2026 DISTRICT OF COLUMBIA

Vaccines For Children Provider Manual

DC HEALTH
GOVERNMENT OF THE DISTRICT OF COLUMBIA

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

Community Health Administration —
Immunization Division, Health Care Access Bureau

vaccines.dc.gov | (202) 576-7130 | doh.immunization@dc.gov
2201 Shannon Place SE, Floor 5 | Washington, DC 20020
dchealth.dc.gov/service/vaccines-children-vfc

Table of Contents

Introduction

The District of Columbia Vaccines for Children Provider Manual provides an overview of the DC Vaccines for Children (VFC) Program and summarizes requirements and responsibilities. Additional materials and trainings are available through the DC VFC Program and the Centers for Disease Control and Prevention (CDC). The Government of the District of Columbia Department of Health (DC Health) VFC Program recognizes the vital role providers play in serving the needs of our community. Vaccines remain the best way to protect individuals and communities against vaccine preventable diseases.

For the purposes of this document the word “vaccine” refers to any vaccine and immunizing agent available through the VFC Program.

Acronyms

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices
AI/AN	American Indian/Alaska Native
CDC	Centers for Disease Control and Prevention
DC	District of Columbia
DDL	Digital Data Logger
DOCIIS	District of Columbia Immunization Information System
EPA	Environmental Protection Agency
FQHC	Federally Qualified Health Center
IQIP	Immunization Quality Improvement for Providers
NCVIA	National Childhood Vaccine Injury Act
OSHA	Occupational Safety and Health Administration
PIN	Provider Identification Number

STI	Sexually Transmitted Infection
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children
VIS	Vaccine Information Statement
VOMS	Vaccine Ordering Management System
BUD	Beyond-Use Date
SDV	Single-Dose Vial
MDV	Multi-Dose Vial

Chapter 1: VFC Program Overview

In 1994, Congress established the Vaccines for Children (VFC) program to increase vaccine access for children who might not get vaccinated because of financial barriers. VFC serves children through 18 years of age who meet at least one of the following criteria:

- American Indian or Alaska Native (AI/AN)
- Medicaid-eligible
- Uninsured
- Underinsured

CDC uses federal funds to purchase vaccines and distribute them at no cost to public health clinics and provider locations enrolled in the program. CDC provides funding to 63 state, local, and territorial immunization program award recipients to implement and oversee the VFC program. The DC VFC Program provides vaccines to participating provider locations to meet the specific needs of eligible children in the District.

VFC providers agree to follow all VFC requirements. These include screening patients for VFC eligibility at each immunization encounter and documenting their eligibility status. Providers can only administer VFC-purchased vaccines to children who are eligible for the program.

The DC VFC Program provides guidance and monitors provider locations to ensure compliance with VFC program requirements.

Benefits of the VFC Program

- Allows children to remain in their medical home for vaccination services
- Reduces a VFC-enrolled provider's out-of-pocket expenses for vaccines
- Eliminates or reduces vaccine cost as a barrier to immunizing eligible children

VFC Vaccines

The current list of VFC vaccines and their current CDC price list is available online.

The ACIP provides recommendations for the VFC program. When recommending a new vaccine or a change in vaccine use, the ACIP votes on a resolution to include the vaccine change in the VFC program.

Providers must administer vaccines procured through the VFC program according to the guidelines outlined by the ACIP in VFC resolutions unless:

a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child; and

b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

DC Health aligns immunization recommendations with the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP) and the American College of Obstetricians and Gynecologists (ACOG).

Chapter 2: VFC Eligibility

Providers enrolled in the Vaccines for Children (VFC) program agree to screen patients for program eligibility at **each immunization encounter** and document their eligibility status. Providers can only administer VFC vaccines to children who meet the congressionally mandated eligibility requirements for the program.

VFC serves children through 18 years of age who meet at least one of the following criteria:

- American Indian or Alaska Native (AI/AN)

- Medicaid-eligible
- Uninsured
- Underinsured

Patient eligibility status must be documented in the District of Columbia's Immunization Information System (DOCIIS). All immunization administrations in the District of Columbia must be reported to DOCIIS within 24 hours of vaccine administration, regardless of age.

When they screen patients, providers should choose and document the VFC eligibility category that poses the lowest out-of-pocket expense for the patient's family.

VFC-eligible children must be 18 years old or younger and meet at least one of the following criteria:

Table: VFC Eligibility Criteria for Patients

VFC Eligibility Criterion	**Definition**
American Indian or Alaska Native (AI/AN)	Children who are a part of this population as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603) Note: AI/AN children are eligible for VFC under any circumstance.
Medicaid-eligible	Children who are eligible for the Medicaid program Note: The VFC program uses the terms "Medicaid-eligible" and "Medicaid-enrolled" interchangeably.
Uninsured	Children who are not covered by any health insurance plan
Underinsured	•Children who have health insurance, but coverage does not include any vaccines •Children who have health insurance, but coverage does not include all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) •Children who have health insurance, but coverage has a fixed dollar limit (or cap) for vaccines •Children who have health insurance, but insurance does not provide first dollar coverage for vaccines

Eligibility Considerations

American Indian or Alaska Native (AI/AN)

The VFC program uses the definition of the AI/AN population established by the Indian Health Care Improvement Act [25 U.S.C. 1603].

AI/AN children are eligible for VFC under any circumstance. But, because VFC is an entitlement program, participation is voluntary.

When an AI/AN child also fits a second VFC eligibility category, the provider should always choose the category that will pose the lowest out-of-pocket cost for the family. Depending on the delivery location of vaccine services, the parent may be responsible for the vaccine administration fee for VFC vaccines. If the child has private insurance (non-grandfathered plan under the Affordable Care Act (ACA) of 2010) or is enrolled in the Children's Health Insurance Program (CHIP), receiving vaccines through these programs instead of VFC may cost less out of pocket for the family; this is because there would be no cost sharing. Likewise, if the child is also Medicaid-eligible, the provider should use Medicaid for the administration fee; doing so will pose the lowest out-of-pocket expense for the family.

Medicaid-eligible

The VFC program's initial legislation defined the term "Medicaid-eligible" as a child who is entitled to medical assistance under a state Medicaid plan.

Children enrolled in Medicaid make up the largest category of VFC eligibility.

Medicaid as Secondary Insurance

Some children may have a private primary health insurance plan with Medicaid as their secondary insurance. These children are VFC-eligible because of their Medicaid enrollment. However, participation in the VFC program is voluntary.

Providers have billing options for these children. Providers should choose the option that is most cost-effective for the child's family; **they should never bill the parent for a vaccine or an administration fee**.

Option 1: Administer VFC vaccines and bill Medicaid for the administration fee

In most health care situations, Medicaid is the "payer of last resort." This means that claims must be filed with and rejected by all other insurers before Medicaid will consider payment for the service.

This is not true of the vaccine administration fee for VFC children who are Medicaid-eligible. Medicaid must pay the VFC provider for the administration fee because vaccinations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment program. However, once the provider submits a claim to Medicaid, the state Medicaid agency may seek reimbursement for the administration fee from the child's primary insurer.

Providers should notify the DC VFC Program if the state Medicaid agency:

- Rejects a claim for a vaccine administration fee
- States that the provider must first submit the claim to the primary insurer for payment

Providers should consider that this option:

- Is the easiest way to use VFC vaccines and bill Medicaid for the administration fee
- Poses no out-of-pocket costs to the parent for the vaccine or the administration fee

Option 2: Administer private stock vaccines and bill the primary insurance carrier for both the cost of the vaccine and the administration fee

The primary insurer may reimburse less than Medicaid does for the vaccine administration fee. In these cases, the provider can bill Medicaid for the balance up to the amount that Medicaid pays for the administration fee.

The primary insurer may deny payment of a vaccine and the administration fee, such as in cases where the family has not met their deductible. In these cases, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement on the DC VFC borrowing form.

Providers should consider that this option may reimburse them a higher dollar amount if they:

- Administer privately purchased vaccine
- Bill both the vaccine and administration fee to the primary insurer

Medicaid as Secondary Insurance and High-Deductible Plans

The provider should administer VFC vaccines and bill the administration fee to Medicaid if a child:

- Has Medicaid as secondary insurance
- The primary insurance is a high-deductible insurance plan that requires the parent to pay out of pocket for vaccines.

Underinsured

In DC, underinsured children can only receive VFC vaccines at federally qualified health centers (FQHCs).

VFC defines underinsured as meaning the child has health insurance, but the insurance policy either:

- Does not cover any VFC-provided vaccines
- Does not cover all VFC-provided vaccines (i.e., underinsured for vaccines not covered)
- Does not provide first dollar coverage (which includes copays, coinsurance, or deductibles) for VFC-provided vaccines
- Covers VFC-provided vaccines but has a fixed dollar limit (or cap) for payment. The child is considered underinsured once the family's policy reaches the fixed dollar amount

Before they administer a vaccine, providers must verify whether the child's health insurance plan covers VFC-provided vaccines. If the provider cannot verify vaccination coverage, then the child is considered insured for the purposes of the VFC program; the child is not eligible to receive VFC vaccines at that immunization encounter.

Note: The Affordable Care Act (ACA) requires insurance plans purchased through the Health Insurance Marketplace to cover ACIP-recommended vaccines (including seasonal flu vaccine) for children of all ages without:

- Charging a deductible or copayment or
- Billing coinsurance

Table: Quick View of VFC Eligibility and Insurance Situations

Child's Insurance Status	**VFC-Eligible?**	**VFC Eligibility Category**
Enrolled in Medicaid	Yes	Medicaid

Has private health insurance plan with Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines but either: - Does not include first dollar coverage - Has not yet met plan's deductible or - Has not paid for other services received at visit	Yes	Underinsured This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the family has not met the plan's deductible.
Has health insurance covering all vaccines and has Medicaid as secondary insurance, but: - Has not yet met plan's deductible or - Paid for other services received at visit	Yes	Medicaid
Has health insurance covering all vaccines, but the plan has a fixed dollar limit (or cap) on amount that it will cover	Yes	Insured until the family meets the plan's fixed dollar limit Underinsured after the family reaches the plan's fixed dollar limit
Has an insurance plan that does not cover all ACIP-recommended vaccines	Yes	Underinsured The child can only receive vaccines that are not covered by the plan.

