Storage Unit

1.3 Provider Identification Number (PIN)

During the new enrollment process, the VFC Program will issue the practice a unique six-digit Provider Identification Number (PIN). To expedite processing, please reference this number in **ALL** communications and correspondence with SCIOS.

1.4 Provider Profile

The Provider/Clinic Profile is a section within the Provider Agreement in SIMON. This section of the Agreement defines the number of VFC-eligible children and non-VFC- eligible children by age group served by a VFC provider. This information represents the population served by the practice or facility during the past 12 months. Brand new provider sites who have not yet seen patients may utilize "benchmarking" as their data source. This way of determining provider population is **only acceptable for new providers,** who may enter "10" for each category of VFC eligibility, on the provider profile. Once the practice has been seeing patients for 1 year, they will cease using benchmarking and rely on other data sources. When a practice is completing recertification, the Population Profile numbers must be entered with data submitted from the previous year.

For new providers, they must benchmark or estimate the number of patients that they intend to see at the provider/clinic and update it within six months of being enrolled if the provider population has changed. All health care providers participating in the VFC program must complete the Provider Profile annually or more frequently if the number of children served changes or the status of the facility changes during the calendar year.

Providers are required to review and update their patient population numbers annually. To determine the patient population, a provider may use patient records and/or vaccine administration data submitted to SIMON. The SIMON report that yields this data is under "**Reports",** Scroll down to **"Coverage Statistics Section"** called the **"VFC Category Patient Count Report "**. It is essential to be accurate when describing patient population in the Provider/ Practice Profile section; this information determines the amount of vaccine each provider will need in the year ahead.

1.5 Record Retention

Providers are required to maintain all records related to the VFC Program for a minimum of **three years** and make these records available for review upon request. These records include:

- Enrollment documentation
- VFC patient screening and eligibility documentation
- Billing records
- Vaccine Storage Information (SCEVMP, unit/ddl certification, etc.)
- Medical records of that verify administration of vaccine
- Vaccine ordering records
- Vaccine purchase and accountability records (such as packing lists, VFC Borrowing Forms, wastage

*Practices are **required to maintain a private vaccine inventory** that is sufficient to serve their non-VFC eligible patient population, as reported on the Provider Profile in the Provider Agreement. The CDC generally considers a "sufficient" supply to be a four to six-week inventory,based on the size of the practice's stated non-VFCpatient population.*

1.6 Changes in Staff/Facility Status

Providers are required to submit a SIMON Helpdesk Request to the VFC Program in the timeframe listed below for any change to the following:

a) Agreement Signatory (Certifying Provider that signed Provider Agreement)

➢ Changes must be **reported immediately,** and a new Provider Agreement must be received by SCIOS **within 48 business hours**. A valid Provider Agreement is required to continue participation in the VFC Program; non- compliance will result in suspension of vaccine ordering and possible VFC vaccine retrieval.

➢ Strongly recommended new signatory complete the SCVFC approved training within 30 days of the departure of the former Agreement Signatory.

b) Primary and/or Back-up Vaccine Coordinators

- Changes to a Vaccine Coordinator must be reported **within 10 days**. Must complete the SCVFC approved training within 30 days of the departure of the former Vaccine Coordinator.
- If the Primary Vaccine Coordinator is new, an educational visit with the RIR is required within 90 days of the departure of the former Primary Vaccine Coordinator. This visit can be conducted via phone, virtually or in person.

c) Listed medical providers, report **within 10 days.**

Provider are required to submit the following changes within SIMON (not via helpdesk request):

d) Mailing/shipping address, report **immediately.**

e) Vaccine delivery hours, report **immediately.**

f) Facility status (e.g., closure, merge, moving).

- Changes to the facility status must be reported **at least 30 business days** before moving VFC vaccine to a new geographical site.
- Any time a provider moves locations, the RIR will need to conduct a relocation visit **prior** to VFC vaccine being moved to new location.
- Once vaccine storage units are moved to a new location, **two** days of in- range temperatures will need to be submitted to SCIOS for review and approval **prior** to vaccine being placed in these units.

1.7 VFC Recertification

VFC re-certification in the VFC Program is required for all providers when announced by SCIOS in mid to late-March. Providers must complete recertification of their VFC application in SIMON **within 75 days after** the certification period begins to avoid any interruption in the receipt of vaccine. VFC Providers will receive a recertification reminder notification message via SIMON 3 weeks prior to the start date of the recertification. If a Provider Agreement expires without renewal, the facility will be considered to have voluntarily withdrawn from the VFC Program. The provider will not be able to order VFC vaccine and will be contacted by the RIR so that any remaining VFC vaccine may be collected. To re-join the VFC Program, the facility must complete the full initial enrollment process, including an Enrollment Site Visit, if more than 14 days has elapsed between certifications.

Steps to complete Recertification:

Recertification is an annual renewal of the VFC enrollment and is completed directly through SIMON.

2. Add, select, and complete the VFC Re-certification online Provider Agreement in SIMON.
3. Instructions on How to Recertify: Log into SIMON >Go to Clinic Tools>Enrollments

>Select Add Enrollment> Select the preferred Recertification enrollment template.

4. Both Primary and Back-Up Vaccine Coordinators must complete approved annual training. To meet this requirement, complete the following trainings prior to recertification (refer to page 9 within this guide for training and pretest option):
    - Complete both CDC *You Call the Shots* training modules (Vaccine Storage and Handling and Vaccines for Children) for the current calendar year (January-December). The modules can be accessed at: VFC & Vaccine Management Information
    - Complete SIMON Application Training Course "DPH VFC Provider/WebIZ Training" can be accessed at CDC Train
5. Complete and sign pages as indicated of the SCREVMP, DPH 1225 and keep at site.
6. The Primary Vaccine Coordinator will be notified via an alert message in SIMON when there is a change in the status of the online Provider Agreement.

1.8 South Carolina State Vaccine Program

The South Carolina Department of Public Health (DPH) also offers the SC State Vaccine Program (SC State Program) as a supplement to the Federal VFC Program. The purpose of the State Vaccine program is to allow non-FQHC/non- RHC providers to serve the "underinsured" child also known as SC State Underinsured in their medical home. Participation in the SC State Program also allows all VFC enrolled providers to vaccinate certain insured-hardship children.

Providers may opt to participate in the VFC Program only or both the VFC and SC State Programs. Only one provider agreement is required in SIMON for VFC and VFC/SC State Program to ensure accountability, which is the VFC Provider Agreement (New or Re- certifying). All providers who participate in the SC State Program will need to indicate in their provider profile they intend to serve under-insured children.

The SC State Vaccine Program offers all ACIP recommended vaccines just like the VFC program with the exception of RSV, COVID-19, and MPOX.

1.9 Voluntary Withdrawal or Termination from the VFC Program

Either SCIOS or the provider may terminate the VFC Provider Agreement at any time.

Facility Request

A facility closing or withdrawing from the VFC program must provide SCOIS at least **30 business days** written notice to allow time for VFC vaccine to be retrieved by the RIR. Submit notice of your intent to dis-enrollment via the automated Dis-enrollment form.

Failure to Comply with program

A facility that fails to comply with the VFC Program requirements or that fails to implement appropriate and timely corrective action risks being suspended and/or dis-enrolled from the program.

Failure to Complete annual Recertification

A facility who allows their current Provider Agreement to expire without being renewed will be removed from the program and required to re-enroll.

Vaccine ordering

A facility that has not placed a vaccine order in the past 12 months will be removed from the program and required to re-enroll.

SCIOS will contact providers that have been removed from the program to provide instructions on the transfer or return process for all VFC vaccines on hand. The provider is responsible for maintaining proper storage, temperature monitoring, and temperature logs until vaccine is retrieved by the RIR.

2. Fraud and Abuse

Federal fraud and abuse laws apply to the VFC Program; good stewardship of federal entitlement program taxpayer dollars is a top priority. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC Program. The following definitions are consistent with "fraud" and "abuse" as defined in Medicaid regulations 42 CFR § 455.2:

1. **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 another person. It includes any act that constitutes fraud under applicable federal or state law.
2. **Abuse:** Provider/provider location practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program(also includes 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. Also includes program recipient practices that result in unnecessary cost to the Medicaid program.
3. Well-organized and correctly administered VFC accountability programs are the cornerstones for preventing potential fraud and abuse incidents. Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier for the VFC Program to prevent or detect than others.

Any person may contact the SCIOS to report concerns or questions about possible fraud or mishandling of VFC vaccines. Reports may be submitted anonymously via the three methods outlined below. SCIOS treats all reports as confidential.

Fraud and Abuse Examples*

- Failing to comply with any part of the Provider Agreement
- Providing VFC vaccine to non-VFC-eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for VFC vaccine
- Charging more than the established maximum regional fee for administration of VFC vaccine
- Over-ordering VFC vaccine (e.g., quantities or patterns do not match the provider's profile)
- Waste of VFC vaccine
- Denying VFC-eligible children VFC-funded vaccine because of parents' inability to pay the administration fee
- Failing to screen for and document eligibility status at each visit
- Failing to maintain VFC records for a minimum of three years
- Failing to fully account for VFC-funded vaccine
- Failing to properly store and handle VFC vaccine

**This list provides examples only, and should not be considered comprehensive.*

1. **Written report** – Print and complete the VFC Program Suspected Fraud and/or Abuse form (D-1997). Submit the completed form the SCIOS – Vaccine Operations Manager via:
    - Mail: South Carolina Immunization Operations Section (Attn: VFC Operations Manager), 2100 Bull Street, Mills/Jarrett Bldg., Columbia, SC, 29201
2. **Telephone Report**- Call the South Carolina Immunization Section toll free at 800-277-4687 and request to speak to the Vaccine Operations Manager or VFC Coordinator.
3. **Online Report** - Go to the online reporting tool at SIMON helpdesk Request and select Suspected Fraud and Abuse and enter description of events.

Additional resources may also be found on the Federal DHHS Office of Inspector General Exclusions Program website.

3. Vaccine Eligibility and Documentation

For children to receive vaccines through the VFC Program, **eligibility screening and documentation must take place at each immunization visit**, up to 24 hours prior to vaccination. The only factors considered when screening for VFC eligibility are age and whether the child meets the definition of at least one of the VFC criteria described below.

3.1. VFC Eligibility Categories

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

1. **Medicaid-eligible** – For the purposes of the VFC Program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably and refer to children who have or are eligible for health insurance through the South Carolina Department of Health and Human Services (SCDHHS) program. Children covered by private insurance who have SCDHHS as a secondary insurer **ARE** eligible for VFC vaccine.

> ***NOTE:*** *A child is VFC-eligible in South Carolina if they are insured by Medicaid in any state.*

2. **Uninsured** – A child who has no health insurance coverage. Self-reported status is accepted.
    - A child covered by Health Care Sharing Ministries (ex. Medi-Share) is considered "uninsured" in South Carolina. These plans are nonprofit alternatives to purchasing health insurance and are not recognized as insurance by the South Carolina Department of Insurance.
3. **American Indian or Alaska Native (AI/AN)** – As defined by the Indian Health Care Improvement Act (25 U.S.C. CHAPTER 18).
4. **Underinsured*** –
    1. A child who has health insurance, but the insurance policy does not include **any** ACIP-recommended vaccines.
    2. A child whose insurance policy does not cover **all** ACIP-recommended vaccines. The

child is eligible to receive VFC vaccines not covered by the insurance.

3. A child whose insurance policy caps its payment for vaccine coverage. The child is eligible to receive VFC vaccine after the insurance cap has been reached.

*Note** Special Circumstances: Where vaccination services are delivered is generally not a factor in determining VFC eligibility. However, there are some locations and provider types that require additional consideration when offering VFC vaccines.*

***NOTE:** Underinsured children may receive VFC vaccine only at an FQHC, RHC, or deputized provider*

FQHCs, and RHCs that serve underinsured children are REQUIRED to verify a child's underinsurance status.

