2024 DISTRICT OF COLUMBIA

Vaccines For Children Operations Manual

DC | HEALTH
GOVERNMENT OF THE DISTRICT OF COLUMBIA

GOVERNMENT OF THE DISTRICT OF COLUMBIA
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Introduction

The District of Columbia Vaccines for Children Program Provider Manual provides an overview of the Vaccines for Children (VFC) program and summarizes requirements and responsibilities. Additional materials and trainings are available and regularly provided by the DC VFC Program and the Centers for Disease Control and Prevention (CDC). The Government of the District of Columbia Department of Health's (DC Health) VFC program appreciates the efforts of providers who administer vaccines and recognizes the vital role providers play in serving the needs of our underserved and at-risk populations. Vaccinating all children and adolescents in accordance with Advisory Committee on Immunization Practices (ACIP) recommendations is the best way to protect individuals and communities against vaccine preventable diseases. The VFC program makes vaccines available to children and adolescents who might otherwise go unvaccinated because of an inability to pay for the vaccine.

For the purposes of this document the word "vaccine" refers to all vaccines and immunizing agents 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 System
BUD	Beyond-use date
SDV	Single Doses Vials
MDV	Multidose Vials

Chapter 1: VFC Program Overview

The Vaccines for Children (VFC) Program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of an inability to pay.

Publicly purchased vaccines for eligible children are supplied at no charge to VFC-enrolled public and private providers in all 50 U.S. states, the District of Columbia and U.S. territories.

Benefits of the VFC Program

- Provides cost savings to states, territories, and DC through bulk purchase of vaccines at lower prices using CDC's contracts.
- 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.

How the VFC Program Works

- The CDC awards federal funding to state health departments and certain local and territorial public health agencies to implement and oversee VFC program activities.
- State, local, and territorial public health agencies actively enroll public and private providers into the program to meet the specific needs of the jurisdiction.
- The CDC purchases vaccines at a discount from manufacturers.
- The CDC distributes the vaccines at no charge to enrolled VFC providers.
- The CDC leads policy development, operational oversight, and technical assistance to state, local, and territorial public health agencies.
- State, local, and territorial public health agencies manage and implement the VFC program within their jurisdiction.

Advisory Committee on Immunization Practices

Established in 1964, the Advisory Committee on Immunization Practices (ACIP) is a federal advisory committee that provides guidance on the most effective means to prevent vaccine-preventable diseases. In 1993, Congress gave ACIP unique legal authority to determine recommendations for routine administration of vaccines to children and adults. Major functions of ACIP are:

- Develops technical recommendations on vaccine use and immunization practices.
- Approves vaccines provided through VFC.
- Recommends immunization schedules that align with the recommendations of other advisory groups, such as the AAP and the AAFP.

After approval, ACIP recommendations are published in the Morbidity and Mortality Weekly Report (MMWR), a scientific periodical prepared by the CDC, and approved recommendations become the standard for administering the vaccine(s). Once a new or amended recommendation is published, ACIP approves it for inclusion in the VFC program by passing a VFC resolution. VFC resolutions determine which vaccines are available through the VFC program including dosage, schedule, and contraindication information.

Chapter 2: VFC Eligibility

VFC is an entitlement program that requires screening and documentation of eligibility status for all patients from birth through 18 years of age. The purpose of this chapter is to describe VFC eligibility and provide information on how to determine which eligibility category applies in various situations. For children to receive vaccines through the VFC program, **eligibility screening and documentation must take place at each immunization visit prior to immunization**. All providers and their staff must fully understand the VFC eligibility categories and perform this basic program requirement.

The only factors considered when screening for VFC eligibility is age and whether the child meets the definition of at least one of the VFC categories described below.

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

- **Medicaid-eligible or Medicaid-enrolled:** A child who is eligible for the Medicaid program (including children who have health insurance covered by the DC Medicaid program.) Children enrolled in DC Healthcare Alliance are eligible for VFC vaccine.
- **Uninsured:** A child who has no health insurance coverage.
- **American Indian/Alaskan Native:** As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).
- Underinsured:
    - **NOTE:** Underinsured children are eligible to receive VFC vaccines only through a FQHC in the District of Columbia.
    - A child who has health insurance, but the coverage does not include vaccines, or
    - A child whose insurance does not cover all ACIP-recommended vaccines. This child would be eligible to receive those vaccines not covered by insurance.

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 has not yet met plan's	No	Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine

	deductible or paid for other services received at visit		and its administration because the plan's deductible has not been met.
	Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit and has Medicaid as secondary insurance	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 fixed dollar limit is met Underinsured after the fixed dollar limit is reached
	Has health insurance, but plan does not cover any vaccines	Yes	Underinsured. With implementation of ACA, this situation should be rare.
	Enrolled in a Health Care Sharing Ministry	Depends	• Uninsured unless plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by the plan • Insured if plan is recognized by the state insurance department and covers vaccines • Underinsured if plan is recognized by the state insurance department and does not cover all ACIP-recommended 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
	Has private health insurance that covers all vaccinations and is AI/AN	Yes	AI/AN. However, provider should choose the eligibility category most cost-effective for the child and family.
	Has Medicaid and is AI/AN	Yes	Medicaid or AI/AN. Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family.

Children with private health insurance (who are not Medicaid-eligible, Medicaid-enrolled and/or AI/AN) whose insurance covers the cost of vaccinations are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration are denied payment by the insurance carrier because the plan's deductible has not been met. Occasionally, children may be VFC-eligible under more than one eligibility category.

A provider must select and document the VFC eligibility category that will require the **least amount of out-of-pocket expenses** to the parent/guardian for the child to receive necessary immunizations. For example: Children that are both AI/AN and Medicaid-eligible, either eligibility may be documented. However, Medicaid should be used for the administration fee as it is the least out of pocket expense.

Some children may have a private primary health insurance plan with Medicaid as their secondary insurance. These children **are considered VFC-eligible** because of their Medicaid enrollment. However, their parents **are not required to participate in the VFC program**. There are billing options for the parent and provider in this situation. **The parent of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee**.

NOTE:

- Eligibility screening and documentation must occur at each immunization visit regardless of insurance type.
- Providers must maintain documentation for a minimum of three years.
- Patient eligibility status must be documented in the District of Columbia's Immunization Information System (DOCIIS). Immunizations must be reported into DOCIIS within 24 hours of vaccine administration, regardless of age (22-B DCMR 129)1.

