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VFC OPERATIONS GUIDE

JULY 1, 2025 – JUNE 30, 2026

National Center for Immunization and Respiratory Diseases
Immunization Services Division

Vaccines for Children

Vaccines for Children (VFC) Program Operations Guide

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About This Guide

The 2025–2026 Vaccines for Children (VFC) Operations Guide:

- Spans a budget period of July 1, 2025, through June 30, 2026
- Reflects current operational policies and processes of the VFC program
- Defines VFC program requirements and outlines the steps or components necessary to meet them
- Informs state, local, and territorial immunization programs about operational policies and processes of the VFC program

Design

For easy reference, colors indicate different sections of this document.

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Green boxes, see below, indicate VFC program requirements for award recipients (“recipients”).

REQUIREMENT

Readers can find important and supplemental information in callout boxes throughout this guide.

The guide notes best practices throughout its pages. The Centers for Disease Control and Prevention (CDC) encourages readers to use these practices where possible, even if they are not required.

Terms Used in This Guide

For purposes of this guide:

- **Award recipient (or recipient)** refers to immunization program staff responsible for implementing the VFC program. This includes VFC coordinators and immunization program managers.
- **Facility** refers to a specific physical location of a VFC provider.
- **Medicaid-enrolled** and **Medicaid-eligible** are interchangeable terms that refer to children who have health insurance covered by a state Medicaid program.
- **Parent** refers to anyone who has legal authority to make decisions on behalf of a VFC-eligible child. This can refer to parents, legal guardians, or individuals of record.
- **Provider** refers to individual health care providers authorized to administer vaccines. The term also applies to staff within a provider location who:
  - Store and handle vaccines
  - Order and bill for vaccine administration
  - Screen for VFC eligibility
- **Provider location** refers to a specific VFC provider facility, practice, or clinic. Enrollment and site visit data are entered based on provider location.
- **VFC site visit reviewer (or reviewer)** refers to an individual who conducts VFC site visits on behalf of an immunization program.

Additional Resources

This guide mentions additional resources to assist award recipients throughout its pages. The Provider Education, Assessment, and Reporting (PEAR) system and the VFC Cooperative Agreement Management Platform (CAMP) Knowledge Center house many of these resources. Award recipients may request access to PEAR and the VFC CAMP Knowledge Center through their assigned Immunization Operations and Services Branch (IOSB) project officer.

Future Changes to This Guide

If information in this guide changes after publication, CDC will revise and replace the updated modules. CDC will also notify award recipients of any changes by email. Unless stated otherwise, any new requirements will take effect one year after notice of change.

Questions

Award recipients with questions about this guide may contact their IOSB project officer.

Summary of 2025–2026 VFC Program Requirements

	Requirement	Steps/Components
	Module 1 – Patient Eligibility and Insurance Criteria	
M1	**Award recipients must ensure that providers:** • **Understand the Vaccines for Children (VFC) eligibility categories** • **Document VFC eligibility for each immunization visit**	
	Module 2 – Recruiting and Enrolling Providers	
M2	**Award recipients must verify that providers meet the eligibility criteria for enrollment in the VFC program.** **If a state Medicaid agency notifies award recipients that a provider is on the List of Excluded Individuals and Entities (LEIE), award recipients cannot enroll that provider in VFC.**	VFC providers must be: • Authorized in the award recipient's jurisdiction to administer vaccines to children aged 18 years and younger • Willing and able to follow all requirements, operational policies, and procedures for the VFC program. These include participating in site visits and educational opportunities • Able to order, receive, manage, store, and monitor the temperature of public vaccines • Open at least four consecutive hours on a day other than a Monday to receive VFC vaccines

	Requirement	Steps/Components
	Module 2 – Recruiting and Enrolling Providers	
M2	**Award recipients must use the Centers for Disease Control and Preventions (CDC) Provider Agreement for:** • **Initial program enrollment** • **Program reenrollment** **Provider recertification**	• Providers must complete and sign CDC's Provider Agreement. • The medical director in a group practice must be authorized to administer pediatric vaccines under state law. • The provider signing the Provider Agreement on behalf of a multi-provider location must have authority to sign on the entity's behalf. • For an enrolled practice, the Provider Agreement must list: o All licensed health care providers in the practice o Their corresponding professional license numbers • If a pharmacist is administering vaccines under a physician's direct supervision, both the pharmacist and the physician must sign the Provider Agreement. • All parties involved with implementing the clinics must sign the Provider Agreement if there are: o Community vaccinators enrolled or o Circumstances where the enrolled provider is not providing direct service and other parties are involved with administering vaccines
M2	**Award recipients must collect a Provider Profile at initial program enrollment or reenrollment and every 12 months thereafter.** **They should also obtain an updated Provider Profile whenever patterns in provider ordering indicate a change in populations served.**	
M2	**Award recipients must advise providers on acceptable method(s) for documenting results of patient eligibility screening.** **Providers must use either CDC's Patient Eligibility Screening Record or alternative forms or guidance from award recipients.**	
M2	**Award recipients must review key information of VFC provider locations every 12 months.**	A provider review includes: • Collecting and validating Provider Profile data • Verifying that provider locations meet the annual training requirement defined by the award recipient

	Requirement	Steps/Components
	Module 2 – Recruiting and Enrolling Providers	
M2	**Award recipients must recertify VFC provider locations every 24 months.**	Provider recertification includes: • Verifying provider eligibility • Collecting a signed Provider Agreement and ensuring that it is complete and accurate • Distributing the CDC Patient Eligibility Screening Record or written guidance developed by the award recipient to support eligibility screening and documentation
M2	**If the Provider Agreement is terminated, the award recipient must retrieve any unused VFC vaccine from the provider location within 30 days of termination.**	Award recipients should follow CDC's vaccine transport guidance when retrieving unused VFC vaccines from the provider location. This guidance is outlined in CDC's *Vaccine Storage and Handling Toolkit*.
M2	**When a state Medicaid agency notifies an award recipient that a provider location has a staff member or subcontractor on the LEIE, the award recipient must terminate the provider location from the VFC program.**	
	Module 3 – Vaccine Management	
M3	**Award recipients must monitor provider practices to verify compliance with guidelines for vaccine management.** **Award recipients and providers can find these guidelines in CDC's *Vaccine Storage and Handling Toolkit* and this guide.**	Vaccine management plans must include: • Correct storage units • Digital data loggers (DDLs) with continuous monitoring capabilities and a current Certificate of Calibration • Vaccine receipt and documentation • Daily monitoring and recording of unit temperatures, including responding to any temperature excursion • Management of expired, spoiled, or wasted vaccine • Vaccine handling and preparation • Emergency situations