*****Underinsurance, limited coverage, and "caps" are increasingly uncommon coverage options and may only occur in insurance plans not compliant with the Affordable Care Act (ACA). ACA-compliant plans are required to provide all ACIP-recommended immunizations with no deductible or co-pay when administered by an in-network provider.

Children who are ineligible for VFC vaccines include:

1. **Privately insured** – Children whose health insurance covers vaccinations as a benefit are not eligible for VFC vaccines. This applies even 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.
2. **South Carolina (SC) State Vaccine Program** – This vaccine program serves children who are not federal vaccine eligible (non-VFC eligible). Providers must be enrolled in the SC State Vaccine Program to serve State vaccine-eligible children and must have this vaccine stock prior to serving these children. There are two eligibility categories:

NOTE: The RSV, COVID-19, and Mpox Vaccines are not apart of SC State Vaccine Program

SC State Underinsured Served by providers who are **NOT** FQHCs/RHCs or deputized provider. LHD's and other VFC providers would use the SC State Underinsured to service these children.	The child meets the same definition as VFC underinsured for VFC program, however; they are non-VFC eligible children and must be served SC State Vaccine.

SC State Insured- provider must be enrolled in SC State Vaccine Program	SC State Insured- Child whose health insurance covers the cost of vaccinations: 1. **Insured:** These children are considered insured and are not eligible for vaccines through the VFC program. *2.* **Insured Hardship:** These children have a health insurance deductible that 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 family cannot afford to pay for vaccine)*

Insured exceptions include

American Indian/Alaska Native with health insurance that covers immunizations	AI/AN children are always VFC-eligible. For AI/AN children that have full immunization benefits through a primary private insurer, the decision to participate in the VFC Program should be made based on what is most cost-beneficial to the child and family.
Insured, with Medicaid as secondary insurance	A child may have private health insurance and Medicaid as secondary insurance. The child is VFC-eligible as long as they are enrolled in Medicaid. However, the parent is not required to participate in the VFC Program. There are two options: 1. Administer VFC vaccine and bill Medicaid for the administration fee 2. Administer private stock vaccine and bill primary insurance for both the cost of vaccine and the administration fee.

3.2 Documentation of Eligibility Screening

VFC eligibility screening and documentation of eligibility status must take place with each immunization visit, up to 24 hours in advance. Documentation of the eligibility status of all children under 19 years who are immunized in the practice must be retained and accessible in the health care provider's office for a minimum of three years from the date of service or longer if required by state law. This documentation must be recorded in the providers EHR (via HL7) or SIMON (DDE) within 10 days of administration.

If the EHR or SIMON are offline then the eligibility may be recorded on the Patient Eligibility Screening Record (DPH 1146) and then entered into the EHR or SIMON once the system is back online within 10 days of administration. This record may be completed by the parent, guardian, individual of record, or by the health care provider. Eligibility status documentation (paper or electronic) must include each of the following:

5. Child's first and last name and middle initial
6. Child's date of birth
7. Parent/Guardian/Individual of Record's first and last name and middle initial.
8. Primary provider's name
9. Date of each immunization visit
10. One of the following eligibility statuses:
    - Medicaid eligible/enrolled
    - Uninsured
    - American Indian/Alaska Native
    - Underinsured (served at FQHC, RHC, or LHD)
    - Insured (Private stock vaccine)

VFC Providers must document data entry in all appropriate fields specifically related to patient eligibility, dose eligibility, and funding source to ensure that the appropriate vaccines have been selected.

3.3 Manual Entry for Direct Data Entry (DDE) VFC Providers:

Accurate VFC Eligibility documentation in SIMON is directly tied to a process called manual vaccine inventory decrementing (DDE). This process associates an administered dose directly to a vaccine lot number in a provider's inventory. When adding VFC- eligible administered vaccinations in SIMON manually, VFC Providers must associate a VFC lot number from their inventory for VFC eligibility to be recorded correctly in SIMON. At the time of entering the administered vaccination into SIMON. This will also automatically adjust inventory numbers for a more accurate, real-time reflection of VFC inventory. It is **highly encouraged** that manual entry VFC Providers begin to decrement each administered vaccine in SIMON.

3.4 Fee Policies for Vaccines:

A provider receiving federal vaccine must comply with the following fee policies:

1. VFC vaccine is provided to eligible children at no cost to the patient or health plan (i.e., payer) for the vaccine itself.
2. A provider may charge a non-Medicaid VFC-eligible child a vaccine administration fee of up to **$20.16** per vaccine dose. Payment for vaccine administration to Medicaid VFC-eligible children is set by the contracted health plans.
3. A provider must not deny access to federally purchased vaccine to an established patient whose parent/guardian/individual of record is unable to pay the administration fee.
4. Effective January 1, 2020, providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service **may issue only a single bill to the patient within 90 days of vaccine administration**. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program.
5. Providers may charge an office visit fee, in addition to the administration fee.

3.5 Vaccine Administration Documentation

In accordance with 42 U.S.C. § 300aa–25, all VFC providers must maintain immunization records that include **ALL** of the following elements:

6. Name of vaccine administered
7. Date vaccine was administered
8. Date VIS was given
9. Publication date of VIS
10. Name of vaccine manufacturer
11. Lot number
12. Name and title of person who administer the vaccine
13. Address of clinic where vaccine was administered

VFC providers are **required** to record in SIMON, every vaccine administered to all patients < 19 years of age, regardless of VFC status, within two weeks of administration date.

3.6 Vaccine Information Statement (VIS), Vaccine Adverse Events

The National Vaccine Childhood Injury Act (NCVIA) requires all immunization providers to give the appropriate VIS to the patient (or parent or legal representative). The appropriate VIS must be given **prior** to vaccination and prior to **each dose** of a multi-dose series. It must be given **regardless of the age** of the recipient.

Ways to give a Current Vaccine Information Statements (VIS)/An Immunization Information Statement (IIS)/Emergency Use Authorization (EUA):

In the past, healthcare providers and public health entities interpreted federal law as a requirement that a paper copy of each VIS is handed to the recipient prior to vaccination, and that the recipient must take this copy away with him or her following the vaccination.
The evolution of electronic media has resulted in broadening this interpretation. For example, now:

3.6.1 Current Vaccine Information Statements (VIS)/An Immunization Information Statement (IIS)/Emergency Use Authorization (EUA) must be presented to parents at every vaccination prior to the vaccine being administered.

3.6.2 A practice may produce permanent, laminated, office copies of these statements, which may be read by recipients prior to vaccination.

3.6.3 These statements may be reviewed on a computer monitor (or any video display).

3.6.4 These statements may be downloaded by the recipient to a smartphone or other electronic device to read at his or her convenience. (VISs have been specially formatted for this purpose.)

3.6.5 These statements may be made available to be read before the immunization visit (e.g., by giving the patient or parent a copy to take home during a prior visit or telling them how to download or view a copy from the Internet). These patients must still be offered a copy in one of the formats described previously to read during the immunization visit, as a reminder.

3.6.6 Providers must still offer a copy (which can be an electronic copy) of each appropriate statements to take away following the vaccination. However, the recipient may decline. It is recommended that you sign up for email updates to receive notification when the above statements has been updated. To sign up, go to: https://www.cdc.gov/vaccines/hcp/vis/index.html

Providers must maintain records in accordance with the NCVIA, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) by mail or online at http://www.vaers.hhs.gov. Deaths or severe reactions possibly associated with immunization should also be reported to SCIOS by phone.

4. Vaccine Order and Accountability

4.1. Vaccine Ordering Overview

All VFC and SC State vaccine requests must be placed online via SIMON for all vaccine management activities. Training materials consisting of short videos and/or PDF instructions about the VFC/SC vaccine programs vaccine management are available on the SIMON homepage under the SIMON Training Resources tab. Training Guides are available on the homepage for vaccine related processes. Questions regarding this process may be sent by a provider directly to the SIMON Helpdesk request.

4.2. Vaccine Ordering via SIMON

Vaccine orders with the order intention "**Pediatric**" is automatically set for the VFC program. If a provider needs to place an order for the SC State Vaccine Program the site must submit a vaccine order separate from the VFC order and inform SCIOS in the "**Clinic Comments**" section that the order is for the SC State Vaccine program.

Request Vaccines in Packages

Vaccine orders requested are based on the number of packages needed.

Ex. Requesting vaccine packages in SIMON, see chart below:

Vaccine	# Doses in Package	# of Doses Needed	# of Packages to enter into SIMON
Pediarix®	10	10	1
Pediarix®	10	40	4
Pneumovax®23	1	4	4
Pneumovax®23	1	10	10

➢ *The following vaccines: PPSV23, and TD can be ordered in a single pack (1) dose.*

A SIMON Helpdesk request ticket must be submitted to SCIOS if the office is requesting more than one dose of the following vaccine: *PPSV23, and TD before the vaccine order is submitted in SIMON.*

Merck Frozen Vaccine Order Request

Varivax® and ProQuad® total dollar amount cannot exceed $25,000 on one vaccine order per site. If a site needs additional Varivax® and ProQuad doses that exceeds $25,000, a separate vaccine order must be placed. SIMON will block all Varivax® and ProQuad® orders that exceed $25,000.

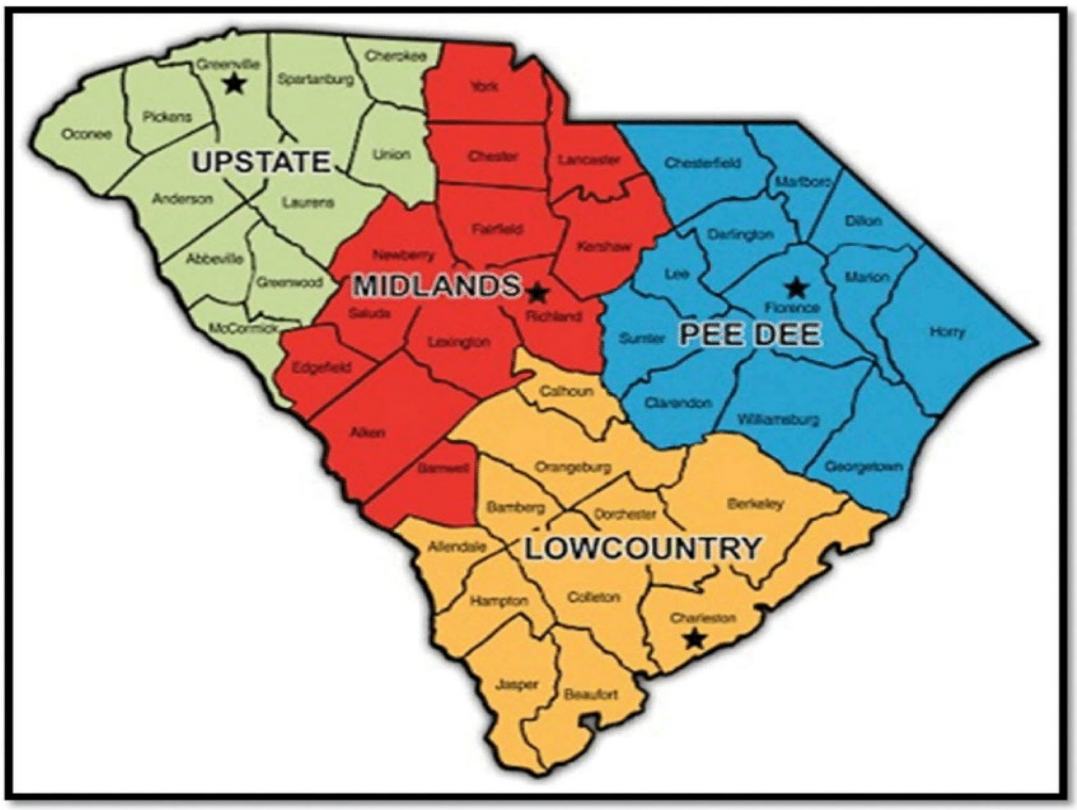
Vaccine Order Processing

VFC Providers are to allow 14 business days for vaccines to arrive onsite after the vaccine order is submitted and **APPROVED** in SIMON by SCIOS. Please note that SCIOS will modify the provider(s) vaccine order as needed to manage vaccine supply.