Chapter 3: Location of Service – Special Circumstances

SCHOOL-BASED CLINICS

Children who receive vaccines in a school-based clinic must not automatically be considered VFC-eligible. All children must be screened and their eligibility documented prior to administering a VFC vaccine.

PATIENTS FROM A NEIGHBORING STATE

Providers who administer VFC vaccine to Medicaid-eligible child from a neighboring state must be a Medicaid-enrolled provider for the state where the Medicaid VFC-eligible child resides to receive reimbursement for the administration fee from the neighboring state's Medicaid program.

STD, FAMILY PLANNING CLINICS, AND JUVENILE DETENTION FACILITIES

1 (DCR Vol 68_No 33 Aug 13, 2021 (pg. 008156-008162)

Family planning clinics, sexually transmitted disease (STD)/HIV clinics, and juvenile dentition facilities may have special VFC eligibility circumstances. These facility types should contact DC VFC Program for more details regarding enrollment and patient eligibility.

FEDERAL QUALIFIED HEALTH CENTERS (FQHC)

Community-based Healthcare Providers who offer services in underserved areas. This may include Community Health Centers, Migrant Health Centers, health facilities servicing the unhoused and other specific population groups.

Chapter 4: VFC Billing Practices

VFC providers must adhere to proper billing practices for vaccine administration fees and understand that VFC vaccines are provided at no cost to the provider and eligible children.

Insurance type and Current VFC Eligibility must be indicated in the DOCIIS record/Vaccine administered report.

There are two costs associated with a vaccine, the cost of the vaccine and the administration fee. As part of the billing requirements of the VFC program, providers must not charge patients, Medicaid, or private insurers for the cost of VFC vaccines.

Vaccine Administration Fee

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 per vaccine dose (not per antigen).

For Medicaid VFC-eligible children, the provider must accept the reimbursement for immunization administration set by DC Medicaid or contracted Medicaid health plans.

If a parent cannot afford to pay the administration fee, the fee must be waived, and the vaccine (s) must be given to the VFC patient. Providers **must not deny access** to federally purchased vaccine to an established patient who is unable to pay the administration fee and **may not send the unpaid fee to collections**. Provider locations that choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.

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 5: VFC Provider Enrollment Criteria Overview

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 and younger.
- The Medical Director or equivalent signing the Provider Agreement must have a valid, active Medical License issued by the District of Columbia Board of Medicine and ability to administer vaccines under DC law. Specialty locations (e.g. school-based faculties, juvenile detention centers, pharmacies, etc.) must have a Medical Director with the highest-ranking clinical license.
- Provider and provider staff must not be included on the Office of the Inspector General List of Excluded Providers.
- Ability to follow all VFC program requirements, policies, and procedures, 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.
- Maintain Correct storage unit and digital data loggers with current certificates of calibration.
- Be open at least 4 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 with prospective providers.

Chapter 6: Key Clinic Staff Responsibilities

MEDICAL DIRECTOR

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

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

- Annual submission of a provider profile representing populations served by the practice/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 and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet the eligibility criteria outlined in Chapter 2: VFC Eligibility.
- Offer **all** ACIP-recommended vaccines and immunizing agents and comply with the immunization schedules, dosages, and contraindications that are established by ACIP unless:
    - Provider is a specialty provider servicing a select population that will only need a subset of ACIP recommended vaccines
    - 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;
    - The particular requirement contradicts DC law, including laws pertaining to religious, medical or 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, including:
    - Not billing for cost of vaccine when administered to VFC-eligible children.
    - Vaccine administration fee to non-Medicaid VFC-eligible children, if billed, does not exceed federal administration fee cap per vaccine (not per antigen).
    - Accepting the reimbursement for immunization administration set by DC Medicaid or contracted Medicaid health plan(s).
        - If a vaccine administration fee is charged within the allowable cap, only a single bill is issued to the patient after the date of service and within 90 days of vaccine administration.
    - Agreeing to not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian is unable to pay the administration fee.
        - Agreeing to not send unpaid administration fees to collections.
- Ensure that a current Vaccine Information Statement (VIS) (and/or other immunization information materials, as applicable) is distributed each time a vaccine is administered and maintain record in

accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Agree to comply with the 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;
- Refrigerator and freezer storage units and temperature monitoring equipment must meet the VFC storage and handling requirements;
- Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
- Agree to participate in VFC program compliance site visits, including unannounced visits, and other educational opportunities associated with VFC program requirements.
- Agree to replace vaccine purchased with federal funds that are deemed non-viable due to provider negligence on a dose-for-dose basis. Providers are expected to notify and revaccinate, at their own cost, any child who received compromised or potentially compromised vaccine due to provider negligence.
- Agree to register as a provider with DOCIIS.
- Report the administration of all vaccines within twenty- four (24) hours of providing any vaccine dose, regardless of age of the vaccinated patient.
- Understand that the provider or the VFC program may terminate the Provider Agreement at any time and all 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 staff are educated in proper vaccine ordering, inventory maintenance, and storage and handling practices.
- Ensure that all staff members who receive deliveries and/or handle or administer vaccines are familiar with storage and handling policies and procedures at the facility, and confirm that all policies are accessible to 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, e.g., vaccine storage equipment, shipping address, delivery hours, office email address, during the enrollment year.
- The medical director is responsible for ensuring that their staff is ordering an appropriate amount of vaccine to vaccinate the provider's eligible population until the next scheduled order date. Medical directors are encouraged to keep vaccine orders to the assigned interval to reduce the risk of vaccine expiration and loss due to storage and handling issues. Providers are expected to have enough vaccine on hand to cover anticipated and unanticipated delays in vaccine shipment, e.g., natural disasters that might interrupt delivery, holidays, unexpected ordering system outages. It is suggested that provides maintain a safety stock of one month.
- The medical director will be held accountable for program compliance for the entire organization. The VFC program provides education during the enrollment visit and all subsequent site visits. The VFC program also requires primary and backup vaccine coordinators to complete educational programs annually.
- It is the medical director's responsibility to ensure that all staff members who receive deliveries and/or handle or administer vaccines are familiar with storage and handling policies and procedures at the facility. All policies must be accessible to staff. Privately purchased vaccines should be handled in accordance with the standards outlined in the manufacturers' instructions and the CDC's Vaccine Storage and Handling Toolkit.

Providers should offer storage and handling training to all vaccine management staff:

- as part of new employee orientation
- annually
- when new vaccines are added to inventory
- when recommendations for storage and handling of vaccines are updated

Record the names of trainings, dates, and participants of all trainings.