	Requirement	Steps/Components
	Module 3 – Vaccine Management	
M3	**Award recipients must work with providers to develop plans for vaccine management. These plans must include feasible standard operating procedures (SOPs) for routine and emergency vaccine management.** **Providers must update the plans annually.**	Vaccine management plans must include: • Contact information for current primary and backup vaccine coordinators • Provider staff roles and responsibilities • Documented training related to vaccine management • Proper storage and handling practices, including procedures for handling a temperature excursion • Procedures for vaccine ordering and receipt; inventory control; stock rotation; and handling of vaccine loss and waste • Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disasters • Systems and procedures to ensure: o Patient referral to pre-identified site(s) for vaccination not available on-site and o Close-follow-up with patients who are vaccinated outside of their medical homes
M3	**Award recipients must monitor vaccine orders to ensure that providers are:** • **Ordering vaccine in the appropriate amounts** • **Properly maintaining their vaccine inventories**	
M3	**Providers are not allowed to routinely borrow VFC vaccine for privately insured patients who are not eligible for the VFC program.** **Award recipients can only approve vaccine borrowing when:** • **There are unforeseen delays or circumstances in vaccine supply** • **It will not impact the ability of a VFC-eligible child to receive vaccine.**	Award recipients must complete the Vaccine Borrowing Report when either: • A VFC-eligible child receives privately purchased vaccine or • A privately insured child receives VFC vaccine

	Requirement	Steps/Components
	Module 3 – Vaccine Management	
M3	**Award recipients must approve, coordinate, and document vaccine transfers between VFC provider locations.**	Vaccine transfers can only occur: • With the immunization program's approval and direct guidance • When a process is in place to ensure vaccine viability during transfer • When temperature monitoring documentation validates that the vaccine has not been exposed to a temperature excursion.
M3	**If award recipients implement a vaccine order replacement model, proposal must first be submitted to their IOSB project officer for CDC approval.**	Before submitting a proposal, award recipients must make sure they can: • Verify provider eligibility • Oversee the process for vaccine replacement • Ensure that replaced doses directly reflect the VFC-eligible children served by the provider location Proposals for vaccine replacement models must meet the following criteria: • Each vaccination encounter must include VFC screening and documentation. • The award recipient must have an immunization information system (IIS). The IIS must capture eligibility status at the dose level based on the required eligibility categories. The IIS must also document all doses administered and eligibility data within 30 days of the vaccination encounter. • Providers must submit replacement dose orders monthly. • The award recipient must assess doses-administered data, replace vaccines according to data from the last 30 days, and ship replacement vaccine directly to the provider location. • The total public vaccine inventory must be submitted to the Vaccine Tracking System (VTrckS) with each vaccine order—it must represent the public portion of the provider location's inventory on hand. • Public vaccine returns must represent the public portion of the total vaccine returns.
M3	**If award recipients establish a restitution policy, it must require providers to replace federal vaccine on a dose- for-dose basis (instead of financial payment).**	Award recipients' restitution policies must state that providers are required to replace vaccine on a dose-for-dose basis. This allows doses to be restored to the VFC-eligible children for whom they are intended.

	Requirement	Steps/Components
	Module 4 – Ensuring Provider Compliance	
M4	**Award recipients must use CDC's Provider Education, Assessment, and Reporting (PEAR) system to record visits to provider sites as well as follow-up.**	Award recipients must enter and submit data for site visits online in PEAR. Award recipients may use a hard copy process when there is no internet or computer access. In these cases, award recipients must enter and submit site visit data within 10 business days. Award recipients must use PEAR to: • Enroll and unenroll provider locations • Conduct and document all site visits • Perform site visits using the appropriate Site Visit Reviewer Guide (which is posted on PEAR) • Document award recipient or provider follow-up actions for compliance issues discovered during the visit • Record annual provider training • Monitor and evaluate program performance Reviewers must ask the questions exactly as written in the Site Visit Reviewer Guide. The Site Visit Reviewer Guide and its content must not be shared with providers at any time.
M4	**Award recipients must conduct an enrollment site visit for all new and reenrolling VFC provider locations before they receive VFC vaccine.**	The enrollment site visit must include: • Review of all VFC requirements as well as confirmation of provider understanding • Confirmation that the provider knows whom to contact if problems arise, especially with storage and handling issues • Assessment of storage and handling equipment
M4	**Award recipients must conduct and record VFC compliance site visits with each provider location every 24 months.** **Reviewers for VFC site visits must conduct the first site visit within 12 months of a provider location's enrollment in VFC, or within six months if the enrollment visit is conducted virtually.** **Reviewers must educate the provider on VFC program requirements, including storage and handling.**	Compliance site visits must cover specific requirements for: • Provider details • Eligibility • Documentation • Storage and handling (per unit and sitewide) • Inventory management

	Requirement	Steps/Components
	Module 4 – Ensuring Provider Compliance	
M4	**At least 5% of VFC provider locations must receive an unannounced site visit on storage and handling during the cooperative agreement budget period.**	Site visits on storage and handling must include: • Specific requirements outlined for storage and handling (per unit and sitewide) • Assessment of temperature monitoring • Responses to temperature excursions
M4	**Award recipients must provide comprehensive training on VFC requirements to each VFC provider location every 12 months.** **The training must cover all VFC requirements in the Provider Agreement and the current VFC Operations Guide.**	• The primary and backup vaccine coordinators at each provider facility must complete the required training. At the award recipient's discretion, additional staff closely associated with vaccine management can take the same training. • Award recipients may provide the annual training online, by webinar, or through an in-person, classroom-style presentation. • VFC compliance site visits with an educational component are allowed to serve as annual training requirements. • Award recipients must document annual training for provider locations in the Annual Training module in PEAR.
	Module 5 – Fraud and Abuse	
M5	**Award recipients' policies and procedures for the VFC program must address** • **Prevention, detection, investigation, and resolution of VFC fraud and abuse allegations as well as** • **Federal requirements regarding reporting of suspected fraud and abuse.**	Procedures must include specific requirements related to: • Overseeing and training personnel • Monitoring fraud and abuse • Addressing provider noncompliance with VFC requirements • Reporting allegations and referrals to the Fraud and Abuse module in PEAR