Vaccine Order Schedule

VFC Providers will order vaccines based on the DPH Region that the providers office is located. If a provider needs to place a vaccine order outside of the order schedule, submit a SIMON Helpdesk ticket. See the following vaccine order schedule:

- 1st through the 15th of the month: Low Country and Upstate VFC providers may submit vaccine orders submissions in SIMON
  - ❖ DPH Health Departments are included in the 1st through 15th ordering schedule
- 16th through the 30th/31st of the month: Pee Dee and Midlands VFC providers may submit vaccine orders in SIMON



SC State Vaccine Program Order Schedule

SC State Vaccine Program vaccine orders will be accepted quarterly (every 3 months). Please see the chart below to review the submission schedule for the SC State Vaccine Orders.

* SC STATE Ordering Submissions

Quarterly Submission of SC STATE Vaccine Accepted on Designated Month
January
April
July
October

**The program will make modifications to this schedule on a case-by-case basis.*

Seasonal Influenza Pre-Booking and Ordering

Currently influenza vaccine ordering and prebooking are not managed in SIMON. Providers must complete the automated Influenza Pre-booking Order (DPH 1095) Form that is sent to providers in late spring/early summer to prebook doses for the upcoming influenza season.

Traditionally, the initial prebook is allocated to providers in late September/early October. To receive supplemental doses of influenza vaccines providers will submit vaccine orders into SIMON after all initial pre-booked doses have been allocated to providers. Traditionally, the supplemental Influenza is allocated in late October/early November. Supplemental doses are sent to providers on-demand until the seasonal influenza supply is depleted.

Request for Seasonal Influenza Flu Automated Form Access

SCIOS will notify providers announcing the ability to prebook the initial seasonal influenza doses. Upon receiving the notification providers will receive an the automated DPH 1095 form link in the notification. All requests will be submitted via the automated DPH 1095 form link.

4.3 Vaccine Inventory

REQUIREMENT: Providers serving both VFC and non-VFC eligible children must store public stock separately from private vaccine stock types. All vaccine stock types VFC/ STATE (public) and privately purchased] must be labeled and separated within the vaccine storage unit for easy identification by provider staff member, as well SCIOS field representatives.

VFC providers must offer all ACIP-recommended vaccines for the population they serve and are responsible for proper maintenance of vaccine inventory. Providers must reconcile their VFC vaccine inventory every 30 days in SIMON. Reconciliation is required by CDC and is an accounting of vaccine doses administered, wasted, expired, lost /unaccounted for, and vaccine doses currently in inventory. SCIOS recommends providers maintain a **four to six-week supply** of vaccine to allow for any potential shipping delays.

1. Providers are required to have separate vaccine inventories: one for publicly purchased vaccines and one for privately purchased vaccines. Vaccine inventories do **not** have to be stored in separate units.

2. Providers are required to reconcile their vaccine inventory monthly, **even if a vaccine order is not placed.**

3. Any Provider who repeatedly fails to reconcile their vaccine inventory in a timely and accurate manner will be required to complete mandatory SIMON training, and further noncompliance may result in suspension from the VFC and VFC/State Program.

4. Vaccine orders cannot be processed unless reconciliation reports are up to date in SIMON.

5. Providers should review the SIMON Manual Vaccine Inventory Reconciliation Checklist or the SIMON Aggregate Vaccine Inventory Reconciliation Checklist for details.

6. SIMON is only for ordering and inventory reporting of federal and state funded vaccines. Private stock should be entered into SIMON for borrowing and reconciliation purposes.

Vaccine Brand Switch Request:

VACCINE BRAND SWITCH

If a provider wishes to switch from one brand of vaccine to another they must:

- *Submission the request in writing.*
  - *A signed statement by the Signatory on the letterhead of the facility indicating which brand of vaccine the site would like to begin ordering prior to submitting the order in SIMON;*
  - *The letter can be submitted via a SIMON Helpdesk request as an attachment.*

Failure to submit the request with 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 a new brand will be a violation of the VFC program.

4.4 Receiving VFC Vaccine

Providers must have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity. All staff must be trained to recognize a vaccine shipment and the procedures to follow once received. The following steps should occur upon receipt of a vaccine shipment:

1. Open vaccine packages immediately.
2. Inspect the vaccine and packaging for damage.
3. Compare the vaccine received with the products on the packing list.
4. Check the temperature monitor readings in the shipping package.
5. For frozen vaccine only, verify the length of time that the vaccine was in transit. Check the shipping insert supplied in the box; this insert defines the acceptable transit time based on the shipment date on the packing list.
6. If the vaccine shipment is compromised, the order is incorrect (not the vaccine or the quantity ordered), or there is a problem with the temperature monitors, **contact SCIOS immediately** at (800) 277- 4687select Option 2. It is critical that SCIOS contact McKesson the **same day** the vaccine arrived at the provider to hold the supplier accountable for replacing a damaged or improper shipment.
7. Log into SIMON and electronically review and accept the vaccine order into inventory by clicking on Inventory module and select "On-Hand."
8. SCIOS checks pending orders in SIMON monthly for any orders that were not correctly received into provider inventory. Any provider who has failed to accept an order into their inventory will be contacted by SCIOS and asked to do so. Repeated failure to accept orders into inventory will result in mandatory SIMON training and risk of suspension from the VFC Program.

IMPORTANT NOTE:

Frozen vaccine is always shipped by the manufacturer directly to the VFC provider site. The shipping invoice will state the vaccine has been paid for by CDC in Atlanta, Ga for VFC vaccine or by DPH in Columbia, SC for State Vaccine Program vaccine. In certain situations, it may take up to 15 business days for Merck frozen vaccines to reach the provider office once the order has been placed. DT vaccine will always be listed as "STATE" on the provider's packing list. Please refer to your order in SIMON to determine from which program the vaccine has been ordered.

4.5 VFC Vaccine Returns

All VFC vaccine that has expired or has been spoiled or wasted must be reported in SIMON so that it may be returned to the supplier. The return process must be completed in SIMON so that it may be returned to the CDC distribution supplier McKesson for the Federal Excise Tax Credit (FETC). The return process must be completed in SIMON to generate a shipping label to send back to the supplier. Expired vaccine must be returned within 60 days. To review the steps for this process, reference the **Create and Submit Vaccine Returns** which is a Quick Reference Guide available on the SIMON under Training Resources. Expired Influenza vaccine returns will be entered in SIMON. Please refer to specific instructions provided by the Vaccine Manager for return of expired influenza vaccine each year.

4.6 Vaccine Wastage

In the event that a site must waste a VFC/State vaccine on site due to certain circumstances such as: drawn-up but not administered, dropped/broken vials, lost and unaccounted for in inventory (missing does), and spoilage (ex. IPOL), etc. where the vaccine cannot be returned to McKesson, the site must document the wastage within SIMON. The site will need to make, and adjustment form the On-Hand Inventory in SIMON. The site must select a "VTrckS" reason option for the vaccine to be included in the wastage report sent to CDC. A return label will **NOT** be generated for a vaccine that is wasted on site, but documentation must be entered in SIMON for any VFC/STATE vaccine that is wasted on site.

Important Note: A provider' private stock vaccine cannot be returned within SIMON; the site must follow the practice's return policy for private inventory.

4.7 Vaccine Borrowing

VFC-enrolled providers are expected to maintain a **minimum** of four weeks inventory of vaccine to administer to privately insured and VFC-eligible children. Borrowing of vaccine between VFC and private vaccine inventories **is not permitted**, unless specifically authorized in advance by SCIOS and due to extraordinary circumstances. **Prior approval for borrowing is needed,** complete the appropriate automated online Vaccine Borrowing Request Form for the quickest response. RIR and/or SCIOS will review the request and reply with a decision in real time.

- VFC Influenza Borrowing Form
- VFC RSVP/COVID-19 Borrowing Form
- VFC Routine Borrowing Form

If approved, borrowing must be documented "dose-for-dose" for each patient in SIMON for reconciliation purposes. The provider must use the appropriate VFC paper borrowing of the form to assist the documenting the event and use the Borrowing Vaccine Guidance. This paper form must be kept for the providers record keeping. Doses borrowed from VFC inventory must be replaced within **30 days** and appear in SIMON under appropriate vaccine on-hand inventory.

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.

Borrowing and Private Inventory

If a VFC/State provider has private inventory; the private inventory **should** be entered into SIMON. If a situation arises where the provider needs to borrow between vaccine stocks; a prior approval must be granted by SCIOS/RIR. The provider must complete the following steps to make a request to borrow vaccine:

1. Complete the appropriate **online** Vaccine Borrowing Request form. Once the information is received, SCIOS/RIR will reach out to the provider with decision.
2. Ensure that all private vaccines are entered into SIMON for review by SCIOS/RIR. If approval is granted, the provider will need to document the borrowing in SIMON dose for dose on the paper version of the VFC Vaccine Borrowing Report (DHPH 1167) to maintain it for their records for review for their upcoming site visit.

How to Comply with Borrowing of Private Inventory

If it has been determined that there are discrepancies with the VFC/STATE vaccine stock inventory and the site did not enter in the private inventory that is located at the site, the provider must complete following steps:

- Immediately enter in the private vaccine inventory into SIMON
- Document all borrowing transactions in SIMON

Vaccine Invoices:

SCIOS will 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 correlate with the information that is entered into SIMON showing that the replacement of the vaccine in the inventory. Failure to replace any borrowing publicly funded vaccines is fraud and abuse to the VFC program

Noncompliance of Borrowing of Private Inventory

If discrepancies with the vaccine inventory cannot be resolved the site will be required to replace the vaccine dose for dose with private stock. Continued violations related to vaccine inventory management will result in the provider being Disenrolled from the VFC/ State program.

Seasonal Influenza Vaccine Borrowing

For seasonal influenza vaccine, providers may use PRIVATE-STOCK seasonal influenza vaccine to vaccinate VFC/State eligible children, if VFC/State seasonal influenza stock is not yet available. Those PRIVATE STOCK doses used on VFC/State eligible children can later be replaced when VFC/State stock becomes available. This ONE Directional (private to VFC/State) borrowing exception is unique to seasonal influenza vaccine only. See the Seasonal Influenza Vaccine Borrowing Report (DPH 3226) for details.

Guidelines for Borrowing Seasonal Influenza

- VFC providers who borrow seasonal influenza vaccine must accept the VFC presentation allocated for replacement of private influenza vaccine stock.
- VFC providers will need to complete the following steps in SIMON:
  1. Upon receiving the VFC/State Influenza vaccine shipment, the doses must be manually entered in SIMON and added to the On-Hand Inventory.
  2. The provider will review the DPH 3226 to account for the number of VFC/State doses that need to be changed to Private doses and make the adjustment in the inventory.

Doses must correlate with the number of doses borrowed on the DPH 3226.

4.8 Vaccine Transfers and Vaccine Transport

Routine Vaccine Transfers

Routine transfer of vaccines is NOT recommended by CDC. All routine vaccine transfers must be approved by SCIOS prior to the transfer. The provider will submit a SIMON Helpdesk request to receive permission. A RIR will contact the provider site to arrange a time for the routine vaccine transfer to occur. The RIR will assist the provider site(s) in completing the transfer within SIMON as this will be a permanent absorption of vaccine in the receiving provider's inventory.