PRIMARY VACCINE COORDINATOR AND BACK-UP VACCINE COORDINATOR

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. Coordinator responsibilities include:

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 Accountability and 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 VFC program and must be consistently present during normal business hours. The VFC program requires that primary and back-up vaccine coordinators complete annual training (every 12 months). Proof of completion must be submitted to the VFC program.

NEW COORDINATORS

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

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 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 and conditions of the VFC program. The Provider Agreement is the final step in the enrollment process and is signed through the Vaccine Ordering and Management System (VOMS). A VFC provider cannot order or receive VFC-purchased vaccine without a provider agreement.

VFC Profile

This form captures information about the practice, including the number of VFC-eligible children and non-VFC-eligible children served by 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.

- A unique PIN number will be assigned to your site to use as facility identification and administration reporting.
- Each office location that administers federally funded vaccine must have its own PIN number.

Vaccine Management Routine & Emergency Plan:

This form is the plan the site will follow in case of emergency and who is responsible for emergency activities. It includes contact information for all responsible persons.

Provider Education

All staff involved in vaccine management must complete required trainings and remain up-to-date on trainings. These include CDC You Call the Shots Modules 10 and 16:

- 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

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 Immunization Division requires that providers electronically connect to DOCIIS through our provider onboarding process.

iWeb is the system to use 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)
- Placing orders (on established cadence, monthly for most, during first week of month)

As part of the enrollment process, the VFC team will connect vaccine coordinators with the DOCIIS Access Specialist to begin the steps for DOCIIS training.

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

Ordering

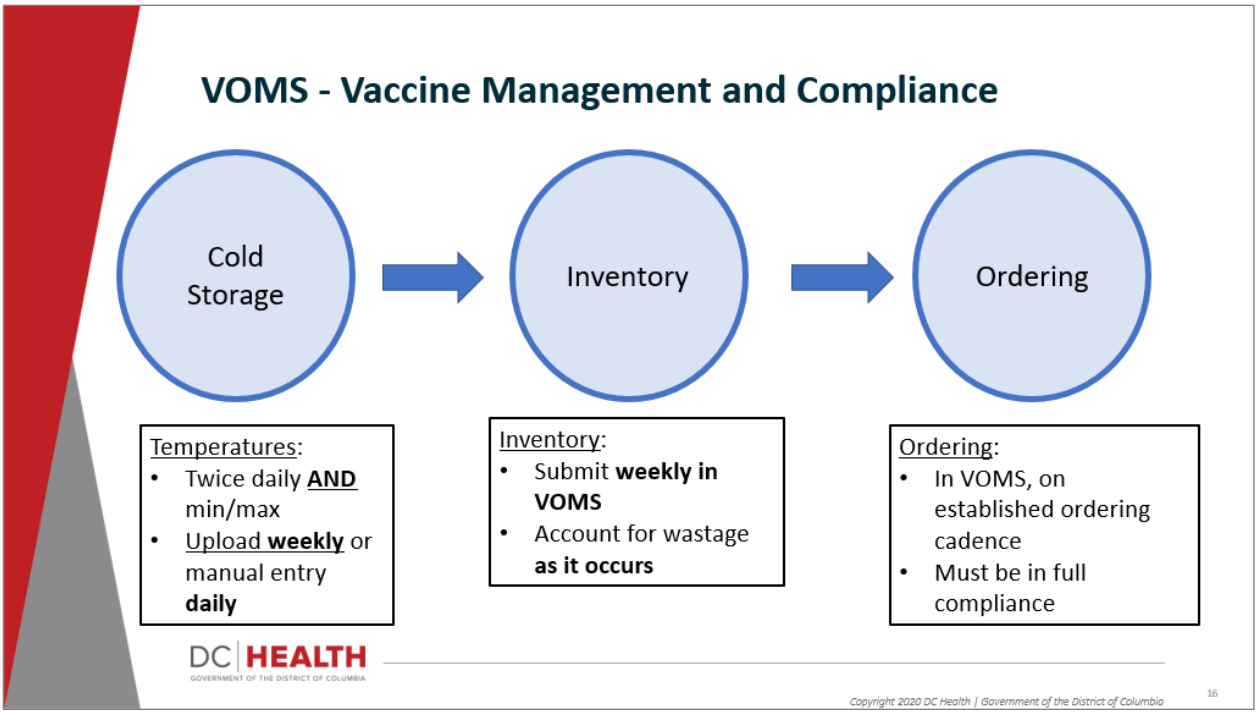
Enrolled providers are assigned an ordering frequency based on the size of their reported eligible population. Providers must submit a current profile every 12 months or more frequently if the number of children served changes or the status of the facility changes during the calendar year.

The ordering frequency may be adjusted over time based on the number of administered doses.

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

Most providers will submit orders on a monthly basis. 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. VFC flu orders can be placed outside of the schedule during flu season. 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 VFC team will review and verify the required elements prior to order approval.



Short-dated Vaccine Notification

Providers should notify the VFC Program of any vaccine doses that will expire before they can be administered. 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. A member of the VFC team will review the notice and communicate next steps.

It is important that providers constantly assess and reassess their patient population to reduce the need to transfer or waste vaccines. VFC orders in VOMS should be realistic for the site's needs. Vaccine stock should be checked for expiration dates weekly or biweekly to avoid expired vaccines. Stock should be rotated on a frequent basis and providers must routinely administer vaccines with the earliest expiration dates first. If you are seeing a low amount of administration, resubmit a VFC Profile form to change your order schedule.

Short-dated vaccine notification forms can be found online here:

- dchealth.dc.gov/sites/default/files/dc/sites/doh/service_content/attachments/2024-04-Short-Dated-Vax-Notification-form-IA.pdf

Order Status

Order status can be checked in VOMS. If the vaccine order has not been received, or there are issues creating and/or submitting an order, please contact the VFC team.

DC VFC Vaccine Supply Policy

The DC VFC program allows all participating providers to choose the brand of vaccines they wish to order, when applicable, from all ACIP-recommended vaccines available for order through the VFC program. The VFC Program may override provider preference at times to ensure equitable distribution and access. Special circumstances such as vaccine allocation (quantity of a given product available to awardee to distribute to providers is restricted by CDC), shortage or other restrictions in supply may lead to modifications in orders.