	Requirement	Steps/Components
	Module 6 – Program Operations	
M6	**Award recipients must maintain all VFC program documentation for at least 3 years (or longer if required by state law).**	This requirement applies even if: • A provider retires • A provider location closes
M6	**Award recipients must establish and use policies and procedures for effective program operations.**	These policies and procedures must address: • Staffing • Staff training • Systems for program monitoring • Systems related to fraud and abuse
M6	**Award recipients must establish and use policies and procedures related to provider recruitment.**	Award recipients must establish protocols for: • Assessing gaps in vaccine access for VFC-eligible children in their jurisdictions and • Recruiting and enrolling providers to improve vaccine access for VFC-eligible children
M6	**Award recipients must establish and use policies and procedures for all aspects of the enrollment process for provider locations.**	Award recipients must establish protocols for: • Verifying provider eligibility to participate in the program • Conducting an enrollment visit, including completion of the Provider Agreement, the Provider Profile, and the document for Patient Eligibility Screening (or similar guidance) • Entering data for the enrollment visit into PEAR
M6	**Award recipients must confirm that CDC-approved, deputized provider locations have a signed memorandum of understanding (MOU) between** • **A federally qualified health center (FQHC) or rural health clinic (RHC) and** • **The state or local immunization program allowing them to serve underinsured VFC-eligible children.**	Award recipients can find an MOU template, deputization agreement forms, and supplemental materials in the VFC Cooperative Agreement Management Platform (CAMP) Knowledge Center.

	Requirement	Steps/Components
	Module 6 – Program Operations	
M6	**Award recipients must establish and implement policies and procedures to validate provider compliance with:** • **Screening and documenting VFC eligibility for each vaccination encounter** • **Administering VFC-funded vaccine only to children who are eligible for the program** • **Screening patients for state vaccine and, if applicable, documenting and administering state vaccine** • **Complying with the immunization schedule, dosages, and contraindications recommended by the Advisory Committee on Immunization Practices (ACIP)** • **Making available all appropriate vaccines for the population served** • **Following requirements for vaccine billing and administration fees** • **Complying with the National Childhood Vaccine Injury Compensation Act** • **Complying with management requirements for VFC vaccine** • **Maintaining all records for at least three years, or longer if required by the state**	CDC addresses provider compliance through: • Site visits • Storage and handling visits • Training for provider locations
M6	**Award recipients' policies and procedures for vaccine management as well as storage and handling must include standards necessary to:** • **Prevent vaccine waste** • **Ensure that appropriate public vaccine stock is available by fund type**	Areas to address include vaccine: • Storage and handling • Ordering • Loss and restitution • Borrowing • Transfer If applicable, award recipients also need policies and procedures related to: • Implementing and monitoring a vaccine replacement model • Overseeing and managing temporary, mobile, off-site, or satellite clinics

Vaccines for Children (VFC) Program Overview

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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

For more information on patient eligibility for VFC, see Module 1 – Patient Eligibility and Insurance Criteria.

VFC Fast Facts

- VFC benefits an estimated 40 million children.
- VFC has approximately 38,000 enrolled health care provider sites.
- There are 63 VFC state, local, and territorial immunization program award recipients.
- CDC distributed approximately 73 million VFC vaccine doses in 2024.

To reach VFC-eligible children, the Centers for Disease Control and Prevention (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. These award recipients provide vaccines to participating provider locations to meet the specific needs of eligible children in their jurisdictions.

VFC Program Benefits:

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

VFC Program At a Glance

CDC's immunization program award recipients enroll public and private health care provider locations in the VFC program. This allows award recipients to meet the immunization needs of VFC-eligible children in their respective jurisdictions.

Award recipients educate enrolled providers on VFC program requirements, vaccine management, and fraud and abuse violations.

CDC contracts with vaccine manufacturers to buy vaccines at a discount.

VFC provider locations order vaccines (including seasonal influenza vaccine) recommended by the Advisory Committee on Immunization Practices (ACIP). They place the orders at no cost through their state, local, or territorial VFC program.

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.

Award recipients provide guidance and monitor provider locations to ensure compliance with VFC program requirements.

VFC Vaccines

The Advisory Committee on Immunization Practice (ACIP) is a federal advisory group of medical and public health experts that develops recommendations on vaccine use to prevent and control diseases in the United States. The group provides guidance on:

- Age for vaccine administration
- Number of doses and dosing intervals
- Precautions and contraindications to vaccination

Per the ACIP's recommendations, the VFC program covers vaccines to protect infants, children, and teenagers from vaccine-preventable diseases.

The current list of VFC vaccines and their current CDC price list is available online. CDC's child and adolescent immunization schedule is also available online.

VFC Program History

- Congress created the VFC program in response to the 1989–1991 measles outbreak in the United States. At that time, vaccination coverage was low. The measles epidemic resulted in tens of thousands of cases and hundreds of deaths.
- The VFC program was created as part of the Omnibus Bud- get Reconciliation Act of 1993. The law established VFC as a new entitlement program that must be a part of each state's Medicaid plan. The VFC program is a Title XIX Medicaid program.
- Section 1928 of the Social Security Act (42 U.S.C.§1396S) provides the legal authority for the VFC program. The law requires each state to establish a program for distributing pediatric vaccine to registered provider locations. It also provides authority for purchase of vaccines to administer to eligible children using federal Medicaid and state funds (including Section 317 discretionary funding).
- VFC was officially implemented in October 1994 as part of the President's Childhood Immunization Initiative.
- The VFC program is available in all 50 states, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands.

Medicaid

Title XIX of the Social Security Act is a federal/state entitlement program that pays for medical assistance for certain individuals and families with low incomes and limited resources. This program, known as Medicaid, became law in 1965. Medicaid is a cooperative venture, jointly funded by the federal and state governments (including the District of Columbia and the territories) to assist states in providing medical assistance to eligible persons. Medicaid is the largest source of funding for medical and health-related services for America's low-income citizens.