Has health insurance, but plan does not cover any vaccines	Yes	Underinsured With the ACA in place, this situation should be rare.
Enrolled in a Health Care Sharing Ministry	Depends	Uninsured unless the state insurance department recognizes the plan as insurance, regardless of the vaccine coverage that the plan provides Insured if: - The state insurance department recognizes the plan - The plan covers vaccines Underinsured if: - The state insurance department recognizes the plan - The plan does not cover all VFC-provided vaccines
Enrolled in a Medicaid-expansion Children's Health Insurance Program (CHIP)	Yes	Medicaid
Enrolled in a separate Children's Health Insurance Program (CHIP)	No	Insured The state CHIP program is responsible for vaccine payment for its members.

Has no health insurance coverage	Yes	Uninsured
Is AI/AN and has private health insurance that covers all vaccinations	Yes	AI/AN However, the provider should choose the eligibility category that is most cost-effective for the child's family.
Is AI/AN and has Medicaid	Yes	Medicaid or AI/AN The provider should use Medicaid for the administration fee. This poses the lowest out-of-pocket expense for the child's family.

Vaccination Location

The delivery location of vaccination services does not usually determine VFC eligibility. However, some locations and provider types require additional consideration when offering VFC vaccines.

Temporary, Mobile, Off-Site, or Satellite Clinics

Providers should not assume a child is VFC-eligible when vaccinating in temporary, mobile, off-site or satellite clinics. Providers must screen all children and document their VFC eligibility before administering VFC vaccines.

Bordering U.S. State

Some children may receive health care in a bordering state instead of their state of residency.

A provider may administer VFC vaccines to a VFC-eligible child from a neighboring state. If the child is enrolled in the neighboring state's Medicaid program, the provider must be Medicaid-enrolled for the child's state of residency to receive reimbursement for the administration fee from that Medicaid program.

Chapter 3: VFC Billing Practices

VFC providers must adhere to VFC billing requirements.

VFC providers cannot charge a fee for the cost of the vaccine. However, they can charge an administration fee for each **vaccine** administered (**not per antigen**).

Providers cannot deny access to federally purchased vaccines to a patient whose parent or guardian is unable to pay the fee for vaccine administration.

Note: Providers may charge an office visit fee as well as the vaccine administration fee if other services were provided in addition to vaccinations.

Vaccine Administration Fee

Medicaid-enrolled children

Providers agree to accept the administration fee reimbursement set by the state Medicaid agency or the contracted Medicaid health plan.

VFC-eligible children not enrolled in Medicaid

Providers are permitted to charge a vaccine administration fee to non-Medicaid VFC-eligible children. This administration fee cannot exceed the federal administration fee cap.

CMS published the most recent fee schedule in November 2012. As of the publication of this manual, the current regional maximum fee for the District of Columbia is $24.48 per vaccine administration.

The fee cap does not have a lower limit. Providers may charge what they feel is fair up to the fee cap. They may also decline to charge a fee at all.

If providers choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service, they may only issue a single bill to the patient. The bill must be issued within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for VFC-eligible children who qualify through Medicaid.

Providers may not send unpaid administration fees to collections. Also, providers may not refuse to vaccinate an eligible child whose parents or guardians have unpaid vaccine administration fees.

If a VFC provider chooses to use a billing company for billing patients, the provider is responsible for ensuring all VFC billing requirements are met.

Chapter 4: VFC Provider Enrollment

To enroll in the DC VFC Program, providers must meet the following criteria:

- Licensed in the District of Columbia to administer vaccines to children aged 18 years and younger
- Provider and provider staff must not be on the Office of the Inspector General List of Excluded Providers
- Ability to follow all DC VFC Program requirements, including but not limited to participation in site visits and educational opportunities
- Capacity to order, receive, manage, store and monitor the temperature of VFC-supplied vaccines
- Ability to maintain cold storage units and digital data loggers with current certificates of calibration
- Be open at least four consecutive hours on a day other than a Monday to receive VFC vaccines

Prospective providers can visit dchealth.dc.gov/service/vaccines-children-vfc for more information and to access a provider checklist and profile. These two documents can be completed and submitted to DC VFC Program at doh.immunization@dc.gov. DC VFC Program staff will then review and schedule next steps.

Prospective DC VFC Provider Resources

- VFC Enrollment Requirements
- Provider Enrollment Checklist
- VFC Annual Provider Profile Form

Who Can Be a VFC Provider?

Health care provider locations that serve VFC-eligible populations can include, but are not limited to:

- Pediatricians
- Family practitioners
- General practitioners

Specialty care provider locations can include, but are not limited to:

- Birthing facilities (e.g., birthing hospitals or centers)
- Obstetrician/gynecologists (OB/GYNs)

- Providers who serve adolescents in nontraditional environments (e.g., long-term juvenile correctional facilities, family planning, and sexually transmitted disease [STD]/human immunodeficiency virus [HIV] clinics)
- Specialty provider practices
- Pharmacies*
- School-located vaccination clinics*
- Urgent care centers*
- *These providers must agree to vaccinate all walk-in children who are eligible for VFC.
    - Walk-in refers to any VFC-eligible child who presents requesting a vaccine, not just established patients. Walk-in does not mean that a provider must serve VFC patients without an appointment. If a provider's policy is for all patients to make an appointment to receive vaccinations, then the policy would apply to VFC patients as well.

Specialty Providers

For the VFC program, "specialty providers" are those who offer limited care in a specialized environment, or for a specific age group, within the general population of children aged 0–18 years. Specialty providers have the option to order and administer only vaccines recommended for the specific populations that they serve.

Chapter 5: Key Clinic Staff Responsibilities

Medical Director

The medical director will be held accountable for VFC program compliance for the entire facility.

A medical director's responsibilities include, but are not limited to, the following:

- Sign the DC VFC Provider Agreement
- Submit an annual provider profile representing populations served by the facility
    - Providers must submit the profile more frequently if the number of children changes or the status of the facility changes during the calendar year
- Screen patients and document VFC-eligibility status at each immunization encounter
- Administer VFC-supplied vaccine only to VFC-eligible children 18 years of age and younger

- Administer vaccines procured through the VFC program according to the guidelines outlined by the ACIP unless:
    - The provider considers such compliance to be medically inappropriate for the child based on accepted medical practice.
    - The particular recommendation contradicts state law, including any law pertaining to religious and other exemptions.
- Ensure that all records related to the VFC program are maintained and available for review for a minimum of three years.
- Ensure that all VFC billing requirements are strictly adhered to.
- Ensure that a current Vaccine Information Statement (VIS) (and/or other immunization information materials, as applicable) is distributed each time a vaccine is administered
    - Maintain record in accordance with the National Childhood Vaccine Injury Act (NCVIA)
    - Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Comply with VFC requirements for vaccine management, including:
    - Ordering vaccine and maintaining appropriate vaccine inventories
    - Not storing vaccine in dormitory-style units at any time
    - Storing vaccine under proper conditions at all times
    - Ensuring cold storage units and temperature monitoring equipment meet VFC storage and handling requirements.
    - Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
    - Participating in VFC program compliance site visits, including unannounced visits, and other educational opportunities associated with VFC program requirements
    - Replacing vaccine purchased with federal funds that are deemed non-viable due to provider negligence on a dose-for-dose basis
- Notify and revaccinate any child who received compromised or potentially compromised vaccine
- Register as a provider with DOCIIS
- Report all vaccine administrations to DOCIIS within twenty- four hours of administration
- Understand that the provider or the VFC program may terminate the Provider Agreement at any time

  - Any unused federally funded vaccine must be returned to the VFC program upon termination.
- Ensure that all healthcare providers in the enrolled practice, and their corresponding professional license numbers, are listed on the provider profile.
  - Providers who are on the Office of the Inspector General Exclusion list or employ individuals on the Office of the Inspector General Exclusion List cannot participate in the VFC program
- Ensure that all vaccine managing staff are educated in proper vaccine ordering, inventory maintenance and storage and handling practices.
- Ensure that all vaccine managing staff are familiar with storage and handling policies and procedures at the facility
- Ensure that vaccine management policies are accessible to all staff
- Designate, train and oversee a primary vaccine coordinator and a backup vaccine coordinator
- Submit a Change of Information (COI) form whenever there is a change in the medical director, primary/backup vaccine coordinators, profile or office information

Vaccine Coordinators

The VFC program requires that providers designate a Primary and Back-up Vaccine Coordinator. These coordinators must be fully trained in routine and emergency policies and procedures.

The vaccine coordinator must be onsite for each facility. The vaccine coordinators are responsible for overseeing all vaccine management within the facility, including:

- Ordering vaccine in VOMS
- Updating and documenting vaccine inventory in VOMS
- Organizing vaccines in storage units
- Overseeing receipt and storage of vaccine deliveries
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures at the start and end of workday
- Checking current storage unit temperatures prior to accessing and administering vaccines
- Reviewing and analyzing temperature data weekly for any shifts in temperature trends
- Rotating stock to ensure vaccines with the earliest expiration dates are used first
- Removing expired vaccine from storage units

- Responding to temperature excursions (out-of-range temperatures)
- Maintaining all VFC documentation, such as inventory and temperature logs, for a minimum of three years
- Ensuring staff training is up to date
- Maintaining the Vaccine Management Plan
- Monitoring storage and handling and vaccine administration practices in the facility
- Notifying the Immunization Program at least 120 days in advance if vaccines will expire before they are administered

The primary vaccine coordinator and back-up vaccine coordinator must be fully trained and actively engaged in routine and emergency standard operating procedures for vaccine ordering, storage, handling, transport and inventory management.

The vaccine coordinators serve as the liaisons with the DC VFC Program and must be consistently present during normal business hours. The DC VFC Program requires that primary and back-up vaccine coordinators complete annual training. Proof of completion must be available to the DC VFC Program upon request.

New Coordinators

VFC providers are required to notify the DC VFC Program anytime there is a change in vaccine coordinator staff. Provide a Change of information (COI) form signed by the medical director. New vaccine coordinator will be required to complete annual training.

Please see the DC Immunization Quality Improvement for Providers (IQIP) Provider Library for VFC vaccine coordinator resources, including an overview document summarizing main duties.

Chapter 7: VFC Enrollment and Documentation

VFC Enrollment Checklist

The VFC Provider Enrollment Checklist is a tool designed to confirm if the provider meets all of the VFC requirements and to ensure the provider has the necessary vaccine storage equipment on site. A completed checklist should be sent to doh.immunization@dc.gov.