Providers choice of vaccine brand is subject to the following:

- Provider must plan and order only products that the provider plans to use.
- Provider must notify the 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 plan to completely use all vaccines in inventory of the previously ordered product and/or integrate the use alongside the newly selected product, ensuring all vaccines are completely used before their expiration dates.
- Understand that a request to transfer vaccines due to a change in vaccine brand/choice will not be accepted.
- Understand that a provider is responsible for the replacement (dose for dose) of any vaccine that becomes unusable due to brand changes.

Providers who face **unanticipated** vaccine shortages between scheduled orders can contact the 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 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 national shortage of a particular vaccine.
- Providers have not completed the re-enrollment process.
- Providers have a history of not submitting required reports to VFC.
- Providers have not met requirements of the VFC program.

Chapter 9: VFC Annual Review and Biannual Reenrollment

Reenrollment Every Two Years

Providers are required to re-sign the provider agreement every two years in VOMS, unless a significant change in the site's operations necessitates resubmitting an agreement before the two-year mark.

- A change in the site's medical director will require resubmission of a provider agreement.

Renewal Every Year

The annual renewal packet must be completed by December 31st each year to remain active and compliant in the VFC Program.

The renewal packet consists of:

- The Patient Population table representing populations served by the practice/facility in the last 12 months. The provider must submit more frequently if:
    - The number of children served changes, or
    - The status of the facility changes.
- Valid certificates of training. The VFC Program requires completion of CDC "You Call the Shots" Modules 10 and 16 and strongly recommends Module 18.
- A new Vaccine Management Plan or a signed attestation form indicating that the current Vaccine Management Plan is up to date and accurate.

IMPORTANT: Providers who fail to complete the required renewal and re-enrollment 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,
- Re-sign a new provider agreement,
- Receive an enrollment 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 disenrolled from the VFC Program. Federally funded vaccine will be removed from the office by VFC Program staff.

Provider Disenrollment

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 disenroll must complete the following:

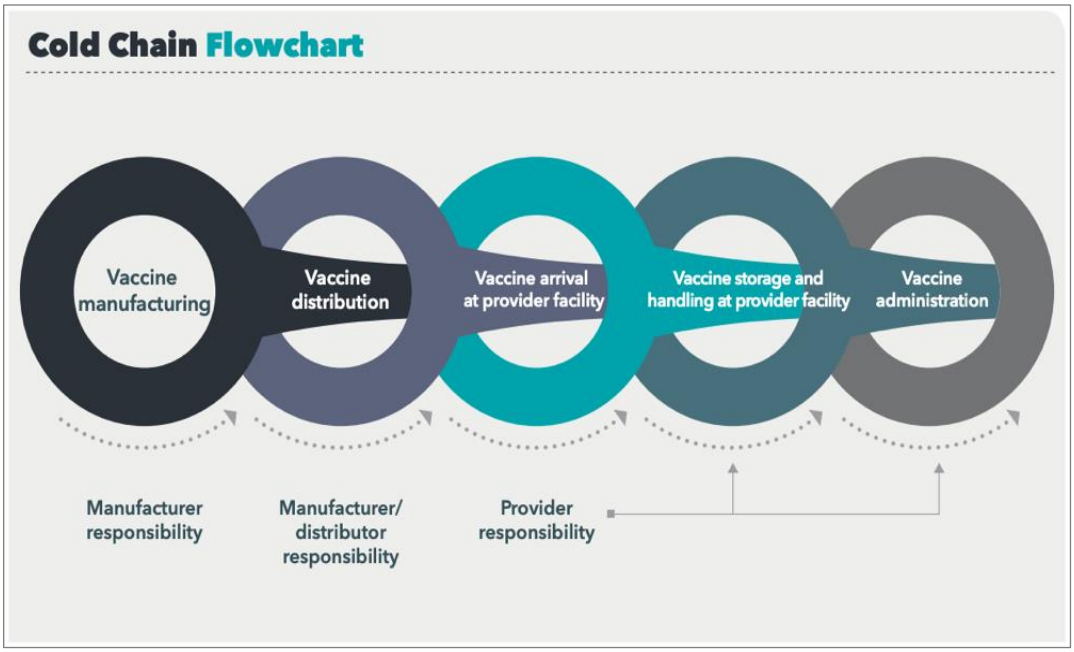
- Complete the Provider Change of Information form.
- Schedule a practice close-out visit to collect a final inventory (if vaccine remains on site)
- Ensure that all doses administered have been reported to DOCIIS.

Chapter 10: Vaccine Management

Vaccine loss is both costly and preventable. DC Health and providers are responsible for maintaining vaccine quality from the time a shipment arrives at a facility until a dose is administered. Therefore, sound vaccine management practices related to ordering, inventory maintenance, and storage and handling are critical to minimizing vaccine loss, waste and compromised vaccine administration.

The Vaccine Cold Chain

Proper storage and handling begins with an effective vaccine cold chain. A cold chain is a temperature-controlled supply chain that includes all vaccine-related equipment and procedures. The cold chain begins with the cold storage unit at the manufacturing plant, extends to the transport and delivery of the vaccine, correct storage at the provider facility, and ends with administration of the vaccine to the patient.



Excessive hot and cold temperatures damages the vaccine. Once vaccine potency is lost, it can never be regained and the vaccine becomes ineffective at preventing disease. Visual inspection of a vaccine is an unreliable method of assuring potency. Inactivated vaccines may appear normal, giving no indication of reduced or lost potency if exposed to temperatures out of range.

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)
- Digital data loggers (DDLs) with continuous monitoring capabilities and a current and valid Certificate of Calibration Testing for each unit, as well as at least one back-up

Storage Units (Refrigerators and Freezers)

Best practices:

- Never store food or beverages in a unit with vaccines.
- Do not store vaccines in the deli, fruit, or vegetable bins (remove bins if possible), in the doors or on the floor of the unit, or under or near cooling vents.

- Place water bottles (thermal ballast) throughout units—against walls, in the back, on the floor, and in the doors—to help stabilize temperatures. Thermal ballast may occupy up to 25% of storage space in the unit.
- Place vaccines and diluents in the center of the unit, two to three inches away from walls, ceiling, floor, and door.
- Store vaccines in their original packaging with lids closed until ready for administration.

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.

CDC recommends the following units, in order of preference, for the storage of VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and vending-style units
- Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit
- Least recommended: combination household refrigerator/freezer unit, **using only the refrigerator compartment to store vaccines**—a separate stand-alone freezer should then be used to store frozen vaccines.
- **The use of dormitory or bar-style refrigerator/freezers is prohibited at all times for VFC program provider locations.**

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

Providers must also protect the power source for all storage equipment.