Within broad national guidelines established by the federal government, each state Medicaid program can:

- Establish its own eligibility standards
- Determine the type, amount, duration, and scope of services
- Set the rate of payment for services
- Administer its own program

As a result, Medicaid programs vary considerably from state to state.

VFC Program Funding

- Funding for the VFC program is approved annually by the Office of Management and Budget (OMB).
- The funds are allocated to CDC through the Centers for Medicare and Medicaid Services (CMS).
- CDC awards VFC funding to 63 state, local, and territorial immunization programs through a cooperative agreement.

VFC Program Oversight

- CDC administers the VFC program at the national level through its National Center for Immunization and Respiratory Diseases (NCIRD).
- CDC is the lead agency responsible for developing operational guidelines and requirements for VFC, as well as overseeing the national program.

- CDC's immunization program award recipients manage and implement a VFC program in their state, city, or territory.
- NCIRD's Immunization Services Division (ISD) provides programmatic support to award recipients.

Collaboration with VFC Partners

CDC is responsible for setting operational policy for administering the VFC program, but award recipients should collaborate with state Medicaid agencies. Children enrolled in Medicaid make up the largest category of VFC eligibility. Likewise, provider locations serving Medicaid children represent the largest provider pool for VFC program recruitment. Award recipients and state Medicaid agencies should collaborate on policies that affect the children or providers who participate in the VFC program. State immunization programs and Medicaid agencies are both key in recruiting VFC providers and informing parents and guardians of eligible children that VFC vaccines are available. State government is ultimately responsible for ensuring that its agencies comply with Medicaid requirements.

To successfully implement the VFC program, award recipients should closely collaborate with these key program partners and agencies:

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Nurse Midwives
- American Hospital Association
- Academy of Neonatal Nursing
- CDC
- CMS
- Health Resources and Services Administration (HRSA)
- hospital associations
- Indian Health Service (IHS)
- Medical professional societies
- National, state, and local organizations representing the private health care sector
- Pharmacy associations
- State immunization coalitions
- State, local, and territorial health departments
- State Medicaid agencies
- State Perinatal Quality Collaboratives

ACIP and VFC Resolutions

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. (Providers may also administer VFC vaccines per state laws for school attendance.)

CDC does not establish contracts for VFC vaccines until a VFC resolution is in place.

Vaccine Administration Fees and Fee Caps

VFC providers cannot charge an eligible child's parent a fee for the vaccine itself. However, they can charge a fee to administer each vaccine.

The VFC program's initial legislation limits the dollar amount that a provider can charge and be reimbursed for administering vaccines to VFC-eligible children. A provider may charge a patient any amount up to, but not more than, the fee cap for vaccine administration. This cap varies from state to state and is based on a regional scale determined by CMS.

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.

CMS published an initial Federal Register notice on October 3, 1994. The initial notice set interim maximums on what a participating provider may charge for administering a vaccine to a VFC child. CMS published the most recent fee schedule in November 2012.

Award recipients can find a list of the maximum vaccine administration fees on the VFC Cooperative Agreement Management Platform (CAMP) Knowledge Center.

According to the VFC program's initial legislation, enrolled providers agree to the following fee requirements for vaccine administration:

- Providers cannot deny access to federally purchased vaccines to an established patient whose parent is unable to pay the fee for vaccine administration.
- Providers cannot charge a fee that exceeds the federal fee cap for vaccine administration to VFC-eligible children who are not enrolled in Medicaid.
- For VFC-eligible children who are enrolled in Medicaid, the provider must accept the reimbursement for vaccination set by the state Medicaid agency or the contracted Medicaid health plans.

Note: Providers may charge an office visit fee as well as the vaccine administration fee if other services were provided in addition to vaccinations. The VFC statute does not prohibit this action.

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 have unpaid vaccine administration fees.

Children's Health Insurance Program (CHIP)

The Children's Health Insurance Program (CHIP) was created through the Balanced Budget Act of 1997 to address the fact that one in seven children (more than 10 million nationwide) were uninsured at that time. Being uninsured places these children at significantly increased risk for preventable health problems. Many of these children are part of working families who earn too little to afford private insurance on their own but earn too much to be eligible for Medicaid.

All 50 states, the District of Columbia, Puerto Rico, Guam, U.S. Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands have approved CHIP state plans.

States can structure their CHIP programs as either:

- An expansion of the state's Medicaid program
- A separate CHIP program
- A combination of the two

Two letters—a May 1998 letter to state Medicaid directors and a June 1999 letter from CMS and CDC— clarify the immunization services and vaccine funding that are available for CHIP. The letters outline how vaccinations are covered for each type of CHIP plan. They also discuss how award recipients can purchase and use vaccines for the CHIP program via the federal contract. Award recipients can find copies of these letters on the VFC CAMP Knowledge Center.

CHIP and VFC Eligibility

Children enrolled in a Medicaid expansion CHIP program are eligible for VFC vaccines.

Children enrolled in a separate CHIP program are considered fully insured, so they are not eligible for VFC vaccines. The state CHIP is responsible for vaccine payment for its members. Award recipients must guarantee that the appropriate funding is in hand before placing orders for vaccines that will be administered to CHIP members.

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Module 1 – Patient Eligibility and Insurance Criteria

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Overview

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. (For more information about VFC provider requirements, see Module 2 – Recruiting and Enrolling Providers.)

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.

Award recipients must ensure that providers:

- Understand the VFC eligibility categories
- Document VFC eligibility for each immunization visit

Criteria for Program Eligibility

The VFC program provides vaccines at no cost to children 18 years of age or younger who meet at least one of the following criteria:

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

VFC Eligibility Criteria for Patients

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

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.

Note: Providers should notify the award recipient 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

The award recipient should then work directly with their state Medicaid agency to address the situation.

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 VFC borrowing form. (For more information, see Module 3 – Vaccine Management).

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

A child is considered underinsured and is VFC-eligible if the 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.

The provider should administer VFC vaccines and bill the administration fee to Medicaid.