PROVIDER MOVING LOCATIONS

Important Note: If a provider is moving locations, they MUST contact the SCOIS at least 4 weeks prior to the move to have the vaccine transfer approved. Failure to notify SCOIS and obtain approval will result in suspension of the providers vaccine ordering status and considered an unauthorized transfer. It is also recommended to have transport units inspected prior to the move.

Vaccine Transport during Emergency Situations (Temporary)

Emergency vaccine transport, means that the vaccine is being transported temporarily due to storage unit issues (loss of power, temperature fluctuations), inclement weather (snow and ice), hurricanes, etc. It is recommended that alternative storage locations should be inspected upon establishment (or at least once) prior to an emergency to validate that proper vaccine storage conditions can be maintained.

Should the alternative storage location change, this new location is also recommended to be inspected. The provider will need to refer to the Emergency portion of the SCREVMP, (DPH 1225) for details on how to transport vaccines for this emergency. Because this is a transport which is temporary and not a transfer which is permanent, information will not be required to be documented into SIMON. The provider may use the Vaccine Transport form (DPH 1208) to collect all the necessary information to ensure that they account for the VFC/State vaccine inventory that will be temporarily kept at alternate facility.

4.9 Vaccine Schedules

VFC providers are required to comply with the immunization schedules, dosages, and contraindications recommended by the ACIP, unless:

- In the provider's medical judgment, and in accordance with accepted medical practice, such compliance is medically inappropriate for the child.
- State law, including laws pertaining to religious and other exemptions, applies.

Immunization schedules are available on the CDC website at: https://www.cdc.gov/vaccines/index.html. The CDC Vaccine Schedule App is available on iOS and Android devices.

5. Vaccine Storage and Handling

5.1. Storage and Handling

Vaccine loss is both costly and preventable. Just 10 doses of each routinely recommended child/adolescent vaccine is valued at more than $10,000; most practices have far larger inventories. Vaccines must be stored appropriately in order to maintain efficacy. Failure to store and handle vaccines properly reduces vaccine potency, resulting in inadequate immune response and poor protection against disease. The temperature-controlled environment used to maintain and transport vaccines in optimal condition is called the **vaccine cold chain**. An effective cold chain relies on three main elements:

1. Effectively trained personnel
2. Reliable storage and temperature monitoring equipment
3. Accurate vaccine inventory management A well-trained staff, familiar with key storage and handling principles, is critical to safeguarding the vaccine supply and the safety of vaccinated patients.

5.2. Vaccine Storage Units

Refrigerators and freezers are available in different grades (household and purpose- built), size, and types (stand-alone and combination refrigerator/freezer). Purpose- built units are sometimes referred to as "pharmaceutical grade" and are designed specifically for storage of biologics. It is important that the storage unit has enough space to store the largest inventory at the busiest point in the year (e.g., flu season) without crowding.

The following storage units are acceptable for storing VFC vaccine:

1. A purpose-built unit for vaccine storage designed to either refrigerate or freeze (can be compact, under-the counter-style or large units).

2. A stand-alone household frost-free refrigerator (a self-contained unit that only refrigerates).

3. A stand-alone freezer.

    - A stand-alone automatic defrost freezer.
    - A stand-alone manual defrost freezer may be used; however, a back-up freezer must be available that is approved to store vaccine when the main freezer unit is being defrosted and the provider must:
        - Document a defrost plan in the SCREVMP (DPH1225)
        - Defrost the unit when ice has accumulated to a thickness of approximately 1cm.
        - Review the guidance on defrosting a manual freezer from the manufacturer.

4. Immediate action and Future follow up must be presented if vaccine storage unit does not comply with program requirements.

5. Immediate action must be updated if the freezer section of a combination commercial/ household unit is not maintaining appropriate temperatures. Permanently discontinue use if the affected storage unit is the freezer section of a combination commercial/household unit.

Unacceptable vaccine storage units:

SCIOS consultation is strongly recommended prior to purchasing a new vaccine storage unit to ensure it meets VFC Program requirements. When a provider purchases a new vaccine storage unit, **two** days of digital data logger temperature readings must be entered into SIMON for review and approval **prior to vaccine being placed in the unit(s).**

1. Combination household refrigerator/freezer units
    - Not acceptable for new providers or existing providers (with unit failure of this type),
2. Dormitory or bar-style refrigerators
    - Small combination refrigerator/freezer unit that is outfitted with one external door and has an evaporator plate (cooling coil) which is usually located inside the “freezer” within the refrigerator. Such refrigerators place vaccine at a high risk of freezing.

Storage Unit Placement

Air circulation around the outside of the storage unit is important for vaccine temperature stability. Place a storage unit in a well-ventilated room, leaving space between the unit, ceiling, and walls. Nothing should block the cover of the motor compartment. The unit should be stable and level, with the bottom of the unit raised above the floor. The unit door should open and close smoothly and fit squarely against the body of the unit. If not secured properly, unit doors pose a risk to maintaining appropriate internal temperatures of vaccine storage units. Studies find that most units work best when placed in an area with standard indoor room temperatures, usually between 20° C and 25° C (68° F and 77° F). Check the manufacturer-supplied owner's manual for additional guidance on placement and spacing.

It is important to protect the unit's power source with clear warning labels on both the plug and circuit breaker for each storage unit. Avoid using the same power outlet for both storage units. Avoid using power outlets that may be tripped or switched off including:

1. Built-in circuit switches (may have reset buttons)
2. Outlets that may be controlled by a wall switch
3. Multi-outlet power strips
4. Electrical cords

5.3. Temperature Monitoring Devices

VFC providers are required to use a digital data logger (DDL) with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing VFC vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, and mass vaccination clinics.

To meet VFC Program requirements*, the DDL must be equipped with:

1. A detachable, buffered probe (or digitally buffered device that mimics a buffered probe).
2. Alarm (audible or visual) for out-of-range temperatures – alarm parameters should be set as follows:
    - Refrigerator low alarm (too cold) set to trigger after 30 consecutive minutes or longer below 2.0°C
    - Refrigerator high alarm (too warm) set to trigger after 30 consecutive minutes above 8.0°C
    - Freezer high alarm (too warm) set to trigger after 30 consecutive minutes above -15°C
3. Display indicating current, minimum, and maximum temperatures.
4. An active display outside the unit so that temperatures may be monitored without opening the unit door.

5. Low battery indicator.
6. Ability to accurately report temperatures to +/-0.5°C.
7. Memory storage of at least 4,000 readings.
8. User programmable logging interval (or reading rate) – **It is required by SCIOS that this interval be set for 15 minutes.**
9. Ability to easily download data for review.
10. Ability to report temperatures in Celsius to fully account for the acceptable vaccine storage temperature range.

* Providers may have purpose-built or pharmaceutical-grade equipment (e.g., doorless or dispensing units) with temperature monitoring capabilities that may be as reliable as a DDL in monitoring vaccine temperature. Contact SCOIS to determine if such a unit is capable of meeting VFC temperature monitoring device requirements.

In addition, VFC providers **must have at least one back-up DDL** with a valid and current Certificate of Calibration **on-site** to ensure that temperature assessment and recordings may be performed each day. A back-up DDL must be readily available in case a DDL in use is no longer working or calibration testing of the current DDL is required. CDC recommends that the back-up DDL be stored outside of the storage unit until needed to avoid vaccine space issues and differing temperature readings leading to potential confusion. The back-up DDL should have a different calibration retesting date than the primary so one may be used while the other is being replaced or sent out for re-calibration. Reference **Appendix B** for a guide for selecting a DDL.

5.4. Certificate of Calibration Testing

Valid and current Certificates of Calibration Testing (or Reports of Calibration Testing) must be maintained on all DDLs used in vaccine storage units. Calibration testing and traceability must be performed by:

1. A laboratory accredited by an ILAC MRA signatory body (recommended by CDC). Certificate must include the following elements:
    - ILAC/MRA signatory body-accredited laboratory
        a. Laboratory accreditation should be clearly identifiable (to search ILAC-accredited laboratories, see box below)
        b. An ILAC MRA-accredited laboratory is the easiest way to identify that the instrument has been tested correctly according to international standards

c. The certificate may have an Accrediting Body Symbol, which is the logo, and a unique laboratory code or certificate number included on the certificate

- Name of Device (optional)
- Model/Device Number
- Serial Number
- Date of Calibration Testing (report or issue date)
- Confirmation the instrument passed testing (or instrument in tolerance)

2. An entity that provides documentation demonstrating the calibration testing performed meets ISO/ IEC 17025 international standards for calibration testing and traceability. Certificate must include the following elements:
   - Name of Device (optional)
   - Model/Device Number
   - Serial Number
   - Date of Calibration Testing (report or issue date)
   - Confirmation the instrument passed testing (or instrument in tolerance)
   - Statement that calibration testing conforms to ISO 17025

Contact SCIOS or the local RIR for help if uncertain if a certificate meets the above requirements.

5.5. Temperature Probe Placement

The DDL probe should be placed in the central/middle area of the storage unit **with** the vaccines. Do not place the temperature probe in the doors, near or against the walls, close to vents, or on the floor of the vaccine storage unit. Temperatures in these locations may differ significantly from the temperature in the zone where vaccine is stored. It is recommended that the probe be anchored in the center of the unit to prevent it from being moved.

5.6. Temperature Monitoring

Temperature monitoring is the primary responsibility of the Primary and/or Back-up Vaccine Coordinators. **It is required that min/max temperatures are reviewed and recorded at the start of each clinic day for each** vaccine storage unit. Staff must also review current temperatures prior to administering vaccines.

These temperature readings must be documented daily, as should any actions that are taken if the temperatures readings are out of acceptable range. Download and save weekly temperature data report each MONDAY from digital data logger and upload the same file in SIMON. The provider must save all temperature monitoring records and reports (paper or electronic) for 3 years.

The Primary and or Backup Vaccine Coordinator must record the MIN/MAX temperature on the appropriate temperature log (DPH 3265 or DPH 3266) for each vaccine storage unit daily. Weekly DDL(s) temperature reports must be uploaded into SIMON. If the site does not have a compatible DDL file for SIMON, the site must enter the temperatures manually into SIMON and the weekly temperature file must be sent to SCIOS via SIMON Helpdesk.

Weekly DDL reports must be save electronically and reviewed by the Primary or Back-up Vaccine Coordinators and maintained with temperature logs for three years.

Refrigerators should always maintain temperatures between 2°C and 8°C. The average daily temperature target for a refrigerator is 5°C. Freezers should maintain temperatures between negative (-) 50°C and negative (-) 15°C, with a suggested target of negative (-) 20°C or colder. Most freezers may safely be set on the coldest setting as freezers do not reach -50°C unless specifically designed to do so.

Stand-alone refrigerator

Stand-alone freezer

5.7 What is a Temperature Excursion (TE)?

A TE occurs any time the temperature in a refrigerator is outside the 2°C – 8 °C range or the temperature in a freezer is above -15°C **and** one of the below criteria are met:

1. Refrigerator temperature is below 2°C for ≥ 15 consecutive minutes.
    - Temperatures below 0°C quickly damages vaccine. Quick action may save vaccine.
2. Refrigerator above 8°C for ≥ 15 consecutive minutes.
3. Freezer above -15°C for ≥ 15 consecutive minutes.
    - Frost-free freezer defrost cycles may go above -15°C for short periods. Vaccine stability data supports these types of excursions.
4. TE is part of a pattern of frequent excursions, regardless of duration.
5. There is concern about a TE even though it doesn't meet above criteria.

Power Outage:

If experiencing a power outage, contact the utility company. If restoration is expected within **four** hours, **do not move vaccine**. Keep the door closed and monitor temperature. This brief TE may be less harmful than transporting vaccine. If a power outage is expected to last more than four hours, follow the emergency procedures detailed in your SCREVMP (DPH1225). Notify SCIOS for any planned or unplanned power outages as soon as possible via SIMON Helpdesk

> *Review the Reporting A Temperature Excursion on the SIMON website for more details on reporting a temperature excursion.*

5.8 Reporting a Temperature Excursion (TE)

When a TE is identified, SCIOS must be notified as quickly as possible during business hours or the next business morning (Monday – Friday 8:00am – 4:30pm EST) and before any vaccine is administered.