Prospective providers can visit dchealth.dc.gov/service/vaccines-children-vfc for more information and to access a provider checklist and profile. These two documents can be completed and submitted to the

DC VFC Program at doh.immunization@dc.gov. DC VFC Program staff will then review and schedule next steps with prospective providers.

VFC Provider Agreement

The medical director for the site signs this agreement upon enrollment agreeing to comply with the requirements of the DC VFC Program. The Provider Agreement is the final step in the enrollment process and is signed through DOCIIS. A VFC provider cannot order or receive VFC-purchased vaccine without an active provider agreement.

All VFC provider locations must complete and sign the DC VFC Provider Agreement.

The medical director in a group practice (or equivalent) must be authorized to administer pediatric vaccines under state law to sign the Provider Agreement.

- The provider signing the Provider Agreement on behalf of a multi-provider location must have authority to sign on the entity's behalf.
- **Note**: That provider will be held accountable for the entire location's compliance, including preparing for site visits and meeting educational requirements.

For an enrolled practice, the Provider Agreement must list:

- All licensed health care providers in the practice
- Their corresponding professional license numbers

The Provider Agreement must be signed every 24 months as part of the recertification process for VFC program providers.

The provider must notify the award recipient if the status of the individual signing the Provider Agreement changes. A new Provider Agreement will then need to be signed by the current medical director (or equivalent) in place.

VFC Profile

This form captures information about the practice, including the number of VFC-eligible children and non-VFC-eligible children served by the provider. It helps the VFC program determine how much vaccine will need to be supplied through the VFC program and compare projected vaccine needs with actual vaccine orders and inventory.

Providers must update the Provider Profile **every 12 months** or if:

- The provider reports a change in patient population during the enrollment year
- The provider location's ordering pattern indicates over- or under-ordering vaccines relative to the populations reported on the form

Vaccine Management Routine & Emergency Plan

This form outlines the site's routine vaccine management practices and steps the site will follow in case of emergency. This form also details who is responsible for emergency activities. It includes contact information for all responsible staff members. The DC VFC Program has a blank fillable vaccine management plan available for VFC provider use.

This form must be kept up-to-date, held on-file in a DC VFC provider's VFC binder, and be readily available for DC VFC Program staff review upon request.

Provider Education

All staff involved in vaccine management must complete required trainings **at least annually** and remain up to date on trainings.

At minimum, vaccine coordinators must complete CDC You Call the Shots Modules 10 and 16 **at least annually**:

- Module 10: Storage and Handling
    - www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp
    - To be completed upon hire/designation as vaccine management staff and annually
- Module 16: Vaccines for Children
    - www2a.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp
    - To be completed upon hire/designation as vaccine management staff and annually
- Module 18 (strongly recommended): Vaccine Administration
    - www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp
    - To be completed upon hire/designation as vaccine management staff and every two years

- Vaccine coordinators are required to complete these modules **annually**. You DO NOT have to complete new modules until one year from the date you completed your previous modules.
- As an alternative for experienced health care professionals familiar with VFC and federal storage and handling requirements, CDC offers modules that allow providers to "test-out" of the full modules. These are the Storage and Handling Refresher Test and the VFC Refresher Test.
    - Please note, CE credit is not offered for refresher modules.

Chapter 8: Utilizing DOCIIS – iWeb and VOMS

The District of Columbia Immunization Information System (DOCIIS), sometimes referred to as the immunization registry, contains two primary platforms that VFC providers will use: iWeb and VOMS. The DC VFC Program requires that providers electronically connect to DOCIIS through the provider onboarding process.

iWeb is the system used to enter vaccine administrations, view immunization records and send reminder/recall notices, among other functions.

The Vaccine Ordering Management System (VOMS) is the inventory management and VFC ordering platform. Tasks to be performed in VOMS include:

- Vaccine inventory management (at least weekly, and when ordering)
- Submission of temperature logs (at least weekly, and when ordering)
- Order submission (on established cadence, monthly for most, during first week of month)

As part of the enrollment process, designated provider staff will complete DOCIIS training.

- Vaccine coordinators will complete iWeb and VOMS training and gain access to both platforms upon successful completion of training
- Additional staff members are eligible to complete iWeb (and VOMS) training, as applicable

DC Health's Immunization Division Data Quality Team will connect with provider staff to facilitate submission of immunization administration data to DOCIIS.

General DOCIIS supporting material can be found by:

1. Logging into DOCIIS (after completing training and gaining access)

   a. dccp1web.stchealthops.com/iweb/main.jsp
2. Clicking "Help" on the left-hand menu
3. Scrolling down to desired item:
   a. iWeb:
      i. dccp1web.stchealthops.com/iweb/help/index.htm#t=intro.htm
   b. VOMS:
      i. dccp1web.stchealthops.com/iweb/help/index.htm#t=VOMS_module.htm

The DC VFC team is available to assist with any DOCIIS questions.

Please see the DC Immunization Quality Improvement for Providers (IQIP) Provider Library for VFC vaccine coordinator resources, including VOMS guidance material.

Ordering

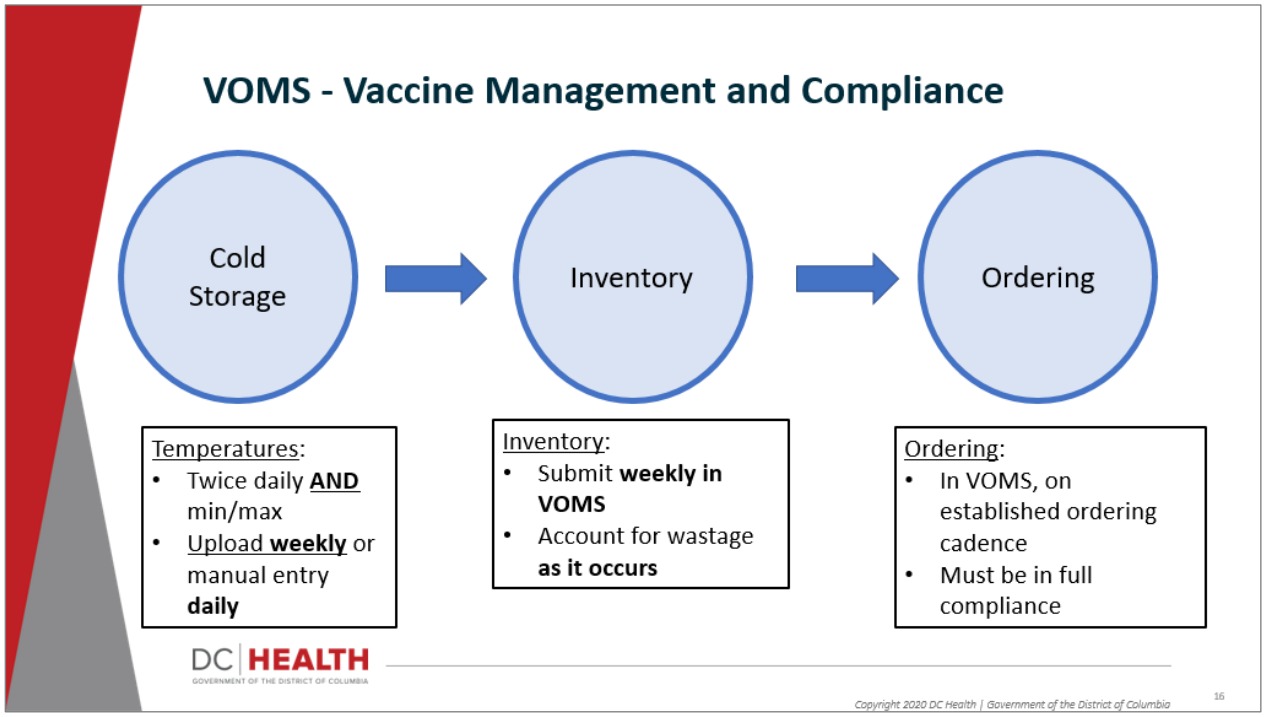
Enrolled providers are assigned an ordering frequency based on the size of their reported eligible population. The ordering frequency may be adjusted over time based on the number of doses administered.

All providers should submit VFC orders in the first week of the month.

Most providers will submit orders monthly. These providers should maintain a month's worth of inventory and order a month's worth of supply when submitting VFC orders in VOMS. Providers with very low throughput can order less frequently.

Routine VFC orders should be placed during the site's order schedule. Respiratory season orders (flu, COVID-19, RSV) and specialty orders can be placed outside of this schedule. VFC Providers must order vaccines through VOMS and will be required to report up-to-date cold storage unit temperatures and inventory at time of order submission. Once an order has been submitted in VOMS, the DC VFC team will review and verify the required elements prior to order approval.

The provider location's ability to immediately store vaccine after receipt is important to the vaccine ordering process. Facilities must be open with appropriate staff at least one weekday other than Monday, for at least four consecutive hours, to receive and immediately store vaccine.



Short-dated Vaccine Notification

Providers should notify the VFC Program of any vaccine doses that will expire before they can be administered via the Short-dated Vaccine Notification form. These notices should be submitted to the VFC Program at least 120 days before the expiration date. A short-dated vaccine notice should be emailed to doh.immunization@dc.gov.The DC VFC team will review the notice and communicate next steps.

It is important that providers order VFC vaccine appropriately to meet the needs of their patient population without overordering. Vaccine stock should be checked routinely for expiration dates (at least weekly or biweekly) to avoid vaccine expiration. Utilize vaccine lots with the earliest expiration dates first.

Order Status

Order status can be checked at any time in VOMS. The DC VFC team is available to assist any time a provider has questions about VFC vaccine ordering (order has not been received, issues creating or submitting an order, etc.).

DC VFC Vaccine Supply Policy

The DC VFC program allows all participating providers to choose the brands to order, when applicable, from all immunizations available for order through VFC. The DC VFC Program may modify orders as necessary to ensure equitable distribution and access. Special circumstances such as vaccine allocation, shortage or other restrictions in supply may lead to modifications. The DC VFC team will notify the provider when a change in their order is necessary.

Provider choice of vaccine brand is subject to the following:

- Provider must order only products that the provider plans to use.
- Provider must notify the DC VFC Program of planned changes in formulary and/or brand choice at least three months in advance of placing a vaccine order for a different product.
    - Provider must use all vaccines in inventory of the previously ordered product.
    - Providers may be held responsible for any vaccine waste due to change in brand preference

Providers who face **unanticipated** vaccine shortages between scheduled orders can contact the DC VFC Program to request additional vaccine doses. Managing inventory and ordering on an established cadence should minimize the need for out-of-cycle requests.