Underinsured

Underinsured means the child has health insurance, but the insurance policy either:

- Does not cover any ACIP-recommended vaccines
- Does not cover all ACIP-recommended vaccines (i.e., underinsured for vaccines not covered)
- Does not provide first dollar coverage (which includes copays, coinsurance, or deductibles) for ACIP-recommended vaccines
- Covers ACIP-recommended 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 ACIP-recommended 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

Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs)

Underinsured children can only receive VFC vaccines at either:

- Federally qualified health centers (FQHCs)
- Rural health clinics (RHCs) or
- Locations under an approved deputization agreement. (See a sample memorandum of understanding, or MOU, in the VFC Cooperative Agreement Management Platform Knowledge Center)

FQHCs and RHCs provide health care to medically underserved areas and meet certain criteria under Medicare and Medicaid programs (see Module 6 – Program Operations).

What is an FQHC?

An FQHC is a health center designated by the Bureau of Primary Health Care of the Health Resources and Services Administration (HRSA) to provide health care to a medically underserved population.

FQHCs include:

- Community and migrant health centers
- Health centers within public housing and Indian health centers
- "Look-alikes" (which meet the qualifications but do not actually receive grant funds)
- Special health facilities (such as those for persons experiencing homelessness and persons with acquired immunodeficiency syndrome, or AIDS, who receive grants under the Public Health Service Act)

What is an RHC?

An RHC is a clinic located in a:

- Health Professional Shortage Area
- Medically Underserved Area
- Governor-Designated Shortage Area

RHCs must be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time that the clinic is open.

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 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
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.

Special Circumstances

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.

Award recipients should have MOUs in place with neighboring states to ensure that VFC-eligible children have access to VFC vaccines within their medical homes. Award recipients can find a sample MOU in the VFC CAMP Knowledge Center.

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

Module 2 – Recruiting and Enrolling Provider Locations

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Overview

Health care providers who vaccinate children are critical to extending the Vaccines for Children (VFC) program's reach. They increase the potential number of children vaccinated in an award recipient's jurisdiction. They also allow VFC-eligible children to stay in their medical homes.

Award recipients must:

- Assess gaps in vaccination access for VFC-eligible children in their jurisdictions.
- Recruit and enroll providers in the VFC program to increase access to vaccines.
- Educate providers on VFC program requirements as well as proper vaccine storage and handling.
- Monitor provider locations enrolled in VFC for adherence to the program's requirements.

Eligibility

REQUIREMENT: Award recipients must verify that providers meet the eligibility criteria for enrollment in the VFC program.

According to the Personnel Aspects of the Indian Self-Determination and Education Assistance Act, Public Law 93-638 (1986), Indian Health Service (HIS) health professionals who are assigned or detailed to tribes or tribal organizations under the Intergovernmental Personnel Act or Memorandum of Agreement are not required to be licensed in the state in which they are assigned or detailed.

Award recipients must still validate the medical licenses of these IHS providers with out-of-state credentials.

To be eligible to participate in the VFC program, providers must be:

- Authorized in the award recipient's jurisdiction to administer vaccines to children aged 18 years and younger
- Able to order, receive, manage, store, and monitor the temperature of public vaccines
- Willing and able to follow all VFC program requirements, policies, and procedures. This includes participating in site visits and educational opportunities.
- Open at least four consecutive hours on a day other than a Monday to receive VFC vaccines. This accommodates the delivery window for VFC shipments.

If a state Medicaid agency notifies the award recipient that a provider is on the Office of Inspector General's (OIG) List of Excluded Individuals and Entities (LEIE), the award recipient cannot enroll that provider in the VFC program.

Recruitment

At least biannually, award recipients must assess whether their VFC-eligible population has adequate access to vaccines. Award recipients must prioritize recruiting provider locations that can address any gaps in access, especially in areas with low vaccination coverage.

To identify new potential VFC providers, award recipients can collaborate with:

- State licensing boards
- The state Medicaid agency
- Medical societies (including hospital associations and pharmacy associations)
- The Indian Health Service (IHS), including Tribal and Urban health facilities for award recipients with federally recognized tribes

These entities may assist award recipients by identifying providers who vaccinate children but are not enrolled in VFC.

Prioritizing Potential Provider Locations for VFC Enrollment

Award recipients should prioritize:

- Newly licensed providers
- Facilities in areas where access to vaccines is a concern
- Facilities serving a large population of Medicaid-enrolled children
- Facilities serving primarily American Indian/Alaska Native children

Additional criteria to consider are:

- Practice size
- Age of patients
- Previous contact with the provider about VFC enrollment

Award recipients must address provider recruitment for their jurisdictions.

For more information, see Module 6 – Program Operations.

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.

Award recipients can allow specialty providers to administer only vaccines recommended for the specific populations that those providers serve.

Pharmacies

Pharmacies are eligible to enroll in the VFC program if state law grants them the authority to administer vaccines by prescription, vaccine protocol, or prescribing authority.

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
- Local health departments

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

- Birthing facilities (e.g., birthing hospitals or centers)
- Obstetrician/gynecologists (OB/GYNs)
- Pharmacies*
- 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)
- School-located vaccination clinics*
- Specialty provider practices
- Urgent care centers*

*These providers must agree to vaccinate all "walk-in" children who are eligible for VFC. They must also meet all general VFC requirements.

Pharmacists must meet all other general VFC requirements including agreeing to vaccinate all "walk-in" VFC-eligible children. "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 pharmacy or provider's office policy is for all patients to make an appointment to receive vaccinations, then the policy would apply to VFC patients as well.

Enrolled provider locations such as pharmacies and off-site vaccination clinics are not required to offer all vaccines recommended by the Advisory Committee for Immunization Practices (ACIP) for the populations that they serve. Instead, they may offer limited types of VFC ACIP-recommended vaccines, such as influenza vaccine, COVID-19 vaccine, or both, to VFC-eligible children. Award recipients have the discretion to determine these offerings.

Enrollment of Multiple Provider Locations Under a Common Health Care Entity

Award recipients may enroll multiple provider locations within a jurisdiction that are under a common healthcare entity or group. They can do so by permitting the medical director or equivalent authority to complete provider agreements for multiple site locations.

Each provider location must adhere to all requirements of the VFC program. These include:

- Having a primary and back-up vaccine coordinator
- Operating within the VFC requirements for storage and handling
- Completing an enrollment site visit
- Completing the onboarding process for the immunization information system (IIS), if required by the jurisdiction

Enrollment

Once a provider has agreed to participate in the VFC program, award recipients must verify the provider's eligibility. The verification process includes collecting enrollment forms and conducting an enrollment site visit.