Temperature is currently out-of-range	1. Attempt to return vaccine to proper storage conditions: • Check to see if the storage unit is unplugged • Check to see if the storage unit door is open and is sealed adequately • Check the thermostat setting • Check location of the DDL probe; should be in the middle of the unit with the vaccine and properly attached to the DDL • Check coils and vents for excess dust 2. Quarantine vaccine: label "Do Not Use until Notified by SCIOS" • Do not administer vaccine until approved by SCIOS! 3. Immediately submit a SIMON Helpdesk request to SCIOS (if during business hours) 4. If instructed by SCIOS, or if after hours, follow the emergency procedures detailed in the sites SCREVMP, posted on or beside the storage unit. If the storage unit is not back in-range, transport vaccine to the designated back-up location. For packing instructions, see Appendix C. 5. Download temperature log from digital data logger and save file to computer. Upload the DDL file or manually enter temperatures (non-compatible DDL only) into SIMON. * 6. Note how long the temperature was out of range 7. Note the minimum/ maximum temperatures 8. Submit a SIMON Helpdesk request to Report a TE **(include the VFC PIN and name of Coordinators)**
Temperature is back in-range	1. Troubleshoot – can you identify why it went out of range? 2. Quarantine vaccine: label "Do Not Use until Notified by SCIOS" 3. Do not use any vaccine until approved by SCIOS! 4. Immediately submit a SIMON Helpdesk request to SCIOS, if during business hours 5. Download temperature log from digital data logger and save file to computer. Upload the DDL file or manually enter temperatures (non-compatible DDL only) into SIMON. * 6. Note how long the temperature was out of range 7. Note the maximum and minimum temperatures **8.** Submit a SIMON Helpdesk request to Report a TE **(include the VFC PIN and name of Coordinators)**

* ***If temperatures are submitted manually into SIMON, the DDL report will need to be submitted to SCIOS via the SIMON Helpdesk request***

Responding to a TE After Business Hours

1. If unit is out-of-range and it cannot be returned to proper temperature, transport the vaccine to the designated back-up location listed in your SCREVMP (DPH 1225).
   - For packing instructions, see Appendix C. A DDL must always be with the vaccine during transport and at the back-up location and checked every hour that vaccine remains in the transport cooler.
2. If the unit is back in-range:
   - Quarantine vaccine: label "Do Not Use until Notified by SCIOS"
3. Contact SCIOS the next business morning to report TE.
   - If vaccines need to be used *before* the next business day do one of the following (still required to call SCIOS the next business morning):
     a. Contact vaccine manufacturer's customer service lines directly to report the problem to obtain guidance.
     b. Contact SCIOS on the next business day to report the temperature excursion via a SIMON Helpdesk request **(include the VFC PIN and name of contact)**.

5.9 Unreported Temperature Excursions:

If the TE is not reported within the next business day, the provider will be placed on a temporary (minimum of three months) probation that includes the following actions:

1. Provider will need to submit weekly temperature logs to their RIR for four weeks and then monthly for the next two months.
2. RIR will conduct a scheduled Storage and Handling Site Visit for the Certifying Provider and Primary and Back-up Vaccine Coordinators.
3. Provider may be required to service or purchase a new unit within six weeks. If so, vaccine orders will be placed on hold. The invoice and **two** days of temperatures will need to be sent to SCIOS before approval is given to store VFC vaccine in unit.
4. If there was vaccine loss, the provider will receive an Unannounced Storage and Handling Visit during the next six-month period.
5. At the successful conclusion of the temporary probation, the provider will resume routine monitoring.
   - If unable to maintain compliance with VFC vaccine storage and handling requirements during this period, the provider will be suspended from the VFC Program for up to a year. The RIR will pick up VFC vaccine and the site will be disenrolled from the VFC program.

6. Vaccine Management

6.1. Vaccine Coordinator(s)

The Primary Vaccine Coordinator at each site is responsible for ensuring all vaccines are stored and handled correctly. Each site is also required to designate a second staff member to serve as back-up in the absence of the Primary Vaccine Coordinator. The Certifying Provider (Signatory) listed on the Provider Agreement should not be designated as the Primary or Back-up Vaccine Coordinators because the provider normally does not carry out Vaccine Coordinator responsibilities. An exception to this may be in circumstances where a more appropriate alternative cannot be identified within the practice and where the Certifying Provider (Signatory) is prepared to comply with all Vaccine Coordinator responsibilities. A Vaccine Coordinator may not be assigned to more than one site; **the assigned Primary and Back-up Vaccine Coordinators must be predominantly on site at their designated location**. An additional vaccine coordinators (nursing directors, practice managers, etc.) can be assigned to more than one site within SIMON and granted limited access to preform vaccine management duties only. All Vaccine Coordinators must be fully trained in routine and emergency policies and procedures.

Vaccine Coordinators responsibilities include:

1. Ordering vaccines.
2. Overseeing proper receipt and storage of vaccine deliveries.
3. Documenting vaccine inventory information.
4. Organizing vaccines within storage units.
5. Setting up temperature monitoring devices.
6. Reading and recording storage unit temperatures a minimum of two times (morning and afternoon) each workday.
7. Electronically saving a weekly digital data logger report for each vaccine storage unit and uploading file to SIMON. If manually entering temperatures into SIMON, provider must submit DDL reports for each unit via SIMON Helpdesk request **(include the VFC PIN and name of Coordinators)**.
8. Saving and analyzing the DDL report each week to detect any concerning temperature trends and/or unreported temperature excursions, and keeping report on file for three years.
9. Rotating stock at least weekly so vaccines with the earliest expiration dates are used first
10. Removing expired vaccine from storage units.
11. Responding to out-of-range temperatures (temperature excursion, "TE").
12. Maintaining all documentation, such as inventory and temperature logs.
13. Ensuring staff is properly trained.

14. Monitoring operation of storage equipment and systems.
15. Overseeing proper vaccine transport (if necessary).
16. Overseeing emergency preparations.
17. Primary Vaccine Coordinators is responsible for providing training to the Back-up Vaccine Coordinators.

6.2. Vaccine Storage and Handling Plan

VFC providers are required to develop, maintain, and implement a vaccine storage and handling plan also known as the South Carolina Routine and Emergency Vaccine Management Plan (DPH 1225). The plan must be updated annually and include a review date and the signature of the individual responsible for the content. The minimum required components of the plan include the following:

1. Name of the current Primary Vaccine Coordinators and at least one Back-up Vaccine Coordinators.
2. General operations for proper vaccine storage and handling practices: Temperature monitoring.
    - Vaccine storage (e.g., equipment, placement)
    - Vaccine shipment receiving procedures
3. Vaccine ordering procedures.
4. Inventory control (e.g., stock rotation).
5. Vaccine expiration, spoilage, and wastage prevention (e.g., protocol for responding to and reporting vaccine loss).
6. Documentation of staff training on all plan elements.
7. Recorded review date within the last 12 months.
8. Signature of the individual responsible for the content.

6.3. Vaccine Storage

Placement and organization within the storage unit is vital to maintaining vaccine stability. The following are best practices for day-to-day vaccine management:

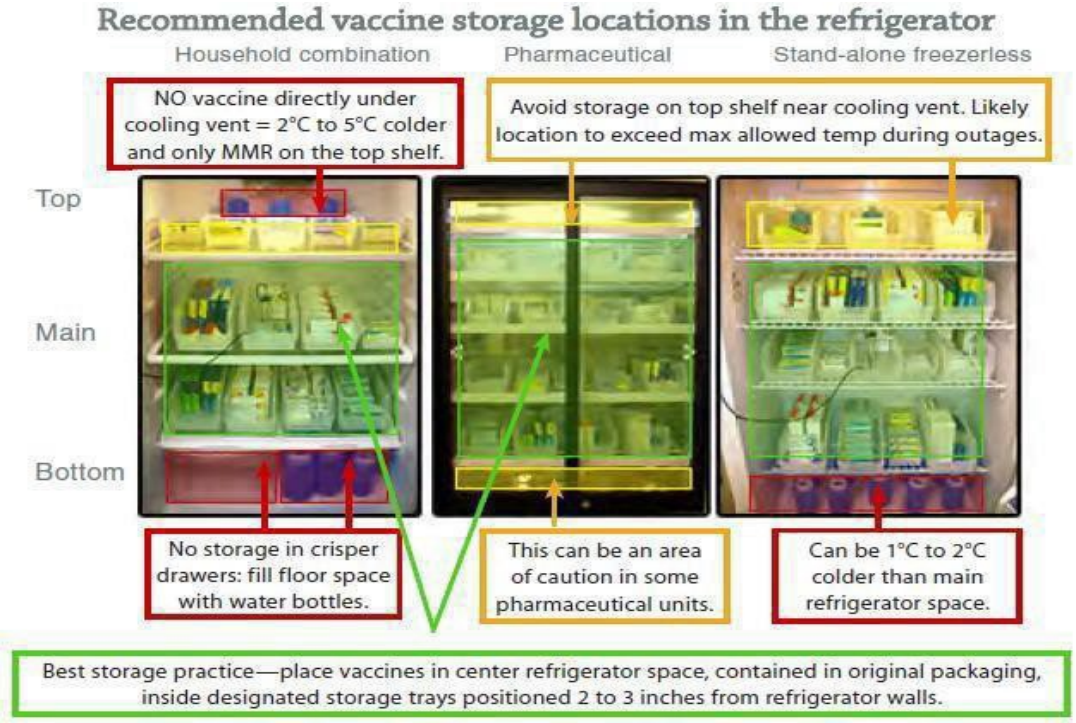
1. Store vaccines in their original packaging (including UV protective bags used by CDC's centralized distributor for repackaged vaccines only).
2. Store vaccines in the middle of the unit, with space between both the vaccines and the side/back of the unit.
3. Do not store vaccines in the doors, vegetable bins, or on the floor of the unit, or under or near cooling vents.
4. Do not store food or drink in vaccine storageunits.
5. Place water bottles throughout refrigerator and freezer storage units and frozen coolant

packs in order to:

- Stabilize or extend temperatures during a power outage.
- Dampen the effects of frequent opening/closing of door.
- Serve as physical barriers preventing the placement of vaccines in areas of the unit that are at higher risk for TEs.

6. Rotate vaccine every week or when a new shipment comes in (whichever happens more frequently) so that newer vaccines are stored toward the back of the unit, while those soonest-to-expire are stored in the front. Immediately remove any expired vaccine from storage units. Bag and label all expired vaccine as "DO NOT USE."
7. Open only one vial or box of a particular vaccine at a time to control vaccine use and allow easier inventory control. For multi-dose vials, indicate on the label the date and time that the vial reconstituted or first opened.
8. Store vaccine products with similar packaging in different locations in the storage unit to avoid confusion and medication errors.
9. Limit access to the vaccine supply to authorized personnel only.
10. Install locks on refrigerators and, if possible, the electrical plugs. Label the plugs "Do Not Disconnect."
11. Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
12. In larger clinics, we recommend a source of back-up power (generator) and a security system to alert personnel in the event of a power outage.
13. If applicable, test back-up generators quarterly and service back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).
14. Vaccines should be prepared immediately prior to administration. CDC and SCIOS strongly recommend against pre-drawing doses before they are needed.

    - Manufacturer pre-filled syringes are a good option in mass vaccination clinics. Although <u>not</u> recommended, in the event of a mass vaccination clinic, a provider may pre-draw up to 10 doses of vaccine from a multi- dose vial and administer them. All doses should be administered by the person who drew them up.