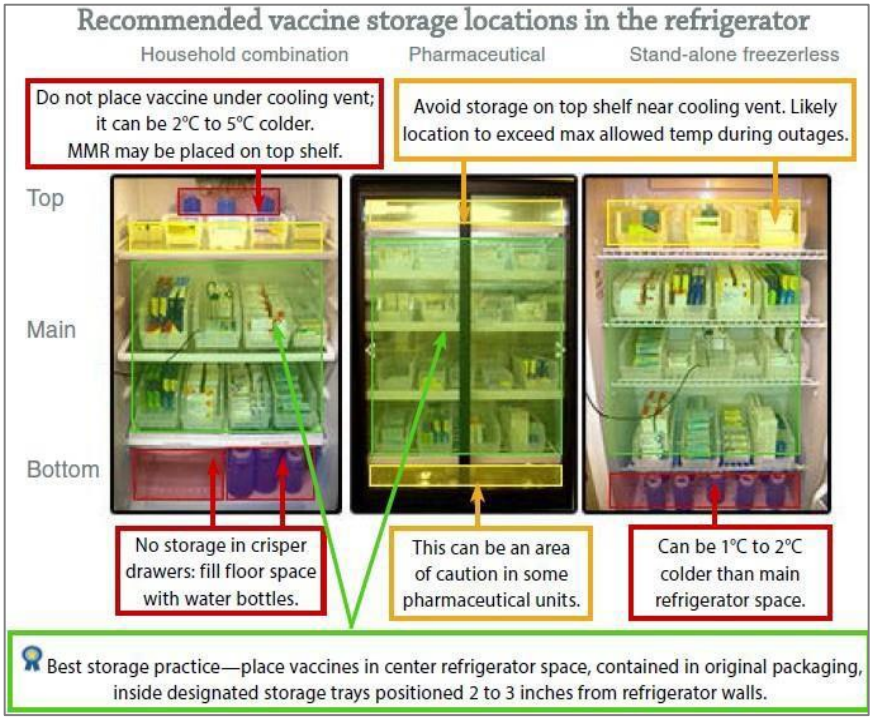
- **"Do Not Disconnect" warning labels should be placed at the electrical outlet and circuit breaker.**

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. The provider must schedule the move of the unit for early in the day. This will allow time for the unit to return to in-range temperatures before the close of business. 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 of the primary units. Back-up units shall not be used longer than two weeks.



DOORLESS/VENDING-STYLE UNITS:

Doorless/vending-style units that are assessed should be identified as such for the type of unit and purpose built for the grade. Please refer to CDC's Vaccines Storage and Handling Toolkit for more information on purpose-built units.

- www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

VFC STORAGE AND HANDLING – VACCINE MANAGEMENT PLAN:

VFC provider locations are required to establish storage and handling policies and procedures in their Vaccine Management Plans, based on the recommendations and best practices in CDC's Vaccine Storage and Handling Toolkit.

These procedures should be easily accessible and kept near vaccine storage units.

Vaccine Management Plan:

VFC provider locations must develop, maintain, and implement a Vaccine Management Plan with detailed and up-to-date SOPs for routine and emergency vaccine management. DC Health provides a Vaccine Management Plan template to assist provider locations, although provider locations can develop their own. Provider-developed plans must be reviewed and approved by DC Health.

Vaccine Management Plans must be updated or verified as current annually, or more frequently as needed, with the vaccine coordinator's signature and date of review.

Vaccine Management Plans must address:

- Contact information for current primary and backup vaccine coordinators
- Provider staff roles and responsibilities
- Documented training related to vaccine management
- Daily monitoring and recording of storage unit temperatures
- Proper storage and handling practices, including how to handle a temperature excursion
- Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste
- Vaccine handling and preparation
- Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disaster

RECEIVING AND DOCUMENTING VACCINES:

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

Actions must include:

- Examining the shipping container and vaccine vials for signs of physical damage
- Comparing the contents of the container to the packing list to be sure they match

Daily Temperature Monitoring and Recording:

Provider locations are required to have protocols for reviewing and recording the minimum and maximum (min/max) temperature readings in vaccine storage units daily. Providers must also document current temperatures for all units twice daily: once in the a.m. and once in the p.m. They should also have procedures for training appropriate staff to document, assess, and interpret temperature monitoring data.

Calibrated, active DDLs should be installed in all units. Temperatures recorded with DDLs should be reported to VOMS at least weekly.

Providers should check the current temperature of the storage unit prior to accessing and administering vaccine.

Information to include when documenting a temperature reading:

- At least one min/max temperature reading per day
- One a.m. temperature reading per day
- One p.m. temperature reading per day
- Time and date of each reading
- Name or initials of the person who assessed and recorded the reading

Provider locations must maintain all paper temperature logs or a backup system of electronic data (both hard copy and electronic copy) for a minimum of three years. This requirement applies even in the case of provider retirement or provider location closure.

Management of Expired, Spoiled, and Wasted Vaccines:

- When managing expired, spoiled, and wasted vaccine, providers must:
- Remove the vaccines from any storage unit that stores viable vaccines.
- Label vaccines “Do Not Use.”
- Report and record the incident, including the reason and number of doses lost, in VOMS.

- Return spoiled and expired vaccines to distributor within six months of the spoilage or expiration date.

Wasted vaccines should be disposed of following state and local disposal requirements.

Vaccine Handling and Preparation:

- Proper vaccine handling and preparation are equally as important as storing vaccines properly. Providers should follow best practices, including:
- Vaccines should be prepared immediately prior to administration.
- Prepare vaccines in a designated, clean medication area, away from any space where potentially contaminated items are placed.
- Always check expiration dates prior to preparing the vaccine. Never administer expired vaccines.
- Reconstitute lyophilized vaccine with the diluent that came with the vaccine—nothing else.
- A single-dose vial contains one dose and should only be used for one patient.
- A separate, sterile needle and syringe should be used for each injection.
- Discard any pre-drawn doses no later than the end of the workday or per the manufacturer's package insert (if sooner).

In instances where provider locations anticipate a high volume of patients needing vaccines (for example, during flu season or back-to-school vaccinations), it is important for providers to remember:

- CDC strongly recommends not pre-drawing doses before they are needed.
- As an alternative to pre-drawing vaccines, CDC recommends using manufacturer-filled syringes.

Receiving and Unpacking Vaccine Shipments

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.