Enrollment Forms

The provider enrollment process has three forms:

1. Provider Agreement
2. Provider Profile
3. Patient Eligibility Screening Record (or similar guidance)

Award recipients can find more information about the enrollment forms in the VFC Cooperative Agreement Management Platform (CAMP) Knowledge Center.

1. Provider Agreement

This form is a contract developed by the Centers for Disease Control and Prevention (CDC). The contract is between the provider location and the award recipient. It outlines requirements with which providers must comply to receive publicly funded vaccines through the VFC program.

- Award recipients must use the CDC-approved Provider Agreement for enrollment and recertification within their jurisdictions.
- Award recipients may request CDC approval to add language specific to their state, city, or program policies.

  These requests must relate to one or more of the following:

  - Delegation of authority for federally qualified health centers (FQHCs) or rural health clinics (RHCs)

    (**Note**: The award recipient must have an approved deputization agreement in place.)

  - Pharmacies, urgent care, or school-based vaccination clinics that are enrolled as specialty VFC provider locations
  - The Vaccine Tracking System (VTrckS)

    (**Note**: This applies only to award recipients who require provider direct entry in VTrckS. This does not apply to award recipients who have an external information system, or ExIS.)
  - Restitution for federal vaccines, state vaccines, or both
  - The jurisdiction's IIS
    (**Note**: Award recipients must include the proposed language that will be included on the Provider Agreement.)
  - Inventory of vaccines for patients who are not eligible for VFC
  - Participation in an approved vaccine ordering replacement model
  - Vaccine storage, administration, and distribution
    (**Note**: This applies to provider locations with approval from their state, local, or territorial immunization program to store and distribute publicly funded vaccines.)

Award recipients must submit these requests to the assigned Immunization Operations and Services Branch (IOSB) project officer on the Award Recipient Provider Agreement Application.

CDC will use the submission to develop the final Provider Agreement and approve it for the award recipient's use.

After receiving CDC approval, award recipients cannot modify the Provider Agreement without repeating the application process.

REQUIREMENT Awardees must use CDC's Provider Agreement for initial program enrollment, program reenrollment, and provider recertification.

Signing the Provider Agreement

- All VFC provider locations in an award recipient's jurisdiction must complete and sign CDC's 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.

Eligibility for State Vaccine

Award recipients may have a finance policy that designates the use of state funds or other funds to purchase vaccines for children who are not eligible for VFC. These award recipients must clearly define these criteria for providers as "state vaccine-eligible" in an addendum to the Provider Agreement.

These award recipients also must confirm that providers are screening for this category of state vaccine eligibility and administering doses to qualified children.

- For an enrolled practice, the Provider Agreement must list:
  - All licensed health care providers in the practice
  - Their corresponding professional license numbers
- In jurisdictions where pharmacists are administering vaccines under the direct supervision of a physician, both the pharmacist and the supervising physician must sign the Provider Agreement.
- All parties involved with implementing the clinics (i.e., community vaccinator, physician, medical director, other groups that are directly administering the vaccines) must sign the Provider Agreement in jurisdictions where there are:
  - Community vaccinators enrolled
  - Circumstances where the enrolled provider location is not providing direct service and other parties are involved with administering vaccines

  Note: In this situation, the CDC Provider Agreement must include an attached agreement that details the responsibilities of each party involved.
- 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.

2. Provider Profile

This form captures the number children by a VFC provider location, categorized by VFC eligibility status. The information in the form represents populations served by the practice or facility during the most recent 12 months.

- The Provider Profile helps award recipients determine how much VFC vaccine to supply to each provider location.
- Award recipients can use the Provider Profile to compare projected vaccine needs with actual vaccine orders and inventory.
- The Provider Profile helps determine vaccine amounts by fund type for distribution to provider locations.
- Providers must update the Provider Profile every 12 months or have award recipients do so on their behalf. Updates must be more frequent 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
    - CDC Provider Profile templates are available for award recipients to use. Each version illustrates a different vaccine purchase policy as well as different categories of children who are not eligible for VFC
- Award recipients can determine the Provider Profile information on a provider location's behalf if they can collect, manage, and incorporate data on the provider location's patient population. They must note patients' age groups and eligibility status for VFC.

3. Patient Eligibility Screening Record

This form guides VFC eligibility screening and offers a location to document each child's eligibility category.

- Award recipients can use a CDC-developed Patient Eligibility Screening Record.
- Award recipients can develop their own form or written guidance as long as it includes the ability to document patient eligibility and all eligibility categories.
- Award recipients reinforce the requirement for eligibility screening and documentation by including a form or written guidance with enrollment materials.

REQUIREMENT: Award recipients must advise providers on one or more acceptable methods for documenting results of patient eligibility screening. Providers must use either CDC's Patient Eligibility Screening Record or alternative forms or guidance from award recipients.

Electronic Enrollment Forms

Award recipients may allow VFC providers to complete and sign enrollment and recertification paperwork through an electronic system. The award recipient's electronic system must meet all program-specific, electronic security requirements.

Electronic forms must use language that:

- Mirrors the content and requirements of the Provider Agreement
- Uses an electronic signature to acknowledge understanding and agreement to maintain the requirements of the VFC program
- Explains that receipt of VFC vaccines after the electronic signature date is further acknowledgement of the Provider Agreement's terms

Enrollment Site Visits

The enrollment site visit provides an opportunity to:

- Educate providers about:
    - Requirements of the VFC program
    - Proper vaccine storage and handling
- Certify that provider locations have the appropriate resources to implement vfc requirements
- Confirm that providers know whom to contact if problems arise, especially with storage and handling issues
- Complete a Vaccine Management Plan

Award recipients must complete the enrollment site visit before a provider location can receive VFC vaccines. For the 2025-2026 budget period, award recipients may offer a virtual enrollment site visit.

See Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance for more information about managing VFC vaccines and conducting site visits.

Award recipients must perform enrollment site visits independently of compliance site visits. They must not administer the VFC Compliance Site Visit Reviewer Guide during enrollment site visits.