6.4 Emergency Vaccine Storage and Handling Plan

VFC providers are required to have an emergency vaccine storage and handling plan. It is recommended to have alternative storage locations inspected (prior to an emergency) to validate that proper vaccine storage conditions can be maintained. The plan must include guidance on what to do in the event of:

1. Refrigerator or freezer malfunctions
2. Power failure to vaccine storage units
3. Natural disasters or other emergencies that might compromise vaccine storage conditions

The plan must include policies and protocols for maintaining the vaccine cold chain during transport to, and storage in, emergency storage locations. Plans should include the use of a commercial vaccine transport box qualified to maintain a temperature of 5^0C, for refrigerated vaccines, for a specified number of hours or the use of the CDC emergency transport vaccine qualified pack-out A DDL must remain with the vaccine at all times, including during transport. The vaccine storage units and DDLs used at the emergency location site must be in compliance with VFC requirements. Coordinators at alternate or back-up storage locations must be contacted annually and agree to accept vaccines during an emergency. A Routine and Emergency Vaccine Management Plan template may be found here: VFC & Vaccine Management Information | South Carolina Department of Public Health (sc.gov)

7. Quality Assurance Visits

Federal and state requirements mandate that SCIOS conduct Quality Assurance (QA) visits/Improvement before site visits (QI) visits, assessments, and education with each VFC provider.

7.1. VFC Enrollment Visits

Enrollment Visits are required for newly enrolling providers or former VFC providers that have had a lapse of 45 days or greater between enrollments. The purpose of this visit is to provide education on VFC Program requirements and verify the facility has the appropriate resources to implement program requirements.

7.2. VFC Compliance Visits

A VFC Compliance Visit consists of an examination of vaccine management and delivery practices to ensure compliance with federal and state VFC requirements. It involves administration of a questionnaire, evaluating compliance with requirements, and providing education. During the visit, there will be a formal review of vaccine management practices, as well as a review of patient records and other documentation to assure appropriate vaccine eligibility screening and administration documentation is occurring. Effective July 2025, VFC coordinators or designees to observe a compliance site visit with each reviewer on an annual basis.

7.3 Unannounced Storage and Handling Visits

The VFC Program requires Unannounced Storage and Handling Visits be conducted to serve as "spot checks" for facility vaccine management practices.

The RIR will meet with the provider and staff after any VFC compliance or unannounced storage, and handling visit is completed to review findings. Education will be provided for any issues identified and a corrective action plan will be completed

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7.4 Annual Education Requirement

The Primary and Back-up Vaccine Coordinators are required to complete an annual educational training session. This requirement may be met by participating in a VFC Compliance or Education Visit with both Coordinators in attendance in the previous 12 months, or by completing the current version of the CDC's online CDC *You Call the Shots* training modules annually: Vaccine Storage and Handling and Vaccines for Children and the new SIMON Application training.

7.5 VFC Contact

"VFC Contact" are communications delivered in person, by phone, or in writing that are directly related to communicating VFC Program requirements. Clarifying vaccine orders, formal educational opportunities to meet the annual training requirement, and follow- up for VFC Compliance or Unannounced Storage and Handling visits are **not** classified as "VFC Contact." A provider may request additional education and training by contacting their RIR.

7.6 Immunization Quality Improvement for Providers (IQIP)

IQIP is CDC's national quality improvement program for VFC providers. The purpose of IQIP is to promote and support the implementation of provider-level immunization quality improvement strategies designed to increase vaccine uptake among children and adolescents, in adherence to the routine schedule recommended by the Advisory Committee on Immunization Practices (ACIP).

RIRs conduct IQIP visits with a select number of VFC providers in their region annually. Providers are prioritized based upon criteria determined by SCIOS. The goals of IQIP visits are to ensure providers are:

7.6.1 Aware of and knowledgeable about their immunization rates,

7.6.2 Motivated to incorporate changes into their current practices,

7.6.3 Ready to try new immunization service strategies, and

7.6.4 Capable of sustaining improvements to their vaccination delivery services

The IQIP process begins with assessments conducted on 24–35-month-old children and 13–17 year-old adolescents, using immunization data from the provider's active patients in SIMON. Children are assessed based on their completeness of the 4:3:1:3:3:1:4 series[1], and adolescents are assessed based on their completeness of meningococcal, Tdap, and HPV (based on their age) vaccines. Coverage rates are shared with the provider and staff during the initial IQIP site visit. The RIR and provider then discuss four core strategies to improve immunization services and raise coverage rates for children and adolescents.

These four core strategies include:

1. Scheduling the next immunization visit before the patient leaves the provider office
2. Leveraging SIMON functionality to support immunization practice
3. Giving a strong vaccine recommendation (include HPV vaccine if provider has adolescent patients)
4. Strengthen Vaccination Communications

During this initial visit, the RIR and provider will develop a strategy implementation plan. The RIR will provide technical assistance to the provider in implementing at least **two** of the core quality improvement (QI) strategies. **Two months** and **six months** after the initial IQIP visit, the RIR will conduct check- ins via telephone to review the provider's progress in implementing their chosen QI strategies. The RIR will provide additional technical assistance, if needed, and update the strategy implementation plan. **Twelve months** after the initial IQIP visit, the RIR will conduct a follow-up with the provider via telephone or in person. During this follow-up, the RIR and provider will review the provider's progress toward strategy implementation and any changes to the provider's coverage rates.

Only immunizations recorded in SIMON are assessed during the IQIP process. For the most accurate coverage rate assessments, practices are strongly encouraged to add missing historical vaccine doses when updating a patient's record. They are also encouraged to remove inactive patients from their facility patient list in SIMON.

[1] 4 DTaP, 3 Polio, 1 MMR, 3 Hib, 3 Hep B, 1 Varicella, 4 PCV

8. Mobile Immunization Clinics

Under conditions outlined below, VFC providers may incorporate a mobile/offsite immunization clinic into their practice. A mobile/offsite immunization clinic allows providers to vaccinate children at non-traditional locations (e.g., schools and health fairs) while maintaining a clinic setting and without a break in the vaccine cold chain.

The mobile/offsite immunization clinic is an extension of the provider's practice and will use the same unique VFC provider identification number (PIN) already assigned to the provider. The mobile/offsite immunization clinic must comply with all VFC Program requirements listed in the Provide Agreement. In addition to adhering to all general VFC Program requirements, the following conditions must be met:

1. The provider must be enrolled in the VFC Program and in good standing.
2. The VFC provider must have protocols in place to ensure that the outreach efforts meet all VFC requirements, including protocols for establishing vaccine needs (provider profile) and overseeing vaccine ordering for each clinic site to ensure that proper amounts of VFC stock are transported on each clinicday.
3. The mobile/offsite immunization clinic must pass the storage and handling site- visit; this is an *initial* and bi-*annual* requirement.
    - Any staff participating in the mobile/offsite immunization clinics must receive VFC training either by the Primary or Back-up Vaccine Coordinator.

    - Any staff participating in the mobile/offsite immunization clinics must complete the same annual VFC required trainings as the Primary and Back-up Vaccine Coordinators.
4. Vaccines must be shipped to the provider's primary clinic site listed in the Provider Agreement. Vaccines are only be transferred to the mobile unit on the day of the clinic.
5. Mobile/Offsite Immunization Clinics may only be **conducted** within the state of South Carolina; VFC-eligible children are **not** required to be SC residents to participate in this activity.
6. The provider must complete the Mobile Immunization Clinic Log that lists the clinic dates, locations and the vaccine amounts, by fund type (VFC and private stock), that will be transported to each mobile clinic and/or offsite location.
7. Vaccine storage and handling equipment on the mobile unit must meet CDC requirements:
    - A portable vaccine refrigerator.
    - A portable vaccine freezer.
    - A qualified container and pack out.
    - VFC-compliant DDL(s) for temperature monitoring in each storage unit.
    - Upload units and DDL's into SIMON for temperature monitoring.
    - Prior to transporting the vaccine onto the mobile immunization clinic, the storage units must be operational and temperatures in-range (refrigerator temperature steady between 2°C – 8°C, hovering around 5°C; freezer temperature consistently colder than minus (-)15°C).
    - DDLs that are routinely stored outside a refrigerator or freezer should be placed in a functioning storage unit at least six hours, or the night before the clinic, to allow time for the DDL and probe to acclimate and register any issue.
    - The vaccine should be transported onto the mobile immunization clinic inside a cooler; transport should not take longer than 15 minutes. If the transport will take longer than 15 minutes, use the "Packing Vaccines for Transport during

Emergencies" guidance or a commercial transport box qualified to maintain proper temperatures during transport.

8. Only staff that have completed VFC training may transport vaccines between the provider's practice and the mobile unit.
9. Only amounts of VFC vaccines that are appropriate, based on VFC need, should be transported to each scheduled clinic.
10. Upon arrival at the clinic site, the mobile clinic staff must ensure that vaccine is stored to maintain appropriate temperature throughout the clinic day:
    - Since the vaccine is at a temporary location, temperature data must be reviewed and documented every hour during the clinic using a DDL.
    - Temperatures during transport (if >15 minutes) and mobile immunization clinic hours must be documented hourly on the Off-Site Vaccination Clinic Temperature Log for Refrigerator (DPH 1236).
11. At the end of each clinic day, the mobile/offsite immunization clinic staff must:
    - Print the temperature data logger report at the end of the clinic day and attach it to the DPH1236. The Primary or Back-up Vaccine Coordinator needs to review the temperature logs and sign the DPH 1236 prior to the vaccine being returned to the primary clinic's storage units.
    - Vaccines exposed to temperature excursions (TEs) must be labeled "Do Not Use", placed in storage unit(s) at the proper temperatures, and SCIOS needs to be contacted in accordance with TE procedures via SIMON Helpdesk described elsewhere in this guide. The vaccines must not be used until SCIOS has verified that the vaccines are usable.
    - Temperature logs from the mobile/offsite immunization clinic must be stored with the primary clinic logs and kept on file for three years. Temperature logs will be reviewed during a VFC Compliance Visit.
12. VFC eligibility must be screened for and status documented at the time of service via EHR (HL7) or SIMON (DDE).
13. All immunizations must be documented according to the National Childhood Vaccine Injury Act (Statute 42 US Code 300aa-25):
    - Name of vaccine
    - Date vaccine given
    - Name of vaccine manufacturer
    - Vaccine lot number
    - Signature & title of person administering vaccine
    - Address of clinic where given
    - Publication date of VIS
    - Date VIS given to parent/guardian

14. All immunizations must be entered in SIMON within **10** business days of administration.
15. VFC Compliance Site Visit will be conducted every 24 months for the mobile unit.
    - The mobile unit will be included in the primary clinic's VF C Compliance site visit. If a compliance visit is not scheduled during the upcoming year, a storage and handling visit will be performed.
    - The immunization records from the mobile/offsite immunization clinic must be available for review during the bi-annual site visit.
    - Failure to meet the VFC requirements for eligibility, documentation and storage and handling may result in withdrawal of approval for use of VFC vaccines in the mobile/offsite immunization clinic.