Never leave a vaccine shipping container unpacked and unattended.

Vaccines and diluents must be carefully unpacked, stored at recommended temperatures, and documented immediately upon arrival. Never place an unopened and/or unpacked shipment box in vaccine storage unit.

When unpacking deliveries:

- Examine the shipping container and vaccines for signs of physical damage.
- Check the contents against the packing list to be sure they match.
    - For frozen vaccines, the packing list will show the maximum time vaccines can be in transit based on shipment date.
    - If the shipment includes lyophilized vaccines, make sure they came with the correct type and quantity of diluents.
- Check both vaccine and diluent expiration dates to ensure you have not received any expired or soon-to-expire products.
- Check the package's cold chain monitor for any indication of a temperature excursion during transit. If an excursion occurs, call the number for the monitoring system and contact the VFC program.
- If there are no concerns, place the products in the appropriate storage units:
    - Store VFC vaccine, 317 program vaccine, and private vaccine separately and ensure funding source is clearly labeled.
- If there are discrepancies between the contents and the packing list or any other concerns about the contents, **put the products in the appropriate storage unit** separate from other vaccines, mark "DO NOT USE" and call the VFC Program immediately.
- **Never refuse a shipment. Always receive all deliveries, even those not ordered, and contact the VFC program.**

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.

Sometimes vaccines must be used before the expiration date – by an earlier date known as the "beyond-use date" (BUD). The BUD is calculated based on the date the vial is first entered and the storage information in the package insert. 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.

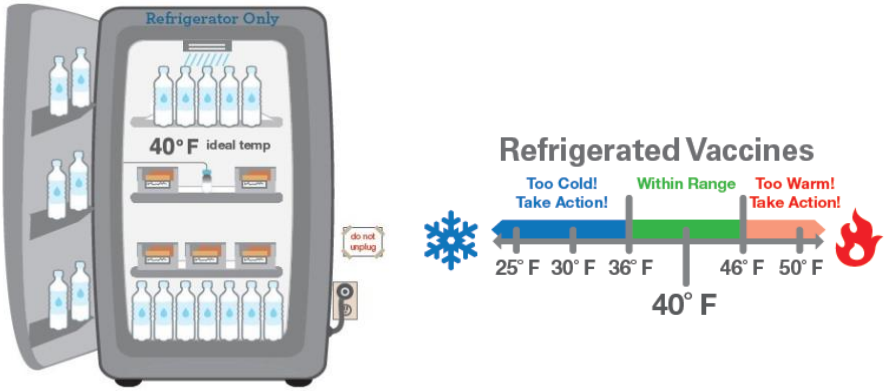
Examples include:

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

REFRIGERATOR SPECIFICATIONS

Any vaccine storage unit must meet the following requirements:

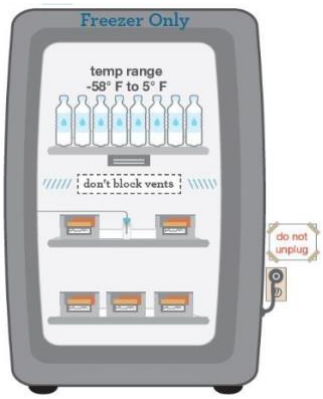
- Maintain consistent temperatures between 36°F and 46°F (2°C to 8°C)
- Be a stand-alone unit at a commercial or pharmaceutical grade. The refrigerator section of a household- grade combo unit is only acceptable and approved storage as a backup storage location for refrigerated vaccines.
- Possess a capacity to store all the practice's vaccines along with sufficient water bottles to stabilize temperatures.
- Defrost automatically
- Seal tightly and close properly

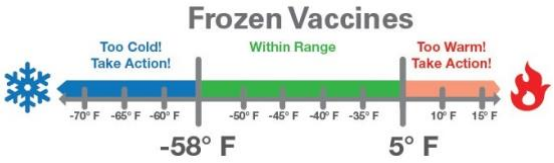


FREEZER SPECIFICATIONS

- Any freezer storage unit must meet the following requirements: Maintain consistent temperatures between -58°F and 5°F (-50°C to -15°C)
- Be either a stand-alone unit (upright or chest) or pharmaceutical grade combination unit. The freezer section of a household-grade combo unit is not acceptable or approved storage for frozen vaccines.
- Possess a capacity to store all of the practice's vaccines along with sufficient frozen water bottles to stabilize temperatures
- Defrost automatically
- Manual defrost is acceptable if the provider has access to an alternate storage unit for vaccine storage during the defrost process

- Seal tightly and close properly
- Use only for vaccine storage





Temperature Monitoring Equipment

VFC Providers are required to have certified calibrated digital data logging thermometers (DDL) in their storage units. Providers need a separate DDL thermometer for each storage unit that holds VFC vaccines. A certified, calibrated back-up DDL must be located on site for use in case the primary DDL is no longer working properly or calibration testing is required.

The calibration certificates must be on file and easily accessible during a site visit and regularly checked to determine when recalibration is necessary.

The expiration date for a certificate of calibration shall be in accordance with the manufacturer's recommendation: i.e., a two-year recommended frequency in calibration would mean the certificate expires two years from the issue date. If there is no manufacturer recommendation for calibration testing or for back-up thermometers that are placed in use, write the "In-Use" date on the certificate. The certificate will expire one year from the in-use date or two years from the issue date, whichever occurs first.

Digital Data Logger (DDL) and Calibration

VFC provider locations must use a DDL with continuous temperature monitoring capability and a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing public vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, and temporary, mobile, off-site, satellite and community vaccination clinics. In some instances, DDLs may be supplied by DC Health. To meet VFC program requirements, the DDL must be equipped with:

- A temperature probe or sensor (a buffered probe is required for DC Health-provided probes and is optional, but recommended, for provider-purchased probes or sensors)
- An active temperature display outside the unit that can be easily read without opening the storage unit's door
- Continuous temperature monitoring and recording capabilities and the capacity to routinely download data

*There may be provider locations that have purpose-built or pharmaceutical-grade equipment (e.g., doorless or vending-style units) with temperature monitoring capabilities that may be as reliable as a DDL in monitoring vaccine temperature. Not all of these units may be capable of digitally logging temperatures. When in doubt, consult CDC's vaccine storage and handling experts at izcoldchain@cdc.gov on whether the unit is capable of meeting VFC temperature monitoring device requirements.