In certain circumstances, the DC VFC Program might reduce or deny orders. Reasons for reducing or denying orders include, but are not limited to:

- Vaccine storage unit temperatures are not current.
- Vaccine storage unit temperatures are noted to be out-of-range.
- There is a large inventory on hand at the time the order is placed.
- There is a shortage of a particular vaccine.
- Provider has not completed the renewal or recertification process.
- Provider is out of compliance

Chapter 9: VFC Annual Review and Biannual Recertification

Recertification Every Two Years

Providers are required to sign the DC VFC provider agreement every two years in DOCIIS.

If a facility has a change in medical director, the facility will need to submit a new agreement.

Renewal Every Year

On an annual basis, providers are required to:

- Send the DC VFC Team an up-to-date VFC provider profile

Additional Annual Renewal Items - Update and Retain on File

- Be sure to have the following on file in your VFC binder and available to our team upon request:
    - Up-to-date CDC You Call the Shots modules 10 and 16 for all VFC coordinators
        - Module 10 - https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp
        - Module 16 - https://www2.cdc.gov/nip/isd/ycts/mod1/courses/vfc/ce.asp
        - Vaccine coordinators are required to complete these modules **annually**. You DO NOT have to complete new modules until one year from the date you completed your previous modules.
        - As an alternative for experienced health care professionals familiar with VFC and federal storage and handling requirements, CDC offers modules that allow providers to "test-out" of the full modules. These are the Storage and Handling Refresher Test and the VFC Refresher Test.
            - Please note, CE credit is not offered for refresher modules.
    - Up-to-date calibration certificates for all DDLs
    - Up-to-date vaccine management plan

IMPORTANT: Providers who fail to complete the required renewal and recertification processes by the designated deadlines will be unable to order vaccines.

Inactivation Due to Failure to Order Vaccine

Practices that participate in the VFC program are reviewed quarterly to determine activity. Practices that have not placed a vaccine order in over 365 days are inactive. Inactive practices will be notified and will not be able to place any vaccine orders until they complete the following requirements:

- Demonstrate that the primary and back-up vaccine coordinators have completed education and training requirements
- Submit a new provider agreement
- Receive a site visit from the VFC Program

Upon completion of the requirements outlined above, the practice will once again be able to order vaccine. If the practice remains inactive, it will be unenrolled from the VFC Program. Federally funded vaccine will be removed from the office by VFC Program staff.

Provider Unenrollment

The VFC Program is an at-will program and can be terminated by either party at any time, in accordance with the Provider Agreement. Providers wishing to unenroll must complete the following:

- Complete the Provider Change of Information form.
- Schedule a practice close-out visit to collect a final inventory (if vaccine remains on site)
- Ensure that all doses administered have been reported to DOCIIS.

Chapter 10: Vaccine Management

Vaccine loss is both costly and preventable. Providers are responsible for maintaining vaccine quality from the time a shipment arrives at a facility until a dose is administered. Consistent, standardized vaccine management practices are critical to minimizing vaccine loss.

Types of Vaccine Loss

- Expired or spoiled vaccine: Nonviable vaccine in its original container (i.e. vial, syringe) that can be returned for excise tax credit. This includes expired vaccine or vaccine spoiled due to:
    - Temperature excursions
    - Transport conditions
    - Emergency situations such as a power failure.

    - Expired and spoiled vaccine doses must be reported in VOMS and returned
- Wasted vaccine: Nonviable vaccine that cannot be returned for excise tax credit. This includes vaccine:
    - In an open vial
    - Drawn into a syringe
    - Compromised because its container was dropped or broken
    - Wasted vaccine doses must be reported in VOMS and disposed in accordance with District medical waste disposal laws
- Lost or unaccountable vaccine: Vaccine that is missing its physical vial or syringe.
    - Lost or unaccountable vaccine doses must be reported in VOMS

Vaccine Coordinators

During the enrollment process, VFC provider locations must designate a primary and at least one backup vaccine coordinator for each facility.

The vaccine coordinator is responsible for overseeing all vaccine management within the facility. The coordinator's duties include but are not limited to:

- Developing and maintaining the Vaccine Management Plan
- Monitoring the facility's practices for storing, handling, and administering vaccines
- Overseeing vaccine ordering and notifying the DC VFC Team if vaccines will expire before they are administered
- Participating in annual training on VFC requirements, and documenting this training
- Storing all required documentation for three years, or longer if required by state laws—even in cases of provider retirement or closure of the provider location
- Ensuring and documenting annual training on vaccine management for designated staff, as well as training new staff upon hire. Providers must contact the DC VFC Team upon hire of new vaccine coordinators

To perform their duties, the primary and backup vaccine coordinators must be fully trained on routine and emergency standard operating procedures (SOPs) for vaccine ordering, storage, handling, transport, and inventory management.

VFC providers must notify the award recipient whenever their vaccine coordinator staffing changes.

Vaccine Management Plans

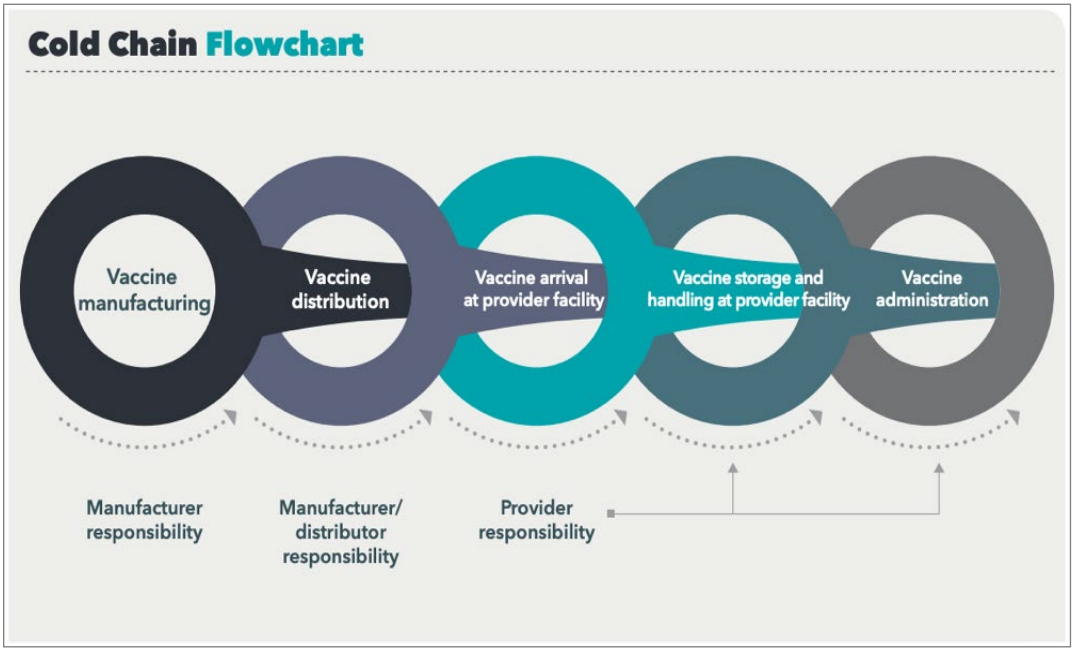
VFC provider locations must develop, maintain, and implement a Vaccine Management Plan with detailed, up-to-date SOPs for routine and emergency vaccine management. The DC VFC Program has a blank fillable vaccine management plan available for VFC provider use.

Vaccine Management Plans must include:

- Contact information for current primary and backup vaccine coordinators
- Detailed information about roles and responsibilities of provider staff
- Documented training related to vaccine management
- Proper storage and handling practices, including how to handle a temperature excursion
- Procedures for vaccine ordering, receiving, inventory control, stock rotation, loss and waste
- Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disasters
- Systems and procedures for making non-routine VFC vaccines available to VFC-eligible children, if not stocked routinely by a VFC provider

Providers must update their Vaccine Management Plans annually, or more frequently as needed. Also, vaccine coordinators should verify the plans as current by providing their signatures and dates of review.

The Vaccine Cold Chain



All VFC vaccine storage and handling requirements and recommendations are in place to ensure that the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant. It includes delivery to and storage at the provider location and ends with administering vaccine to the patient.

Failure to maintain the cold chain (e.g., exposing vaccines to excess heat, cold, or light at any step) can cause vaccines to lose potency. Each time vaccines are exposed to improper conditions, their potency is reduced even further. Vaccine potency cannot be restored once it is lost. When vaccines lose their potency, they are unable to provide immunity for the patients who receive them.

The Centers for Disease Control and Prevention's (CDC) Vaccine Storage and Handling Toolkit provides guidance on safe and effective practices for vaccine management that all health care providers can use. VFC providers must implement certain recommendations and guidance for best practices and are encouraged to adopt all the toolkit's recommendations and best practices. Following the toolkit's guidance can maximize vaccine effectiveness and patient protection. It can also minimize financial burden for providers due to vaccine loss, preventing the need for revaccination as a result.

VFC Storage and Handling Equipment Requirements

To ensure the viability of VFC vaccines, provider locations must have:

- Storage units that maintain correct temperatures at all times:
  - Refrigerator temperature between 2°C and 8°C (36°F and 46°F)
  - Freezer temperature between -50°C and -15°C (-58°F and +5°F)
  - If applicable: Ultra-cold freezer temperature between -90 °C and -60 °C.
- Digital data loggers (DDLs) with continuous monitoring capabilities and a current and valid Certificate of Calibration Testing for each unit
- At least one backup DDL on site

Storage Units (Refrigerators and Freezers)

VFC Providers must follow these cold storage unit best practices for any units containing VFC vaccine:

- Never store food or beverages in a unit with vaccines.
- Do not store vaccines:
  - In the doors or on the floors of the unit

  - Under or near cooling vents
  - In the deli, fruit, or vegetable bins. Remove these bins if possible
- Place water bottles throughout the storage unit—against walls, in the back, on the floor, and in doors—to help stabilize temperatures.
  - Water bottles are recommended for household-grade units and are not recommended for use with the majority of pharmaceutical-grade and purpose-built units. For such units, **follow the manufacturer's guidance.**
- Place vaccines and diluents in the center of the unit, two to three inches away from the walls, ceiling, floor and door.
- Store vaccines in their original packaging with lids closed until you are ready to administer them.
- Label all VFC vaccines (unless on replacement model)
- Maintain distinct spaces (e.g. separate units, separate shelves in same unit, etc) for private and VFC supply (unless on replacement model)

REFRIGERATOR AND FREEZER UNITS:

Storage units must have enough room to store the largest inventory a provider location might have at the busiest point in the year without crowding.