Before a new or reenrolling provider location can receive vaccine shipments, award recipients must:

- Educate the provider on implementing vfc requirements, including proper vaccine management and review of a vaccine management template.
- Verify that the provider location has the appropriate storage and handling equipment in place to receive and store vaccines.
- Document the primary vaccine coordinator and at least one backup coordinator for each facility.
- Complete the enrollment site visit.
- Enter data for the enrollment site visit into the Provider Education, Assessment, and Reporting (PEAR) system.
- Activate the provider location in VTrckS.

Reenrollment, Recertification, and Review

Reenrollment

If provider locations leave the VFC program but later want to be reenrolled, award recipients must complete all steps for a newly enrolling provider location. These include all education and documentation requirements, as well as an enrollment site visit.

Award recipients should be able to track if providers leave the program but later want to be re-enrolled; this allows award recipients to determine if there has been a history of unresolved noncompliance or mandatory exclusion (i.e., inclusion on the LEIE). However, terminated providers should be eligible to reenroll if they are no longer on the LEIE and have addressed all past instances of noncompliance with the VFC program.

REQUIREMENT: Award recipients must recertify VFC provider locations every 24 months.

Provider Recertification (Every 24 Months)

Current VFC provider locations must be recertified to remain in the program. Award recipients have discretion over the recertification's timing as long as all provider locations are recertified every 24 months.

To recertify provider locations, the award recipient must:

- Verify provider eligibility (i.e., licensure in the jurisdiction).
- Collect a signed Provider Agreement and ensure that it is complete and accurate.
- Distribute the CDC Patient Eligibility Screening Record or written guidance developed by the award recipient to support eligibility screening and documentation.

Training Requirements for Provider Locations

Every VFC provider location must receive comprehensive training at the initial site visit for VFC enrollment site. Annual trainings are also required. The training areas include

1. VFC Programmatic Training
This training covers all VFC program requirements, including those in the Provider Agreement.

Award recipients should coordinate and conduct this training every 12 months. At a minimum, the vaccine coordinator and backup coordinator must complete this annual training.

2. Vaccine Management Training
Award recipients provide vaccine management training at the enrollment site visit.

After the initial training, providers must complete annual training on proper storage and handling procedures for all staff involved in the receipt, management, administration, or transport of vaccines.

The award recipient-defined annual training should also cover vaccine management training. See Module 4 – Ensuring Provider Compliance for more information.

Provider Review (Every 12 Months)

Award recipients must review and update key information for current VFC provider locations in order for those locations to remain in the program.

REQUIREMENT: Award recipients must review key information of VFC provider locations every 12 months.

Award recipients have discretion over the review's timing as long as all provider locations are reviewed every 12 months.

To review provider locations, award recipients must:

- Collect and validate Provider Profile data.
- Verify that provider locations meet the requirement for annual training defined by the award recipient.

Termination

Either the award recipient or provider may terminate the VFC Provider Agreement at any time. The award recipient must terminate the agreement if:

- The state Medicaid agency notifies the award recipient that a provider is on the LEIE.
- An enrolled VFC provider location has not ordered vaccine in the past 12 months.
    - In most circumstances, this provider location is considered inactive and should be unenrolled in PEAR.
    - The Provider Agreement should be considered terminated.

If a provider location has not ordered vaccine in the past 12 months, termination may not be warranted. Examples of such circumstances include when:

- The provider location is a specialty provider who only needs small quantities of vaccine.
- The provider location is a store-only location—that is, it stores and distributes but does not administer vaccine.

Award recipients must use PEAR to document the reason for unenrollment and the person who initiated the unenrollment.

The award recipient must follow the guidance for vaccine transport outlined in CDC's Vaccine Storage and Handling Toolkit when retrieving unused VFC vaccines from the provider location.

REQUIREMENT: If the Provider Agreement is terminated, the award recipient must retrieve any unused VFC vaccine from the provider location within 30 days of termination.

List of Excluded Individuals and Entities (LEIE)

The Office of Inspector General (OIG) of the Department of Health and Human Services (DHHS) maintains the LEIE. Providers on this list are excluded from participating in federally funded health care programs because of issues that include:

- Program-related fraud
- Patient abuse
- Licensing board actions
- Default on Health Education Assistance Loans

CMS requires state Medicaid agencies to use the LEIE to identify ineligible Medicaid providers. The VFC program falls under the auspices of CMS, so provider locations with providers on the LEIE are not eligible to enroll, reenroll, or otherwise participate in the VFC program in any way.

Award recipients should work with the state Medicaid agency to develop procedures to ensure that the agency routinely notifies them about changes in providers' eligibility to participate in the VFC program. LEIE exclusion requirements apply to any provider location staff members, including any subcontractors

REQUIREMENT: When a state Medicaid agency notifies an award recipient that a provider location has a staff member or subcontractor on the LEIE, the award recipient must terminate the provider location from the VFC program.

Module 3 – Vaccine Management

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Overview

Vaccine loss is both costly and preventable. Award recipients and providers must maintain vaccine quality from the time a shipment arrives at a facility until a dose is administered. Sound vaccine management practices for ordering, maintaining inventory, and storing and handling are crucial for minimizing vaccine loss and waste. Sound practices also avoid the potential for putting children enrolled in the Vaccines for Children (VFC) program at risk from compromised vaccine.

Award recipients are responsible for:

- Ensuring that vaccine coordinators are properly trained and are using a Vaccine Management Plan in their facilities
- Supplying education and training resources to provider locations on best practices for vaccine ordering, inventory management, and storage and handling
- Establishing and enforcing accountability policies for vaccine inventory

Vaccine Coordinators

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

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, or
  - emergency situations such as a power failure.
- **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
- **Lost or unaccountable vaccine:** Vaccine that is missing its physical vial or syringe.

The vaccine coordinator is responsible for overseeing all vaccine management within the facility. The coordinator's duties include:

- Developing and maintaining the Vaccine Management Plan
- Monitoring the facility's practices for storing, handling, and administering vaccines
- Overseeing vaccine ordering and notifying the award recipient 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 should contact the award recipient, if needed, to provide training for 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

REQUIREMENT: Award recipients must work with providers to develop plans for vaccine management. These plans must include feasible standard operating procedures (SOPs) for routine and emergency vaccine management.

VFC provider locations must develop, maintain, and implement a Vaccine Management Plan with detailed, up-to-date SOPs for routine and emergency vaccine management. Award recipients should provide a Vaccine Management Plan template to assist provider locations, although provider locations can develop their own. Award recipients must review and approve provider-developed plans.