Additional recommended DDL features include:

- Alarm for out-of-range temperatures
- Temperature display showing current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/-1°F (0.5°C)
- User-programmable logging interval (or reading rate) recommended at a maximum time interval of no less frequently than every 30 minutes

Certificates of Calibration Testing must include:

- Model/device number
- Serial number
- Date of calibration (report or issue date)
- Confirmation the instrument passed testing (or instrument in tolerance)

A backup DDL must be readily available in case a DDL fails or calibration testing is required. The backup DDL should have a different calibration retesting date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time. If the backup DDL has the same calibration retesting date, DC Health/providers must have the unit retested prior to expiration, ensuring that a valid DDL is available for required temperature monitoring. Backup DDLs are usually maintained on site.

However, an alternative approach may be used if the provider location can obtain a backup DDL to meet the once-a-day assessment and reporting requirement. This alternative approach must be approved by DC Health and the process must be included in the provider location's Vaccine Management Plan.

Note: Backup DDLs should not be stored in the storage unit. This can result in conflicting temperature readings between the backup and main DDLs, which can lead to potential confusion.

Monitoring Cold Storage Unit Temperatures

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

In addition to reporting DDL data to VOMS weekly, VFC Providers are required to keep a paper log of temperatures. Completed logs must remain on-site and may not be falsified. Keep all temperature logs on file for a minimum of three years. They should be easily accessible during a site visit.

Check and record the minimum and maximum temperatures of each storage unit at the start of each workday. Log one a.m. and one p.m. temperature everyday. Keep the temperature log sheets on the door of every storage unit.

The temperature log sheets have space for the following entries:

- One a.m. and one p.m. temperature reading
- Minimum temperature of the storage unit in the past 24 hours
- Maximum temperature of the storage unit in the past 24 hours
- Date and time of the recording
- Name of the person who checked and recorded the temperature
- Any actions taken if a temperature excursion occurred
- If a reading is missed, leave a blank entry in the log.

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 below:

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 (quarantine) them from other vaccines **in the 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)
- General description (i.e., what happened)
- 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 are not limited to:

- Ensuring that the door of the unit is closed
- Ensuring that the DDL probe is in the center of the vaccines
- Ensuring that the storage unit is plugged in and the there is power to the unit
- Implement 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.
- Notify the VFC program.
- Notify the manufacturer(s) of the temperature excursion and the affected vaccines. In general, manufacturers analyze information about the magnitude of the temperature excursion and the total amount of time that temperatures were out-of-range, as well as information about the vaccine in question to determine whether a vaccine is likely to still be viable. It is important to obtain the manufacturer's determination in writing as you will need to provide this information to the VFC Program.

Upon review and confirmation of the manufacturer's determination of viability, 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 vial. If that is the case, be sure to mark the vial with the new BUD. Remove vaccine from unit if unused at the close of business on BUD date, 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 VFC Program has the authority to suspend vaccine ordering when a temperature excursion is discovered. Suspension remains 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 done 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.
- 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.

Chapter 11: Vaccine Accountability

Vaccine Administrations

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

VFC providers must electronically report all immunizations to the Immunization Information System (DOCIIS).

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
    - Manufacturer
    - Lot Number
    - Administration date
    - Expiration Date
    - Administration Facility (VFC PIN)
    - Patient first and last name
    - Patient Date of Birth

FUNDING GROUP	FUNDING SOURCE	PATIENT ELIGIBILITY
Pediatrics (Children Under 19)*	VFC public funding (VXC51)	-Medicaid (V02) -Uninsured (V03) -American Indian / Alaska Native (V04) -Underinsured (V05)
Bridge Access Program and 317: Underinsured/Uninsured Adults 19 years and older	Public non-VFC (VXC52)	317 patient eligibility (V23)
Pharmacy Bridge Program	Public (VXC50)	Not VFC eligible (V01)
Private/Commercialized	Private (PHC70)	Not VFC eligible (V01)

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

Chapter 12: Borrowing/Transfers

CDC's expectation is that providers maintain adequate inventories of both privately-purchased and federally-funded vaccines. **DC VFC providers are NOT permitted to borrow vaccines as a routine practice**. That means that providers cannot knowingly administer a dose of federally-purchased vaccine to a privately insured patient with the intention of "paying back" the dose at a later time. Every effort should be made to ensure that the provider confirms eligibility to receive federally-funded vaccine prior to vaccine administration. In the event a dose of federally-funded vaccine is inadvertently administered to a non- eligible patient, a provider must contact the VFC program.

The provider must report to the DC VFC Program the following information:

- Vaccine type administered
- Patient name
- Patient date of birth
- Date the dose was inadvertently administered
- Reason the dose was inadvertently administered
- Corrective action instituted to prevent future inadvertent administration
- The vaccine type, lot number, and expiration date of the privately purchased vaccine dose that will replace the inadvertently administered dose in the provider's inventory

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

Transfers

On occasion, even with proper inventory management, a provider might experience a situation where they have stock close to expiring. Vaccine that will expire within 120-150 days may be transferred to another provider if the vaccine cannot be used prior to expiration.

DC VFC Program must be notified before a vaccine transfer occurs. Transfer requests must be submitted in VOMS. Transfer may occur only after DC VFC Program approval.

Providers should submit a Short-dated Vaccine Notification Form to DC VFC Program at least 120 days in advance notifying the program of any doses on-hand the site does not anticipate utilizing.

Remember, sites are responsible for utilizing all ordered and delivered VFC vaccine.

Chapter 13: Vaccine Transport and Materials

In the event that vaccine transfer is required, follow best practices according to CDC's Vaccine Storage and Handling toolkit, beginning on page 23:

- www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

This includes use of a DDL throughout transfer.

Chapter 14: Management of Expired, Spoiled and Wastage Vaccines

Expired or 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
- Compromised, 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 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 together.

Emergencies

Various situations – equipment failure, power outages, severe weather conditions, or natural disasters - may compromise vaccine storage conditions. Vaccines must never be allowed to remain in a nonfunctioning unit for an extended period of time. Therefore, making preparations in advance to retrieve and/or protect vaccines as quickly as possible during a potentially compromising situation could save facilities costly vaccine lost.

Emergency Backup Options

Backup Equipment

- Backup DDL
- Spare batteries
- Flashlights
- Vaccine transport containers and materials

Generators and Backup Battery Power Sources

- An on-site generator can prevent having to transport vaccine to an alternative storage facility during a power outage. Keep sufficient fuel on hand to continuously run the generator for at least 72 hours. A battery power source can also be used in lieu of a generator. If a facility has a backup battery power source, it should be tested quarterly and serviced annually (check the manufacturer's guidance).