9. Mass/Community Vaccinators

Mass/Community Vaccinator clinics can improve access to vaccines for VFC-eligible and privately-insured children. However, these clinics require additional program oversight and vaccine accountability. Mass/community vaccinators must comply with all VFC Program requirements and maintain enhanced storage and handling practices. In addition to adhering to all general VFC Program requirements, the following conditions must be met:

1. The mass/community vaccinator must enroll in the VFC Program.
2. The mass/community vaccinator's office must pass the storage and handling site-visit; this is an initial and bi-annual requirement.
    - Required to have a stand-alone refrigerator that meets VFC program requirements. Vaccine will need to be shipped to the office listed on the Provider Agreement. The day of the mass/community vaccination clinic the vaccine can be transported from the office to the clinic. The vaccine will be required to be transported in an approved portable refrigerator or qualified pack out container. The portable refrigerator will need to be able to plug into the vehicle during transport and plug into the power outlet at the clinic site. The qualified pack out container must be able to maintain stable temperatures for the duration of the clinic day.
    - Required to have a compliant digital data logger (DDLs) with a current Certificate of Calibration for the office (stand-alone refrigerator) and portable transport unit.
    - If the office will not have staff available Monday – Friday to monitor the vaccine, an alarm will need to be purchased for each stand-alone refrigerator. The alarm will need to be able to send out alerts when temperatures are out-of-range.
    - Required to have private vaccine inventory (invoices must be kept for three years).
3. The mass/community vaccinators are required to work closely with the Regional Immunization Representative when scheduling clinics. This collaboration will prevent

duplicate effort/work between the mass/community vaccinator and the local health department to assist in reaching all at-risk populations.

4. The mass/community vaccinator must have protocols in place to ensure that the outreach efforts meet all VFC requirements, including protocols for establishing vaccine needs (provider profile) and overseeing vaccine ordering for each clinic site to ensure that proper amounts of VFC and private vaccine stock are transported on each clinic day.
5. Any staff participating in the mass/community vaccination clinics must annually complete both CDC You Call the Shots VFC and Storage and Handling, along with the new SIMON application trainings.
6. The mass/community vaccination clinics may only be conducted within the state of South Carolina; VFC-eligible children are not required to be SC residents.
7. Complete the Mobile Immunization Clinic Log that lists the clinic dates, locations and the vaccine amounts, by fund type (VFC and private stock), that will be transported to each mass/community vaccination clinic.
8. The following steps are required to be completed/conducted the day of the mass /community vaccination clinic:
    - Portable refrigerator should be at the correct temperature prior to placing vaccine and the DDL inside the unit. It is recommended that the portable refrigerator be plugged in the night before the clinic to allow adequate time for it to acclimate. The DDL should also be placed in the stand-alone refrigerator to allow it to acclimate.
    - Only amounts of VFC vaccines that are appropriate, based on VFC need, should be transported to the clinic site.
    - Once vaccine is moved to the portable refrigeration unit, the temperatures are required to be taken hourly using the DDL. The temperatures are required to be documented on the Off-Site Vaccination Clinic Temperature Log for Refrigerator (DPH 1236).
    - Upon arrival at the clinic site, staff should immediately plug the portable refrigerator into the power outlet.
    - Print the temperature data logger report at the end of the clinic day and attach it to the DPH 1236. The Primary or Backup Vaccine Coordinator needs to review the temperature logs and sign the DPH 1236 prior to the vaccine being returned to the office's stand-alone refrigerator(s).
        a. Vaccines exposed to temperature excursions (TEs) must be labeled "Do Not Use", placed in storage unit(s) at the proper temperatures, and SCIOS needs to be contacted in accordance with TE procedures described elsewhere in this guide. The vaccines must not be used until SCIOS has erified that the vaccines are usable.

- Temperature logs from the mass vaccination clinic must be stored with the office temperature logs and kept on file for three years. Temperature logs will be reviewed during a VFC Compliance Visit.

9. VFC eligibility must be screened for and status documented at the time of service and documented via EHR (HL7) or SIMON (DDE).
10. All immunizations **must** be entered in SIMON within **10** business days of administration.
11. All immunizations must be documented according to the National Childhood Vaccine Injury Act (Statute 42 US Code 300aa-25):

    - Name of vaccine
    - Date vaccine given
    - Name of vaccine manufacturer
    - Vaccine lot number
    - Signature & title of person administering vaccine
    - Address of clinic where given
    - Publication date of VIS
    - Date VIS given to parent/guardian

12. A VFC Compliance visit will be conducted every 24 months.
    - The immunization records from the mass vaccination clinic must be available for review during the bi-annual site: VFC & Vaccine Management Information.
    - Failure to meet the VFC requirements for eligibility, documentation and storage and handling may result in withdrawal from the VFC Program.

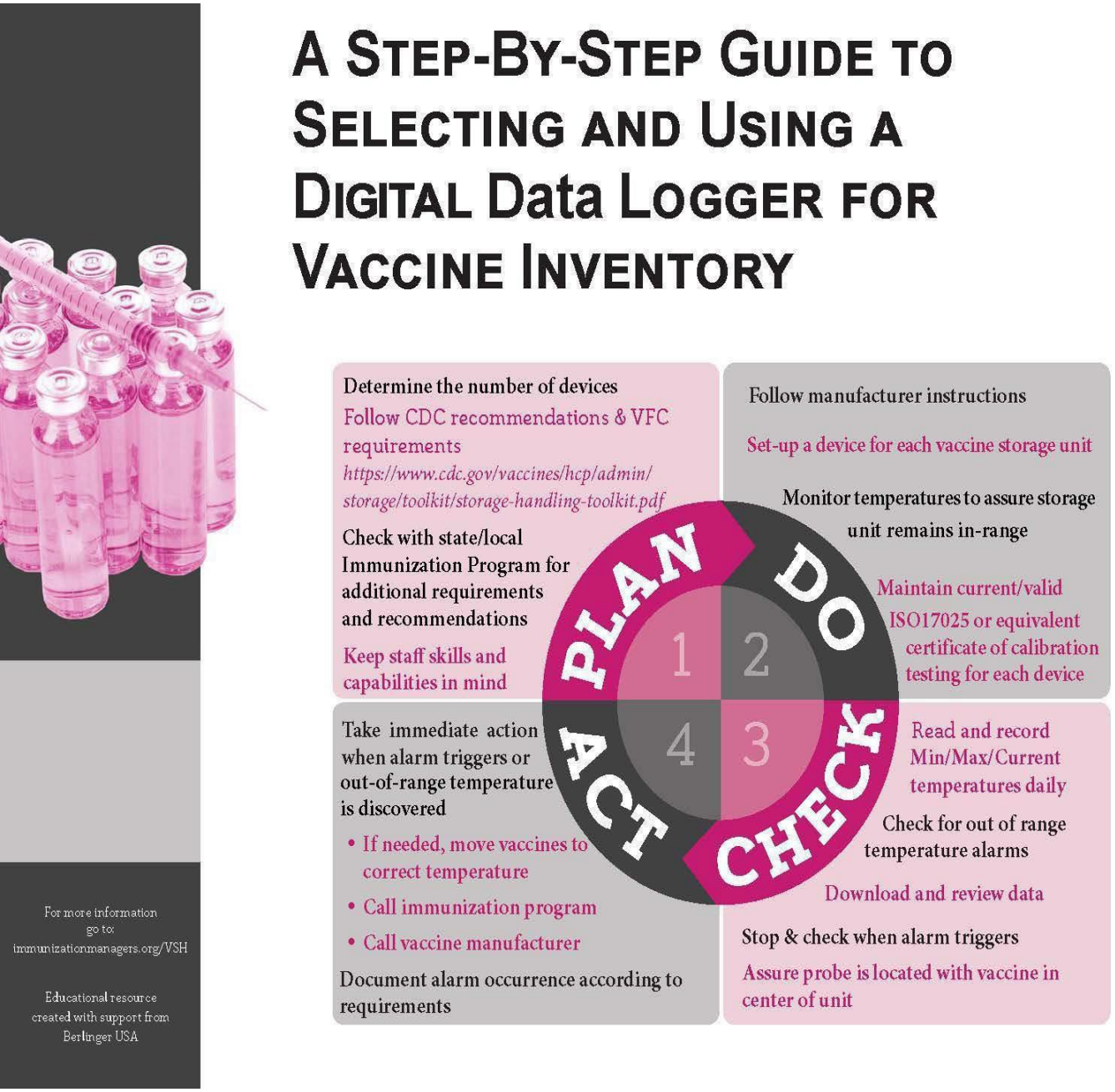
Appendices

Appendix A: Resources

Resource	Information about Resource
CDC: Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook	Includes principles of vaccination, immunization general recommendations and strategies, and information regarding vaccine safety, storage and handling, and details regarding administration of individual vaccines. **Website:** https://www.cdc.gov/immunization-training/hcp/pink-book-education-series/?CDC_AAref_Val=https://www.cdc.gov/vaccines/ed/webinar-epv/index.html
CDC: Vaccines and Immunizations	Provides information on immunization schedules, publications about vaccine-preventable diseases, and much more. **Website:** http://www.cdc.gov/vaccines **Phone:** 1-800-CDC-SHOT (1-800-232-4636)
CDC: Vaccine Information Statements (VIS) and Email VIS Update Service	Current VIS; sign up to receive update notices via email. **Website:** http://www.cdc.gov/vaccines/hcp/vis/index.html
CDC: Vaccine Storage & Handling Toolkit	Information regarding best practices for vaccine storage and handling. **Website:** http://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
Immunization Action Coalition (IAC)	Evidence-based vaccine information, VIS in multiple languages, "Ask the Experts", free print materials, information on vaccine-preventable diseases, and much more. **Website:** http://www.immunize.org
Annual Provider Trainings	Vaccine Storage and Handling (module 10) Vaccines for Children Program (module 16) SIMON Application - SC DPH VFC SIMON/WebIZ- Training **Website:** https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp https://www.train.org/cdctrain/welcome

Appendix B: Guide to Selecting a Digital Data Logger

Step by step instructions on how to install, setup, and use VFC 400 data loggers
https://www.vfcdataloggers.com/vfc400-pdf-instructions/



USING A DATA LOGGER – THE DETAILS

PLAN 1

- Obtain multiple devices one for each storage unit and one backup device with different calibration testing dates
- Ensure each device meets CDC requirements:
  - ✓ Tern pera ture pro be
  - ✓ Active temperature visibly displayed on the outside of the unit
  - ✓ Capacity for continuous temperature monitoring, recording and downloading
- Contact the Immunization Program for additional device requirements and policy/procedures for alarm notification, reporting and calibration testing
- Confirm that report shows alarms, temperature ranges (highest and lowest) and duration of excursions
- Consider other CDC recommendations
  - ✓ Detachable pro be in a thermal, buffered material (e.g., glycol)
  - ✓ Alarm for out-of-range temperatures; audible and visual alarms preferred
  - ✓ Current, minimum, and maximum temperature display
  - ✓ Low battery indicator
  - ✓ Memory: Minimum 4,000 readings or 39 days
  - ✓ Accuracy of+/- 1'F (0S'C)
  - ✓ User programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.