DC VFC recommends the following units, starting with the most preferable, for the storage of VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and vending-style units
- Vaccine storage units that conform to NSF/ANSI Standard 456
- Stand-alone refrigerator and freezer units. These can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit.
- Combination household refrigerator/freezer unit, using **only the refrigerator compartment** to store vaccines. Providers should then use a separate stand-alone freezer to store frozen vaccines.

Provider locations enrolled in the VFC program are **prohibited** from using dormitory or bar-style refrigerators, freezers, or both for VFC vaccine. These units have a single exterior door and an evaporator plate or cooling coil, which usually located in an icemaker or freezer compartment.

Providers should follow the manufacturer's storage specifications for each vaccine. These can be found in the manufacturer's package insert.

Providers must protect the power source for all storage equipment. Providers must place warning labels that say "Do Not Disconnect" at the electrical outlet and circuit breaker. DC VFC has labels available for provider use.

Place the storage unit in a well-ventilated room with good air circulation around the unit. It must be plugged directly into the wall outlet without the use of extension cords. Be sure to avoid outlets with built-in circuit switches or a wall switch that activates the outlet. An outlet cover can be used to keep from inadvertently unplugging the unit.

The unit must demonstrate **five consecutive days of in-range temperatures** prior to being used for vaccine storage; this applies even if the unit is new. The VFC team will review the storage unit to ensure it meets criteria for vaccine storage. Providers will need to supply the VFC team member with a copy of the purchase order for the unit and a temperature log of five consecutive days of in-range temperatures.

For an existing unit being moved due to a change in address, the provider must contact the VFC Program prior to the move to coordinate vaccine transport. All vaccines must be moved to an approved back-up storage location while the unit is being moved. Vaccines can be returned to the primary unit once five days of in-range temperatures have been logged and reported in VOMS. Vaccines cannot be stored overnight in transport coolers.

Back-up storage units must meet the same requirements as the primary units.

Digital Data Loggers (DDLs)

VFC provider locations must use digital data loggers (DDLs) at all times when storing VFC vaccine, including:

- Routine, on-site vaccine storage
- Vaccine transport
- Temporary, mobile, off-site, satellite and community vaccination clinics

VFC provider locations must use a DDL in each unit that stores VFC vaccines. To meet the requirements of the VFC program, each DDL must have:

- Capability to continuously monitor temperature
- Capability to record and routinely download data
- An active temperature display outside the unit that is easy to read without opening the storage unit's door
- A temperature probe or sensor
- A current, valid Certificate of Calibration Testing. This is also known as a Report of Calibration

Some provider locations may have purpose-built or pharmaceutical-grade equipment (e.g., doorless or vending-style units) with temperature monitoring capabilities. When in doubt, consult CDC's vaccine storage and handling experts at izcoldchain@cdc.gov. They will help determine whether the unit can meet the VFC requirements for devices that monitor temperature.

Recommended DDL features include:

- An alarm for out-of-range temperatures
- A temperature display showing current, minimum, and maximum temperatures
- A low battery indicator
- An accuracy of +/-1 °F (0.5 °C)
- A user-programmable logging interval (or reading rate). The recommended maximum time interval is at least once every 30 minutes

Certificates of Calibration Testing must include:

- The model or device number
- The serial number
- The date of calibration (report or issue date)
- Confirmation that the instrument passed testing (or that the instrument is within tolerance)

Backup DDLs

VFC provider locations must have a backup DDL available in case a DDL fails or requires calibration testing. The backup DDL should have a different retesting date for calibration than other DDLs. This avoids the need to send out all DDLs for recalibration at the same time.

If the backup DDL has the same retesting date for calibration, providers must have the unit retested before it expires. This ensures that a valid DDL is available for required temperature monitoring.

Note: Provider locations should **not** store backup DDLs in the storage unit. This can cause conflicting temperature readings between the backup and main DDLs, leading to potential confusion. Backup DDLs should be maintained onsite.

VFC Storage and Handling Best Practices

VFC provider locations must establish policies and procedures for vaccine storage and handling in their Vaccine Management Plans. These procedures should be:

- Based on the recommendations and best practices in CDC's Vaccine Storage and Handling Toolkit
- Easily accessible
- Kept near storage units for vaccines

Provider locations' policies and procedures for vaccine storage and handling must address:

- Receiving and documenting vaccine shipments, including whom to contact about shipment-related issues
- Monitoring and recording storage unit temperatures daily, and responding to any temperature excursion
- Managing expired, spoiled, or wasted vaccine
- Handling and preparing vaccines
- Navigating emergency situations

Receiving and Documenting Vaccines

Never leave a vaccine shipping container unpacked and unattended.

The primary or back-up vaccine coordinators should be present for all vaccine deliveries. All staff members who might accept vaccine deliveries must be aware of the importance of maintaining the cold

chain. They should be trained to immediately notify the Vaccine Coordinator when deliveries arrive so that vaccines can be unpacked and stored quickly.

Providers must immediately unpack, store, and document vaccines and diluents upon receipt. Specifically, they must:

- Examine the shipping container and vaccine vials for signs of physical damage
- Compare the contents of the container to the packing list, ensuring that they match
- Make sure that lyophilized (freeze-dried) vaccines came with the correct type and quantity of diluents
    - Note: Diluents for varicella-containing vaccines are stored in a separate compartment in the shipping container's lid—they are also stored separately in the refrigerator.
- Check the expiration dates of both vaccine and diluent, ensuring that none are expired or soon-to-expire
- Check the cold chain monitor (CCM) for any sign of a temperature excursion during transit:
    - CCMs are stored in a separate compartment of the shipping container. They may not be included when vaccines are shipped directly from the manufacturer.
    - CCMs are for one-time use. Providers should throw them away after checking them.
- If there are no concerns, place the products in the appropriate storage units:
    - Store VFC vaccine, 317 program vaccine (if applicable), and private vaccine separately and ensure funding source is clearly labeled (unless on replacement model)
- If there are any concerns about the shipment, **put the products in the appropriate storage unit** separate from other vaccines, mark "DO NOT USE" and call the DC VFC Program immediately.

Never refuse a shipment. Always receive all deliveries, even those not ordered, and contact the DC VFC program with any concerns.

Vaccine Compromised During Shipment

If providers believe a vaccine shipment was compromised, they must immediately contact the DC VFC Program.

For centralized distributor shipments (most refrigerated shipments):

- Contact centralized distribution immediately at 1-877-TEMP123 (1-877-836-7123) in the event of vaccine compromise during shipment. This must be done on the same day that vaccines arrive. Failure to do so causes CDC to be liable for vaccine replacement, regardless of the temperature excursion's cause.

Temperature Documentation

In addition to reporting DDL data to VOMS weekly, providers must review and record temperature readings utilizing the VFC Vaccine Daily Temperature Log. Then, they must reset the minimum and maximum readings on the DDL display. This helps to identify temperature excursions quickly so that corrections can be made, preventing vaccine loss as a result.

Providers should check the current temperature of the storage unit before accessing and administering vaccine from the unit.

Provider locations must maintain their temperature logs (including their back-up data) for 3 years, unless state laws or rules require longer retention. This requirement applies even in cases of provider retirement or closure of the provider location. Logs should be easily accessible during a site visit.

When documenting a temperature reading, providers should include:

- At least one minimum and maximum temperature reading daily at the beginning of the workday
- One a.m. and one p.m. temperature reading per day
- The time and date of each reading
- The name or initials of the person who performed and recorded the reading

Monitoring storage equipment and temperatures are daily responsibilities that ensure the viability of the vaccine supply.

Download the DDL data at least once a week (preferably on Mondays, or first day after the weekend), whenever the alarm sounds, and whenever out- of-range min/max or current temperatures are noted. Review this data carefully along with the recorded daily min/max temperatures.

IMMEDIATELY TAKE ACTION IF ANY OUT-OF-RANGE TEMPERATURES ARE NOTED.

Handling Out of Range Temperatures

Any temperature reading outside the manufacturer's recommended ranges is considered a temperature excursion and must be immediately addressed. Temperature excursions or inappropriate conditions for any vaccine require immediate action. The steps for handling out of range temperatures are:

1. Any staff member who hears an alarm or notices a temperature excursion on the DDL should notify the primary or backup vaccine coordinator and the medical director **IMMEDIATELY**.
2. If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
3. Label all exposed vaccines, "DO NOT USE," and isolate them from other vaccines **in a working, in-range cold storage unit**. DO NOT DISCARD THESE VACCINES.
4. Notify the VFC Program of the excursion
5. Contact vaccine manufacturer(s) for viability information of exposed vaccine(s)
6. Report determination of viability by manufacturer(s) to DC Health VFC Program
    - You will need to provide the VFC program with:
        - Copies of data logger report and temperature logs immediately preceding the excursion
        - Vaccine Incident Report
        - Vaccine Incident Report Inventory Table
        - Manufacturer's viability reports

DO NOT USE THE VACCINES UNTIL YOU OBTAIN VIABILITY INFORMATION FROM THE VACCINE MANUFACTURER AND YOU RECEIVE APPROVAL FROM THE VFC PROGRAM.

The vaccine coordinator(s) and the medical director should document the event using a Vaccine Incident Report form with the following information:

- Date and time of the temperature excursion
- Storage unit temperature and room temperature (including min/max temperatures during the time of the event)
- Name of person completing the report
- Description of the event (some of this information can be gathered after vaccines are safely in a storage unit with temperatures within the recommended range)
- Inventory of affected vaccine including lot numbers

- DDL data to determine the length of time vaccines may have been exposed to out-of-range temperatures
- List items in the unit (including water bottles) other than vaccines
- Any problems with the storage unit and/or affected vaccines before the event
- Other relevant information

Implement your facility's policies to evaluate the temperature excursion and bring the unit into the recommended temperature range. Depending on the situation, corrective actions might include, but is not limited to:

- Ensuring that the door of the unit is closed
- Ensuring that the DDL probe situated according to manufacturer recommendations in the center of the unit
- Ensuring that the storage unit is plugged in and there is power to the unit
- Implementing your policy for adjusting the storage unit temperatures. Bring the unit into the recommended range of temperatures or move the vaccines to another unit that is operating within the recommended range. Be sure to maintain the cold chain when transporting vaccines.