Alternative Vaccine Storage Facility

- Consider establishing a working agreement with at least one alternative storage facility with a backup generator where vaccines can be appropriately stored and monitored in an emergency, such as hospitals, long-term care facilities, fire stations, and commercial pharmacies. 24-hour access to the facility must be available.

If a site cannot find an alternative vaccine storage facility within a reasonable distance, the site may use qualified containers and pack-outs to store vaccines **temporarily**. Always place a DDL with stored VFC vaccines.

Off-Site Administration

The Provider Agreement states that government-supplied vaccine will be administered at the point of delivery: the address listed on file in the agreement and profile form. Off-site vaccine administration is not allowable without prior written authorization from the District of Columbia Immunization Program.

Chapter 15: Fraud and Abuse

Federal fraud and abuse laws apply to the entire VFC program. A working understanding of what constitutes fraud and abuse is critical for all persons involved with the VFC program including the site medical director and all staff involved with vaccine management.

"Fraud" and "abuse," as defined in Medicaid regulations 42 CFR § 455.2, are:

- **Fraud:** An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.
- **Abuse:** Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

EXAMPLES OF FRAUD AND ABUSE

- Providing VFC Vaccines to non-VFC eligible children
- Selling or otherwise misdirecting VFC vaccine
- Billing a patient or third party for the VFC vaccines
- Charging more than established maximum regional for administration of a VFC-funded vaccine to a federal vaccine-eligible child
- Denying VFC–eligible children VFC funded vaccines because of parents' inability to pay the administration fee
- Failing to implement provider enrollment requirements of the VFC program
- Failing to screen patients for VFC eligibility at every visit

- Failing to fully accounts for VFC vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccines in quantities or patterns that do not match the provider profile or otherwise over-ordering of VFC vaccine
- Failing to implement provider enrollment requirement of the VFC program
- Failing to screen patient for VFC eligibility at every visit
- Failing to maintain VFC records or not complying with other requirements of the VFC program
- Failing to fully account for VFC vaccines
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccines (e.g., expiring vaccines, ordering too many doses of vaccines, storing or transporting vaccines outside of the cold chain procedures, lost or unaccounted for doses, etc.)
- Any activity that results in an overpayment for cost of the vaccines or administration

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.
- Replacement of the provider's 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

Referrals to Other Agencies

It is the policy of the VFC program to work with providers through Corrective Action Plans to avoid referrals to other agencies. However, the VFC program is tasked with ensuring that all providers are good stewards of federally funded vaccine. 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

Chapter 16: Compromised Vaccine Administration and Revaccination

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 the patient notification. Patients will be advised to consult a healthcare provider for counseling and revaccination, as appropriate.

Chapter 17: 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.

VIS 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.

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

The CDC VIS webpage offers a "Get email updates" function that notifies you by email when VISs are changed. 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 19: 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 initial enrollment site visit. This visit will review the site's readiness to receive and administer VFC vaccine.

VFC Compliance Site Visit

VFC 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. Active 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.

Addendum: Special Considerations for COVID-19 vaccine and Nirsevimab

Inventory

VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for COVID-19 vaccine and nirsevimab. During this time, VFC providers will not be required to meet the private inventory minimum requirements for COVID-19 vaccine or nirsevimab if they do not intend to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than August 31, 2025.

If a provider serves only Medicaid-eligible and no privately insured children, they are not required to privately purchase COVID-19 vaccine or nirsevimab.

If VFC providers utilize this flexibility to not maintain private stock during this season, providers should explore if other in-network options exist for their privately insured patients to access COVID-19 vaccine and nirsevimab (i.e., from another local in-network practice or system, Federally Qualified Health Center or fellow VFC provider authorized to immunize underinsured children that does have private inventory of COVID-19 vaccine or nirsevimab). Providers are allowed to order the minimum feasible packaging of COVID-19 vaccine and nirsevimab. Specialty providers may offer a limited formulary of vaccines, based on the populations served in their facility.

Eligibility Criteria

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

Borrowing

DC VFC's borrowing policy applies to Covid-19 and Nirsevimab. **DC VFC providers are NOT permitted to borrow vaccines as a routine practice**. In isolated instances, borrowing may be allowed (see below). Any borrowed VFC doses must be replaced with private stock **within 1 month or after five doses borrowed** (for small practices).

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

Borrowing is only applicable if the provider is purchasing private stock and is approved only for instances when:

- There is a lack of vaccine stock because of delayed or spoiled shipments.
- As part of the initial set up of private purchasing contracts and ordering systems, there has been a delay for the provider in being able to procure private stock of COVID-19 vaccine or nirsevimab.
- Vaccine will expire soon and will be lost if not used.
- Provider locations with a small privately insured patient population can use this option to administer short dated, privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated, VFC dose.
- New staff calculated ordering intervals incorrectly, leading to a lack of sufficient private or public vaccine stock.
- Borrowed COVID-19 vaccine or nirsevimab must be repaid (dose for dose) **within 1 month or after five doses borrowed** (for small practices) and administered to the appropriate population (i.e., if VFC vaccine is borrowed for a privately insured patient and then repaid to VFC inventory, the repaid dose must be administered to a VFC-eligible child). The provider must provide proof that borrowed VFC doses are replaced with private stock. This proof must include the number of doses, lot numbers, and documentation that authenticates doses returned or doses repaid were administered to the appropriate recipients.

Resources and Links

VFC Resources

VFC DC Health Website

https://dchealth.dc.gov/node/1391821

CDC VFC Page

https://www.cdc.gov/vaccines/programs/vfc/index.html

CDC VFC Operations Guide

https://www.cdc.gov/vaccines/programs/vfc/downloads/operations-guide-508.pdf

Vaccine Storage and Handling Toolkit

https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

You Call the Shots Modules

https://www.cdc.gov/vaccines/ed/youcalltheshots.html

DOCIIS User Guide

https://dccp1web.stchealthops.com/iweb/help/index.htm#t=how_help.htm

Immunization Practices

ACIP Vaccine Recommendations and Guidelines

https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

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

http://www.cdc.gov/vaccines/pubs/pinkbook/index.html

Immunize.org

https://www.immunize.org/

Vaccine Adverse Event Reporting

https://vaers.hhs.gov/

Vaccine information Sheets

https://www.cdc.gov/vaccines/hcp/vis/current-vis.html