DO 2

- Check for Immunization Program or manufacturer training
- Reference manufacturer resources for set-up and installation
- Place pro be in the middle of the unit with vaccines
- Thread pro be wire through door hinge side of the unit and tape in place (inside & outside the unit) or place wire in storage unit portal designed for that purpose
- Contact manufacturer and/or Immunization Program for installation trouble shooting
- Monitor temperature and replace vaccine storage unit ifit does not maintain in-range temperatures
- Keep track of z..g at.§ !;11d ISO certificate of calibration testing for each device

CHECK 3

Read and record temperatures at least lx daily noting data/time/temp/initials

- Assess at the start of clinic day and prior to vaccine adminlstra tio n
- Log recording in paper or electronic format

Download and review reports weekly

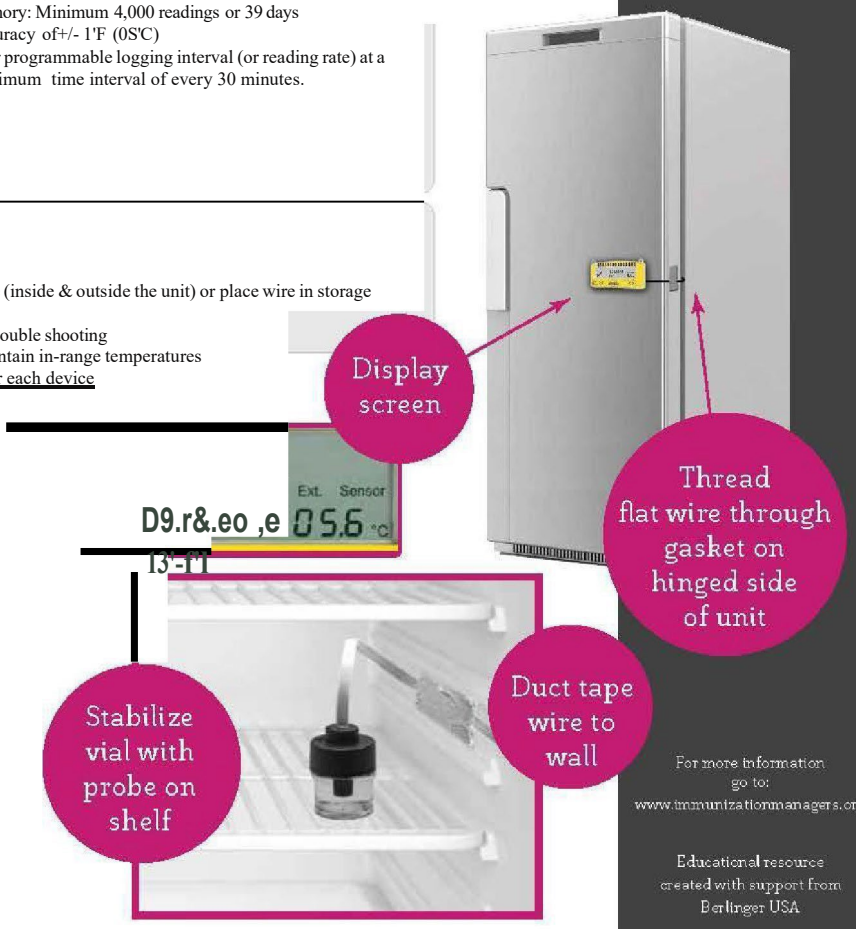
- PDE.re.p.orts simplify re cord keepjng

ACT 4

Take immediate action when there is an alarm or out of range temperature

- Ifneeded, move vaccines to a storage unit with correct temperatures and quarantine vaccine
- Print report and look for clues to the problem e.g. is the ave. temperature S.0°C (41°F)'
  - Ifnot is it too cold or too warm in the unit'
- Document the actions taken and duration of the alarm period with the highest or lowest tern p.
- Communicate alarm information to Immunization Program and vaccine manufacturer

Maintain reports per Immunization Program/CDC **requirements**



For more information go to: www.immunizationmanagers.org

Educational resource created with support from Berlinger USA

Appendix C: Packing Vaccines for Emergency Transport

Be prepared for vaccine transport. Commercially available vaccine transport options are available at a variety of Fscd points and may be preferred. However, the protocol below is designed to safely store vaccines for hours at proper temperatures using readily available materials.

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers

- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles

- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.

Insulating material — You will need two of each layer

- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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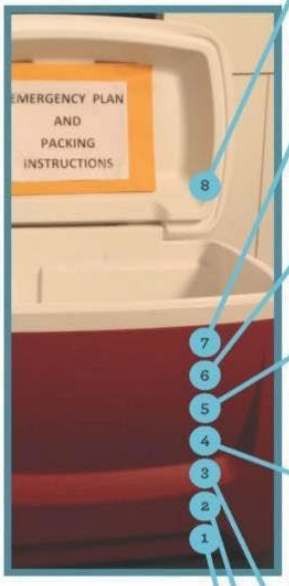
Visit www.cdc.gov/vaccines/SandH for more information, or your state health department.

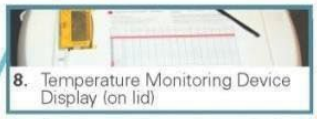
Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles

- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.




8. Temperature Monitoring Device Display (on lid)

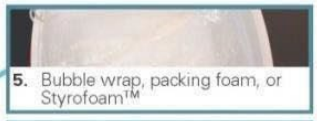
Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.


7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.


6. Cardboard Sheet

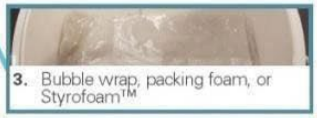
Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.


5. Bubble wrap, packing foam, or Styrofoam™

Insulating material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™


4. Vaccines, Diluents, and Temperature Monitoring Device Probe

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.


3. Bubble wrap, packing foam, or Styrofoam™

Insulating material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).


2. Cardboard Sheet

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.


1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This packout can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.
Storage – Transfer boxes of vaccines quickly to storage refrigerator.
Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

Guide may be found on the CDC website at:
http://www.cdc.gov/vaccines/hcp/admin/storage/downloads/emergency-transport.pdf

Addendum: Special Considerations for COVID-19 vaccine and Nirsevimab

Updated 03/29/2024

This addendum to the VFC Operations Guide provides supplemental information and guidance related to COVID-19 vaccine and nirsevimab in the VFC formulary.

* All text in this blue font are clarifications for all enrolled SC VFC Program Providers

Inventory SCVFC Program will honor this consideration.

- VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for COVID-19 vaccine and nirsevimab. During this time, awardees will not require VFC providers to meet the private inventory minimum requirements for COVID-19 vaccine or nirsevimab if they do not intend to vaccinate their private pay patients. **VFC providers are required to meet the private inventory requirement no later than August 31, 2025.**
- If a provider serves only Medicaid-eligible and no privately insured children, they are not required to privately purchase COVID-19 vaccine or nirsevimab.
- If VFC providers utilize this flexibility to not maintain private stock during this season, providers should explore if other in-network options exist for their privately insured patients to access COVID-19 vaccine and nirsevimab (i.e., from another local in-network practice or system, Federally Qualified Health Center, Rural Health Clinic, or deputized VFC provider authorized to immunize underinsured children that does have private inventory of COVID-19 vaccine or nirsevimab).
- In locations where providers report that demand for COVID-19 vaccine or nirsevimab is low, awardees are to allow providers to order the minimum packaging of COVID-19 vaccine and nirsevimab that is feasible. In these cases, site visit reviewers will observe that COVID-19 vaccine or nirsevimab inventory may be a much lower quantity than other ACIP-recommended vaccines.
- At the discretion of the awardee, certain specialty providers, including pharmacies and birthing facilities (e.g., VFC-enrolled birthing facilities offering nirsevimab should offer hepatitis B vaccine at birth, as well (and vice versa).

Eligibility Criteria SCVFC Program will honor this consideration.

- A child's eligibility criteria for VFC COVID-19 vaccine or nirsevimab are the same as for other VFC vaccines.

Borrowing SCVFC Program will honor this consideration.

birthing hospitals or centers), may offer a limited formulary of vaccines, based on the populations served in their facility.

- For those VFC providers who maintain private stock of COVID-19 vaccine or nirsevimab and vaccinating privately insured children, bidirectional borrowing of COVID-19 vaccine and nirsevimab will be allowed for the 2024-2025 respiratory virus season at the discretion of the awardee and as described below. VFC providers should ensure they have funds to procure sufficient private stock before COVID-19 vaccine or nirsevimab is borrowed from VFC stock for a non-VFC eligible child.
- CDC's borrowing guidance does not supersede jurisdictional policy related to borrowing. VFC providers should refer to awardee or jurisdictional policy to determine if borrowing is allowed in their jurisdiction.
- Borrowing is only applicable if the provider is purchasing private stock and is approved only for instances when:
  - There is a lack of vaccine stock because of delayed or spoiled shipments.
  - As part of the initial set up of private purchasing contracts and ordering systems, there has been a delay for the provider in being able to procure private stock of COVID-19 vaccine or nirsevimab.
  - Vaccine will expire soon and will be lost if not used.
  - Provider locations with a small privately insured patient population can use this option to administer short- dated, privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated, VFC dose.
  - New staff calculated ordering intervals incorrectly, leading to a lack of sufficient private or public vaccine stock.

- Borrowed COVID-19 vaccine or nirsevimab must be repaid (dose for dose) within 1 month or after five doses borrowed (for small practices, at the discretion of the awardee) and administered to the appropriate population (i.e., if VFC vaccine is borrowed for a privately insured patient and then repaid to VFC inventory, the repaid dose must be administered to a VFC-eligible child).
- Awardees must receive proof of privately purchased doses that includes the number of doses, lot numbers, and documentation that authenticates doses returned or doses repaid were administered to the appropriate recipients.

Vaccine Borrowing Documentation

A Vaccine Borrowing Report must be completed when either: SCVFC Program will honor this consideration.

- Privately purchased vaccine is administered to a VFC-eligible child, or
- VFC vaccine is administered to a privately insured child.

- Awardees may document the information using CDC's template or by developing their own once it contains all the components of the CDC template. Awardees may access the template on the ISD Awardees SharePoint portal. See Module 6 - Program Operations for additional information.
- If awardees are not able to capture and provide oversight of vaccine borrowing across their jurisdiction using their Immunization Information System, they should create and maintain a separate internal database.

Replacement

Awardees with replacement models may include COVID-19 vaccine or nirsevimab in these models, but should be extremely judicious in applying these models. New replacement models must be approved in writing (via VFC@cdc.gov) by VFC staff.

SC VFC Program does not use the replacement model due the barrier it would cause to maintain.

Restitution

Given the uncertainty with COVID-19 vaccine or nirsevimab demand and/or the potential for packaging size concerns, awardees with vaccine restitution policies may not penalize providers for COVID-19 vaccine or nirsevimab wastage due to expiration.

SCVFC Program currently does not have a restitution policy. However the program will ensure that the the SCVFC program is protected from fraud and abuse.

Virtual Enrollment Visits

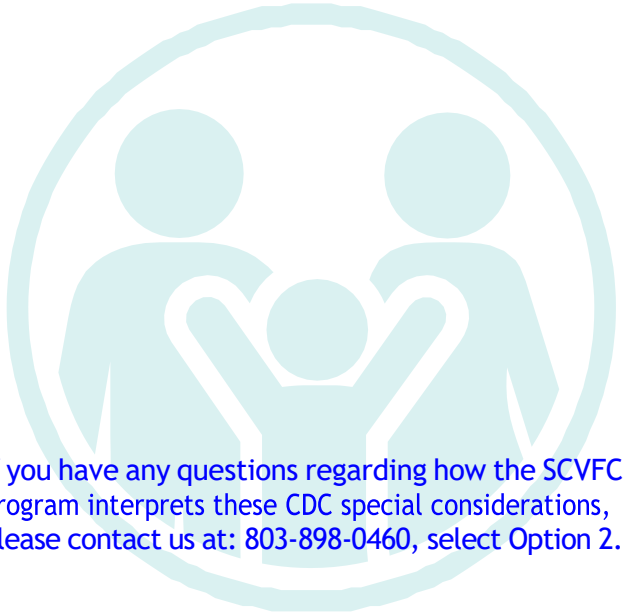
Awardees will be allowed to conduct virtual enrollment visits for specialty providers, including birthing facilities.

and pharmacies, if unable to rapidly enroll these providers through in-person enrollment visits during the respiratory season.

- Virtual enrollment site visits must be approved in writing (via VFC@cdc.gov) by VFC staff. Minimally, awardees should review the following at the virtual enrollment visit:
  - Provider Agreement
  - Provider Profile
  - Vaccine Management Plan
  - Training documentation (if not conducted by program)
    - Pictures of storage units
    - Pictures of DDL probe placement
    - Certificates of calibration
    - Pictures of "Do Not Disconnect" Signage Placement

NOTE: All awardees will be required to resume conducting the entire enrollment visit in-person, if CDC designates.

SC VFC Program will honor this request when there is low prevalence of respiratory disease activity within the community.



If you have any questions regarding how the SCVFC program interprets these CDC special considerations, please contact us at: 803-898-0460, select Option 2.