If the manufacturer's determination of viability indicates the affected vaccine is viable, upon review and confirmation of the manufacturer's determination, the VFC Program will give permission to use the vaccines that were marked "DO NOT USE."

In some cases, the manufacturer may issue a new beyond-use date (BUD). This means that the vaccine will expire before the date marked on the product. If that is the case, be sure to mark the product with the new BUD. If the product reaches its BUD date and has not been utilized, at the end of the BUD date remove vaccine from unit, report expired doses in VOMS and submit return in VOMS.

If the manufacturer states the vaccine is not viable, remove doses from unit, report expired doses in VOMS and submit return in VOMS.

The DC VFC Program may suspend vaccine ordering when a temperature excursion is discovered and maintain suspension until the situation is resolved. Timely submission of all required information will facilitate resolution and decrease the time vaccine ordering privileges are suspended.

Adjusting Storage Unit Temperatures

Storage unit temperatures may need to be adjusted over time. Thermostat adjustments should only be made by well-trained persons, e.g., the primary or backup vaccine coordinator or the medical director. It is recommended that the provider post a warning sign on all storage units stating, “Do not adjust temperature controls. Notify [name of responsible person] if adjustment is necessary.” Routine temperature adjustments should not be made during a busy workday when the unit door is frequently opened and closed.

The storage vaccine unit’s owner’s manual should be readily accessible and referenced when adjusting temperatures.

Remember that temperatures within any storage unit will vary at least slightly, even with normal use. Therefore, before making any adjustment:

- Confirm the unit is securely plugged into the power source
- Check the temperature of the storage unit
- Wait 30 minutes, without opening the door, to allow the temperature to stabilize and check it again to verify if the thermostat should be adjusted. If you believe there could be an issue with your data logger itself, use your backup device to confirm the temperature.

If you confirm that an adjustment is needed:

- Refer to the Owner’s Manual for detailed instructions.
- Turn the thermostat knob slowly to avoid going outside the correct temperature range and make a small adjustment toward a warmer or colder setting as necessary.
- Allow the temperature inside the unit to stabilize for 30 minutes without opening the door.
- Recheck the temperature.
- Repeat the steps as needed until the temperature has stabilized.
- If recommended by unit manufacturer, consider placing additional water bottles in the unit to help improve temperature stability.

If you are using a pharmaceutical-grade combination storage unit, please note that adjustments to the freezer temperature can adversely affect the refrigerator compartment temperature, possibly resulting in frozen vaccines.

Do not leave vaccines in a storage unit that does not maintain temperatures within the recommended range. If you are unable to stabilize the temperature in your unit within the required range, or temperatures in the unit are consistently at the extreme high or low end of the range, your vaccine supply is at risk. Use your emergency storage and handling plan and policies to identify an alternative unit with appropriate temperatures and sufficient storage space until the primary unit can be repaired or replaced.

Vaccine Expiration Dates

Understanding expiration dates is a key component of managing your vaccine inventory. Vaccine and diluent expiration dates indicate when the product must be discarded if it has not been used. These dates are printed on vials, manufacturer-filled syringes, and packages.

When the expiration date has only a month and year, the product may be used up to and including the last day of the month. If a day is included with the month and year, the product may only be used through the end of that day.

Beyond Use Dates

Sometimes vaccines must be used before the expiration date – by an earlier date known as the "beyond-use date" (BUD). The BUD replaces the expiration date and should be noted on the label along with the initials of the person making the change. BUD **shortens** a vaccine's viability – it does not extend.

Examples include:

- Reconstituted vaccines with a limited time frame for use once the vaccine is mixed with diluent. Be sure to read the package insert carefully.
- Multidose vials with a specific time frame for use once they have been punctured with a needle.

- When a vaccine is exposed to out-of-range temperatures. The manufacturer might determine the vaccine can still be used, but with a shortened expiration date.
- Frozen (or ultra-cold) vaccine is moved from freezer (or ultra-cold) to refrigerator. Follow manufacturer BUD guidelines.

Management of Expired, Spoiled and Wasted Vaccines

When managing expired, spoiled and wasted vaccine, providers must:

- **Remove** the vaccines from any storage unit that contains viable vaccines.
- Label vaccines “Do Not Use”.
- Report the expiry, spoilage or wastage in VOMS
- Return spoiled and expired vaccines within 6 months of the spoilage or expiration date.
- Dispose of wasted vaccines according to District disposal requirements.

Expired and Spoiled Vaccine

VFC vaccine determined to be nonviable as a result of expiry or spoilage must be returned to the distributor within six months of spoilage or expiration. This includes vaccine that is spoiled as a result of the following:

- Natural disaster/power outage
- Refrigerator too warm or too cold
- Failure to store properly upon receipt
- Spoiled in transit
- Mechanical failure
- Recall

The following wasted vaccine cannot be returned to McKesson:

- Vaccine drawn into the syringe but not administered
- Vaccine in open vial but doses not administered before Beyond Use Date or Expiration Date, as applicable
- Broken, lost or unaccounted for vaccine

Reporting Wastage, Spoilage, Expiry

Providers are required to do the following when they identify expired, spoiled, or wasted vaccine:

- Remove expired, spoiled, or wasted vaccine from storage units to prevent inadvertent administration (this includes wasted, spoiled, and expired diluents).
    - NOTE: Vaccines in quarantine (exposed to a temperature excursion, stored in unit and labeled "DO NOT USE" while viability is being determined) should remain in unit until viability is confirmed.
- Label all expired, spoiled, and wasted vaccine "DO NOT USE".
- Report vaccine storage and handling incident that result in vaccine loss, reasons for loss, and the number of doses involved in loss to the VFC program.
- Report wasted, spoiled and expired doses in VOMS
- Submit return for spoiled and expired doses in VOMS
- Provider should select "email" as method to receive return shipping label
- Provider must print and retain vaccine packing slip at time of return submission. This slip will go inside box with vaccine to be returned.
- Returns are processed during the first week of each month. All returns submitted for the previous month will be reviewed, processed and submitted to CDC. Upon processing, provider will receive shipping label to affix to outside of box
- Place packing slip inside box with vaccine to be returned, affix shipping label to outside of box, return to distributor.
- DO NOT return expired or spoiled vaccine to DC VFC Program
- **NOTE:** Private stock vaccine cannot be returned with VFC vaccine to McKesson.

Vaccine Handling and Preparation

It is just as important for providers to handle and prepare vaccines properly as it is to store them properly. Providers should follow best practices, including:

- Administering vaccines immediately after preparing them
- Preparing vaccines in a designated, clean medication area, away from any space with potentially contaminated items
- Checking expiration dates before preparing the vaccine (never administer expired vaccines)

- Reconstituting lyophilized vaccine with the diluent that came with the vaccine—nothing else
- Using a single-dose vial, which contains one dose, for only one patient
- Using a separate, sterile needle and syringe for each injection
- Discarding any pre-drawn doses no later than the end of the workday, or per the manufacturer's package insert (if sooner than end of workday)

When provider locations expect a high volume of patients who need vaccines (i.e., flu season, back-to-school vaccinations), providers should remember that:

- CDC does not recommend pre-drawing doses before they are needed
- CDC recommends using manufacturer-filled syringes as an alternative to pre-drawing doses.

Emergency Situations

Provider locations should plan ahead for emergency situations such as power outages, natural disasters, and equipment failure. They should include these plans in their Vaccine Management Plan so providers can follow the plan for protecting vaccines, including possible transport methods and alternative storage locations. Provider locations should keep supplies needed for emergency transport on hand or have ready access to them. Inspect alternative storage locations upon establishment, or at least once before an emergency. This allows provider locations to verify that the alternative location can properly maintain storage conditions for vaccine. If the alternative storage location changes, providers should inspect the new location, too.

Large clinics may have back-up power systems and a security system to alert appropriate staff in the event of a power outage. If provider locations use these, the back-up power systems should be tested quarterly and serviced annually based on manufacturer specifications for testing procedures and maintenance schedules.

Vaccine Inventory Accountability

Separating Pediatric Vaccine Stock

With respect to the VFC program, if a VFC provider serves and plans to vaccinate privately insured (non-VFC-eligible) populations, they should stock a separate vaccine supply for the specific vaccines they plan to offer non-VFC-eligible patients.

CDC is not requiring VFC providers to maintain a full stock of all VFC-provided vaccines for non-VFC-eligible patients if they do not plan to offer all VFC-provided vaccines to this population. This guidance includes, but is not limited to, RSV monoclonal antibody products.

- Example: VFC providers, including birthing hospitals, that serve both VFC-eligible and non-VFC-eligible patients indicated to receive RSV monoclonal antibody products are not required to maintain a separate stock of this product for any non-VFC-eligible patient they do not plan to immunize with this product.

If a VFC provider does not carry privately purchased stock, they are not permitted to use VFC stock on non-VFC-eligible patients.

If a VFC provider does have privately purchased vaccines in addition to public vaccines, they must clearly separate and label these two stocks of vaccines, unless the provider is approved to use a vaccine ordering replacement model.

Providers that plan to vaccinate any non-VFC-eligible patients should have a separate private inventory of vaccines for their non-VFC-eligible population.

Stocking Non-Routine Vaccines

CDC considers the following products* non-routine vaccines:

- Respiratory syncytial virus (RSV) maternal vaccine
- Mpox vaccine
- Pneumococcal polysaccharide (PPSV23) vaccine
- Meningococcal serogroup B (MenB) vaccine
- COVID-19 vaccine

**This list should not be considered comprehensive.*

Stocking non-routine, VFC-covered vaccines at all times may not be a viable option for a provider facility. DC VFC providers have options to make these vaccines available to VFC-eligible children, including:

- Maintaining a limited amount of stock
- Ordering non-routine vaccines as needed

If a VFC provider does not routinely stock non-routine VFC vaccines for VFC-eligible children, the provider location's Vaccine Management Plan must cover the procedure(s) for making these vaccines available to VFC-eligible patients.

The DC VFC Program strongly recommends providers stock all VFC-provided vaccines for which they have the VFC-eligible patient population.

Blended Inventory

Provider locations that are approved to use the replacement model for vaccine ordering do not have to maintain separate stocks of public and private vaccines. They can have a co-mingled vaccine inventory with "virtual" doses attributable to the public and private portions of inventory.

ONLY providers on the replacement model can blend VFC and non-VFC vaccine inventory.

Vaccine Borrowing

VFC-enrolled providers who are not on the replacement model are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Routine, planned borrowing of VFC vaccine is not permissible,** including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory.

All borrowed doses must be recorded on the DC VFC Vaccine Borrowing Report and reported to the District of Columbia Immunization Information System (DOCIIS).

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination.

Borrowed vaccine must be repaid dose for dose **within one month** and administered to the appropriate population.

The DC VFC Program will only approve vaccine borrowing when there are unforeseen delays or circumstances in vaccine supply, and when borrowing will not impact the ability of a VFC-eligible child to receive vaccine.

Hosting a temporary, mobile, off-site, satellite and community vaccination clinic without appropriate amounts of public and private vaccine does not qualify for borrowing.

Providers who have multiple incidents of inadvertent administration of federally-funded vaccines might be subject to further corrective action.

Vaccine Transfer

Proper vaccine inventory management plays a major role in preventing the need to transfer vaccines. However, even with proper inventory management, providers may experience a situation where they have vaccine stock that is soon-to-expire. To avoid wasting vaccine, short-dated vaccine can be transferred between VFC provider locations where practical—and as long as the cold chain is maintained. Providers must notify the DC VFC Program about short-dated vaccine at least 120 days in advance of vaccine expiry utilizing the Short-dated Vaccine Notification Form.

Provider must submit this notification 120–150 days before the expiration date of vaccines. Provider must notify VFC program of any vaccine doses that will expire before they can be administered. Without prior notification, provider may be held responsible for vaccine wastage. Provider is also responsible for transferring vaccine to another VFC facility.

Transfers should be rare. Providers are responsible for utilizing all ordered and delivered VFC vaccine.

Vaccine transfers can only occur:

- With the DC VFC Program's approval and direct guidance
- When a process is in place to ensure vaccine viability during transfer, as outlined in CDC's Vaccine Storage and Handling Toolkit
    - The process must include the use of a DDL with a current, valid Certificate of Calibration Testing for temperature monitoring during transport, as well as other appropriate equipment
- When temperature monitoring documentation validates that the vaccine has not been exposed to a temperature excursion (this documentation must be transported with the vaccine)

Vaccine Ordering Replacement Model

A vaccine ordering replacement model is a process that begins with providers supplying the initial vaccine stock for their patient population. As providers use doses for VFC-eligible children, the DC VFC Program replaces those doses on a regular basis.

The model allows providers to use their private funds to establish an initial vaccine stock. This stock is used to provide vaccination services for all the patients they serve. The model is intended for use by large health systems and hospitals, but it is not limited to only those types of providers.

Provider locations approved to implement a vaccine ordering replacement model must meet all VFC requirements, including:

- Operating within the National Center for Immunization and Respiratory Diseases (NCIRD) Policy for Grantee-Supported Vaccine Depots (as stated in the Centralized Vaccine Distribution Guide)
- Following proper storage and handling practices
- Receiving required site visits for the VFC program

Eligible provider locations must have the financial means to maintain a vaccine inventory sufficient to cover both their VFC and private patients they intend to vaccinate at all times. However, having financial means alone is not sufficient for approval. Providers must also be able to show that they have an electronic process for recording dose-level patient eligibility for each vaccination encounter—and that they can submit this information to the DC VFC Program.

Providers who would like to enroll on the vaccine replacement models must be able to meet the following criteria:

- Each vaccination encounter must include VFC screening and documentation of the patient's eligibility status for VFC vaccine.
- Ability to generate and submit a monthly report that demonstrates:
    - Patient information
    - Date of service
    - Administering facility
    - Patient VFC eligibility criteria
    - Vaccine administered
    - Documentation that billing practices adhere to VFC requirements
        - No charge for cost of vaccine
        - Administration fee in line with program requirements

Large health care systems that use a centralized pharmacy to redistribute vaccines to their clinics may only have vaccine shipped to the pharmacy if both the pharmacy and the clinic(s) are on the same campus.

It is not acceptable for a large health care system to use providers that use a centralized pharmacy to ship vaccine to offsite clinics.

CDC does not allow influenza vaccine to be included in a vaccine ordering replacement model.

CDC recommends that provider locations using the vaccine ordering replacement model identify and separate replacement doses for VFC vaccines. However, provider locations do not have to maintain separate stocks of public and private vaccines; that is, they can have a co-mingled vaccine inventory with "virtual" doses attributable to the public and private portions of inventory.

Vaccine Restitution

Vaccine restitution is the replacement of doses of VFC vaccine that are lost due to provider negligence.

The DC VFC Program may require replacement of spoiled, expired or otherwise wasted VFC vaccine if the DC VFC Program determines that the vaccine loss was due to provider negligence. Providers must replace vaccine on a dose-for-dose basis. This allows doses to be restored for the VFC-eligible children for whom they are intended. Financial payment as a form of restitution will not be allowed under any circumstances.

In the event that a provider must replace lost VFC doses, the provider must:

- Only administer replaced doses to children who are eligible for VFC.
- Replace doses based on the same proportion as the lost doses' original funding source
    - E.g, 10 VFC doses were wasted due to provider negligence, 10 privately procured replacement doses must be administered to VFC-eligible children
- Contact the DC VFC Program for guidance on handling any replaced vaccines that cannot be administered to the eligible population.
- Submit a receipt for vaccine purchase that reflects the dose-for-dose replacement within 90 days of vaccine loss. If the provider location cannot achieve this within 90 days, the DC VFC Program will discuss an alternative replacement plan with the provider that should be met within six months.
- Provide required documentation related to restitution. This includes documentation of administration of replacement doses to VFC-eligible children.

Temporary, Mobile, Off-Site or Satellite Clinics

Some providers may conduct temporary, mobile, off-site or satellite clinics. These opportunities can improve access and vaccination coverage for VFC-eligible children. However, these situations require additional provider oversight and vaccine accountability.

Providers may only administer DC VFC supplied vaccines within the District of Columbia.

These alternative provider locations must adhere to all general requirements for the DC VFC Program, including screening and documenting VFC eligibility. They also must maintain enhanced practices for storage and handling, which include the following:

- Providers should base the number of VFC vaccines transported to a temporary, mobile, off-site or satellite clinic on the expected anticipated number of VFC-eligible children who will be served.
- Vaccines may be transported - not shipped - to a clinic site using procedures for vaccine transportation outlined in CDC's Vaccine Storage and Handling Toolkit. These procedures include transporting vaccines to and from the site at appropriate temperatures and using appropriate equipment. They also include monitoring and documenting temperatures using a DDL with a probe in buffered material.
- Upon arrival at the clinic site, vaccines must be stored correctly to maintain an appropriate temperature throughout the clinic day.
- Providers must review and document temperature data every hour during the clinic using a DDL with a digital display and a probe in buffered material.
- At the end of the clinic day, providers must assess temperature data before placing vaccines back into storage units. This prevents administration of vaccines that may have been compromised.

If vaccines are exposed to temperature excursions at any time, providers must label those vaccines "Do Not Use" and follow DC VFC Program excursion protocol.

Enhanced oversight for community vaccinators or providers conducting temporary, mobile, off-site, or satellite clinics also includes:

- Vaccine ordering:
    - Providers must order adequate VFC supply in advance for all VFC-eligible patients they intend to vaccinate at the event.
    - Providers must order adequate non-VFC supply in advance for all non-VFC-eligible patients they intend to vaccinate at the event.
    - Hosting a temporary, mobile, off-site, satellite and community vaccination clinic without appropriate amounts of public and private vaccine does not qualify for borrowing.
- Records of vaccine transport:
    - These must detail the type of vaccine(s) as well as the quantity being transported.

  - Providers should maintain DDL temperature monitoring for temporary, mobile, off-site or satellite clinics.
- Records of vaccine administration:
  - All vaccine administrations must be reported to DOCIIS within 24 hours of administration.

Best practices for vaccine handling during a temporary, mobile, off-site, or satellite clinic include the following:

- Not drawing up vaccines before arriving at the clinic site
- Not pre-drawing doses at the clinic site before they are needed
- Using manufacturer-filled syringes, if possible, instead of pre-drawing vaccines
- Pre-drawing at the clinic no more than one multidose vial (MDV) at one time
- Monitoring patient flow to avoid drawing up unnecessary doses
- Discarding any remaining vaccine in pre-drawn syringes at the end of the workday
  - Report all wastage in VOMS

Find more information on handling and preparing vaccine in CDC's Vaccine Storage and Handling Toolkit and on CDC's vaccine administration website.

Chapter 11: Vaccine Administration Reporting Accountability

Vaccine Administration Reporting

All immunizations given in the District of Columbia are required to be reported to DOCIIS within 24 hours of administration.

Providers must account for all doses of federally purchased vaccines that they receive. Providers must:

- Report all administrations to DOCIIS within 24 hours of administration.
- Include all required fields when reporting every vaccine administration, including but not limited to:
  - Vaccine Funding Source
  - Patient VFC Eligibility
  - Vaccine CVX
  - Vaccine NDC (unit of sale)

- Manufacturer
- Lot Number
- Administration date
- Expiration Date
- Administration Facility (VFC PIN)
- Vaccination volume of administration
- Vaccine unit of measurement (e.g., mL)
- Vaccination administration route
- Vaccination administration body site
- Patient first and last name
- Patient Date of Birth

Funding Source and Patient Eligibility Reporting

Funding Source Code Values Include:

HL7 code	Description
PHC70	**Privately** funded vaccine stock (includes any external vaccine stock, in addition to Medicare eligibility)
VXC51	**VFC** Publicly funded vaccine stock (this includes any of the VFC eligibility categories (Medicaid, uninsured, underinsured, American Indian/Alaska Native)
VXC52	Public non-VFC: **317**
VXC50	Publicly funded vaccine stock outside of VFC or 317
VXC2	State-funded vaccine (NOT VFC or 317)

Patient Eligibility Code Values Include:

HL7 code	Description
V01	Not VFC Eligible
V02	**VFC** eligible – Medicaid/Medicaid Managed Care
V03	**VFC** eligible - Uninsured
V04	**VFC** Eligible – American Indian/Alaska Native
V05	**VFC** eligible – Underinsured at FQHC/RHC
V23	State Program Eligible (317) - under/un-insured adults
V24	Medicare

VFC funding source and patient eligibility codes are highlighted in the table above. Both funding source and patient eligibility must be reported with every vaccine administration.

For questions or support with DOCIIS connectivity, please contact the DOCIIS data quality team at dociis.helpdesk@dc.gov.

Chapter 12: Fraud and Abuse

Federal fraud and abuse laws apply to the DC VFC Program. The terms "fraud" and "abuse" related to VFC are consistent with the definitions in Medicaid regulations (42 CFR § 445.2).

- **Fraud:** Fraud occurs when a person makes an intentional deception or misrepresentation with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state laws.
- **Abuse:** Abuse occurs when provider practices that are inconsistent with sound fiscal, business, or medical practices result in:
    - An unnecessary cost to the Medicaid program or
    - Reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.
- Abuse also includes:
    - Actions that result in an unnecessary cost to the immunization program, a health insurance company or a patient, or
    - practices that result in unnecessary cost to the Medicaid program.

The following are examples* of non-compliance that may result in fraud and abuse, if repeated and not addressed:

- Failing to comply with any part of the Provider Agreement
- Providing VFC vaccine to children who are not eligible for VFC
- 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., orders do not match the location's Provider Profile)
- Wasting VFC vaccine
- Denying VFC-funded vaccine to VFC-eligible children because the parents are unable to pay the administration fee
- Failing to screen for VFC eligibility status—and document that status—at each visit
- Failing to maintain VFC records for at least 3 years
- Failing to fully account for VFC-funded vaccine

- Failing to properly store and handle VFC vaccine

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

Preventing Fraud and Abuse

Upon enrollment into the VFC program, new immunization providers will receive an educational training session from the program to explain the VFC program in detail. Providers will be educated about the program's purpose, eligibility requirements, and program compliance requirements.

Vaccine management staff must review all incoming vaccine orders and reports of doses administered. Vaccine management staff should address any inconsistencies on these reports (e.g., ordering more vaccines than is usually ordered, report of wasted/expired vaccine) quickly and make adjustments as appropriate.

Ensure administered doses are fully reported to DOCIIS within 24 hours of administration with all required fields.

Ensure VFC supplied vaccine is administered ONLY to VFC eligible patients.

Screen for patient eligibility at every immunization encounter.

Providers may be required to replace, dose for dose, any vaccines that are unaccounted for, spoiled, expired or deemed preventable loss. In these circumstances, providers are required to develop corrective action plans and submit proof of replacement vaccine.

All VFC sites receive a site visit at least once every 24 months.

VFC investigators may conduct additional site visits as necessary, including unannounced visits, for sites needing additional support.

Corrective Action Plans

Whenever the VFC program discovers issues with vaccine management, a provider-specific Corrective Action Plan is developed. Corrective Action Plans may include, but are not limited to:

- Education of providers and staff.
- Restitution of vaccine on a dose-for-dose basis as stipulated in the Provider Agreement.
- In the event of administration of compromised vaccine: patient notification and revaccination.
- Provider replacement of storage units or temperature monitoring devices.

Corrective actions may be necessary when the VFC program discovers that the provider's actions resulted in the following:

- Expired or Spoiled Vaccine
- Wasted Vaccine
- Negligent Waste: Viability of vaccine compromised as a direct result of negligence by the provider
- Vaccine administered to non-VFC eligible individuals
- Administration of compromised vaccine
- Billing outside of allowable VFC billing practices

Referrals to Other Agencies

There are times when the VFC program must make referrals to other agencies. These agencies may include:

- The District of Columbia Board of Medicine or other appropriate licensing or regulatory agency.
- The District of Columbia Office of the Inspector General
- The District of Columbia Department of Healthcare Finance

Chapter 13: Compromised Vaccine Administration and Revaccination

Whenever potentially compromised vaccine is administered or other vaccination errors occur, the provider must notify patients/guardians of the error and provide counseling to the patient/guardian on the need for revaccination. Providers must sign a Revaccination Plan issued by the VFC program which includes the following:

- Determine which persons received the compromised or potentially compromised vaccine doses
- Notify the persons (or guardians) of the affected population, in writing, that they received compromised or potentially compromised vaccine. The letter must be reviewed and approved by the VFC program prior to distribution to the affected parties.
- Provide counseling to those individuals.
- Revaccinate those individuals at the provider's cost using privately purchased vaccine.
- Providers must complete the activities within 180 days of signing the Revaccination Plan.
- Providers are encouraged to follow this same course of action for any privately ensured patients who receive compromised or potentially compromised vaccine.

- Failure to fulfill the terms of the Agreement may result in disenrollment from the VFC program and possible referral to outside agencies.
- If the provider refuses or cannot notify patients (e.g., action is taken against the provider's license by the District of Columbia Board of Medical Examiners), the VFC program may conduct patient notification. Patients will be advised to consult a healthcare provider for counseling and revaccination, as appropriate.

Chapter 14: National Childhood Vaccine Injury Act and VAERS

The National Childhood Vaccine Injury Act (NCVIA) of 1986 was enacted to provide a cost-effective arbitration and compensation system for vaccine injury claims and reduce the potential liability of vaccine manufacturers. It also created a system for reporting and tracking adverse events related to vaccinations. Healthcare professionals who administer vaccines must adhere to the following NCVIA requirements when administering vaccinations.

Vaccine Information Statements (VISs) are published by the CDC and provide information to vaccine recipients about the risks and benefits of the vaccine. **Providers must ensure that patients receive a current vaccine-specific VIS to the vaccine recipient or his/her guardian at each vaccination visit.** In the event that an immunizing product does not yet have a VIS issued, providers must provide the immunization information material recommended by CDC.

VISs are updated periodically, and CDC maintains current print and translated versions on their website.

Visit the CDC VIS webpage at www.cdc.gov/vaccines/hcp/vis/index.html.

VAERS is a national vaccine safety surveillance program created through the NCVIA and co-sponsored by the CDC and the Food and Drug Administration (FDA). VAERS provides a nationwide system for reporting, analyzing, and publishing information on adverse events related to vaccines.

The NCVIA requires healthcare providers to report to VAERS:

- Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of vaccine.
- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination.

You may also report any adverse event that occurs after the administration of a vaccine licensed in the U.S., even if you are unsure whether a vaccine was the cause. vaers.hhs.gov.

Vaccine Charting Requirement

The NCVIA requires that the following information be documented on the patient's paper or electronic medical record or on a permanent office log:

- Name of the vaccine
- Vaccine manufacturer
- Lot number of the vaccine
- Date the vaccine is administered
- Name, office address, and title of the healthcare provider administering the vaccine
- VIS edition date located in the lower right corner on the back of the VIS. When administering combination vaccines, all applicable VISs must be given, and the individual VIS edition dates recorded.
- Date the VIS was given to the patient, parent, or guardian

The federally required information must be both permanent and accessible.

Chapter 15: Site Visits

To ensure the quality of federally-funded vaccine and the integrity of the VFC program, the VFC program is required by the CDC to conduct site visits to enrolled providers. Visits help determine a provider's compliance with program requirements. This includes identifying potential issues with vaccine accountability and determining whether vaccines are being handled, stored and administered in accordance with the laws and policies governing the federally-funded program.

The review and evaluation of provider practices involves assessing verbal, written, and visual evidence encountered during the visit to determine if provider sites are following the requirements of the program.

The goals of these site visits are to:

- Identify areas where providers are doing well and areas needing additional follow-up.
- Identify the educational needs of providers to support them with meeting program requirements.

- Ensure that eligible individuals receive properly managed and viable vaccine.
- Develop and strengthen ongoing relationships.

Enrollment Visit

Providers new to the VFC Program will receive an enrollment site visit. This visit will review the site's readiness to receive and administer VFC vaccine.

VFC Compliance Site Visit

VFC compliance site visits focus on provider compliance with VFC program requirements, including eligibility documentation and proper vaccine storage and handling, and provide an opportunity to perform formal provider training and education. After enrollment, a new DC VFC provider will receive their first compliance visit within 6 months. After the initial compliance visit, active DC VFC providers receive a compliance site visit at least once every 24 months.

Storage and Handling Site Visit

VFC enrolled providers may receive an unannounced or announced storage and handling visit. The goal of this visit is to provide oversight, guidance and education, ensuring viability of VFC vaccine and adherence to best practices.

Follow Up Visit

VFC staff will review progress after a compliance visit. If a site continues to encounter issues, follow up contacts and visits will continue until issues have been resolved. Issues identified during a site visit must be addressed in the specified time frame.

Immunization Quality Improvement Visit (IQIP)

VFC enrolled providers will receive an immunization quality improvement for providers (IQIP) visit by the Immunization Division's IQIP team. The goal of the IQIP visit is to assess immunization coverage rates and provide ongoing education regarding methods to increase immunization coverage levels. The IQIP team assists sites in utilizing tools within and exterior to DOCIIS to drive immunization rates. Additionally, this visit helps analyze clinic flow and identify practices that may be affecting immunization rates and delivery of vaccine services to patients. The IQIP team can be reached at imm.qi@dc.gov.

Please see the DC Immunization Quality Improvement for Providers (IQIP) Provider Library for immunization provider resources.

Resources and Links

VFC Resources

DC VFC Provider Resources Webpage

- VFC Annual Provider Profile Form
- VFC Vaccine Daily Temperature Log
- Change of Information Request
- Short-dated Vaccine Notification

CDC VFC Webpage

CDC VFC Operations Guide

CDC Vaccine Storage and Handling Toolkit

You Call the Shots Modules

DOCIIS User Guide

Immunization Practices

Immunization Schedules:

- AAP
- AAFP
- ACOG

Immunize.org

ACIP Vaccine Recommendations and Guidelines

ACIP Immunization Schedules

Epidemiology and Prevention of Vaccine- Preventable Diseases: The Pink Book

VAERS - Vaccine Adverse Event Reporting

Vaccine information Statements

Provider Library

IQIP Provider Library

- Strengthen Vaccination Communications
    - Early Childhood One Pager Booklet for Families
    - Adolescent Vaccination One Pager for Families
- DOCIIS Technical Support
- VFC Provider Meeting Slides
- CDC IQIP & Strategy Overview Documents

Community Resources

vaccines.dc.gov

Docket