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 (e.g. COVID-19, Mpox, PPSV23) available to VFC-eligible children, if not stocked routinely by a VFC provider (see Module 6 for more detail).

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.

Vaccine Management Training

Vaccine management training first occurs during provider enrollment. The training includes a review of the key components of a Vaccine Management Plan. After enrollment, provider locations must receive vaccine management training annually. See Module 4 – Ensuring Provider Compliance.

The primary and backup vaccine coordinators must be fully trained in routine and emergency SOPs for vaccine:

- Shipments
- Storage and handling
- Transport
- Inventory management

Other provider location staff may also need training, including those who are involved with vaccine management

and storage and handling.

Vaccine Ordering

REQUIREMENT: Award recipients must monitor vaccine orders to ensure that providers are ordering vaccine in the appropriate amounts and properly maintaining their vaccine inventories.

Vaccine loss due to expiration usually happens due to over-ordering, poor inventory management, or both. To prevent this, provider locations need to determine the appropriate amounts of vaccine to order for their private and public inventories.

Provider locations must submit their total vaccine inventory amounts (i.e., number of doses physically on hand) with each vaccine order. CDC recommends that provider locations:

- Place vaccine orders while they still have a four-week supply of vaccine available (to allow for potential delays)
- Place smaller, more frequent orders rather than large orders to minimize vaccine loss should an incident take place during shipment or in the vaccine storage unit

The provider location's ability to immediately store vaccine after receipt is also 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.

Provider locations must keep their Provider Profiles current to reflect any changes to their public and private patient categories. They must also submit updates to their Provider Profiles to award recipients. Award recipients use the profile data to monitor vaccine orders to ensure that provider locations are not inadvertently over-ordering, stockpiling, or building inventory; these ordering actions can put vaccine at risk for waste or indicate fraud or abuse.

Some providers access the Vaccine Tracking System (VTrckS) to order vaccines. Award recipients must monitor these provider locations for compliance with the guidelines outlined in the Centralized Vaccine Distribution Guide, which is available in the VFC Cooperative Agreement Management Platform (CAMP) Knowledge Center.

Provider Profile Estimates

Award recipients must assess whether the patient population estimates reported in a Provider Profile reasonably matches a provider location's patterns in vaccine ordering. To accomplish this, award recipients can compare:

- Patient population estimates with the birth cohort for the state or jurisdiction. Award recipients can determine whether the estimate relative to the birth cohort is an amount that makes sense for the community that the provider location serves, assuming the provider plans to vaccinate all patients.
- Vaccine orders for the provider location with the population estimate. For example, if a Provider Profile estimates serving 100 patients under 1 year of age during a 12-month period, award recipients can compare the amount of DTaP doses ordered against this 100-patient estimate (three doses per eligible child, 300 doses during the year, or 75 doses quarterly).

- Doses administered as reported in an immunization information system (IIS) with the quantity of vaccines ordered. This can help show whether the doses ordered are being correctly administered to eligible populations. It can also help show whether quantities ordered are appropriate amounts for the eligible populations shown in the Provider Profile.

If comparisons show significant discrepancies from estimates in the Provider Profile, award recipients should consult with the provider to determine reasons for the discrepancies. The provider may need to update the Provider Profile.

Storage and Handling

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, but award recipients should encourage providers 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 Equipment Requirements for Storage and Handling

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

- Storage units that maintain the correct temperatures at all times
  - Refrigerators must maintain a temperature between 2 °C and 8 °C (36 °F and 46 °F).
  - Freezers must maintain a temperature between -50 °C and -15 °C (-58 °F and +5 °F).
  - Note that Pfizer-BioNTech COVID-19 vaccine may be stored in an ultra-cold freezer and maintained between -90 °C and -60 °C.
- Digital data loggers (DDLs) with the capability for continuous monitoring and current valid Certificates of Calibration Testing
- Access to at least one backup DDL on site

REQUIREMENT: Award recipients must monitor provider practices to verify compliance with guidelines for vaccine management. Award recipients and providers can find these guidelines in CDC's *Vaccine Storage and Handling Toolkit* and this guide.

Refrigerator and Freezer Units

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

CDC recommends the following units, starting with the most preferable, for storing 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 (which have been tested rigorously to be used for the storage of vaccines)*
- 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. **

**American National Standards Institute (ANSI) is the organization that accredits the National Sanitation Foundation (NSF) after the name change in the 1990s that resulted from the expansion of their services beyond sanitation to broader public health and safety organization.*

***Any provider enrolled in the VFC program on or before June 30, 2024. who currently uses both compartments of a household combination unit that consistently maintains the required temperature ranges may continue to do so. If temperature excursions that cannot be connected to another cause (e.g., power outage) occur, the provider must discontinue the unit's use, even if doing so necessitates purchasing a separate freezer unit. Provider locations enrolled in the VFC program are prohibited from using dormitory or bar-style refrigerators, freezers, or both. These units have a single exterior door and an evaporator plate or cooling coil, which usually located in an icemaker or freezer compartment.*

Best Practices for Storage Units

To protect vaccine viability:

- 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. *
- 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.

**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.*

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

Providers must also protect the power source for all storage equipment. This is usually accomplished by placing warning labels that say "Do Not Disconnect" at the electrical outlet and circuit breaker.

Digital Data Loggers (DDLs)*

VFC provider locations must use digital data loggers (DDLs) for routine, on-site vaccine storage; during vaccine transport; and in temporary, mobile, off-site, satellite and community vaccination clinics. In some cases, award recipients may supply DDLs.

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:

- Capabilities to continuously monitor temperature and 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 (DDLs provided by award recipients must have buffered probes. DDLs purchased by providers do not have to be buffered; however, CDC recommends using buffered probes)
- A current, valid Certificate of Calibration Testing. This is also known as a Report of Calibration

Doorless or Vending-Style Units

For doorless or vending-style units, providers must identify the units':

- Type (i.e., refrigerator or freezer)
- Purpose or style (i.e., doorless or vending style)

Award recipients determine which purpose-built units providers can use to meet the requirements of the VFC program. Providers can refer to CDC's Vaccines Storage and Handling Toolkit for more information on purpose-built units.

**Some provider locations may have purpose-built or pharmaceutical-grade equipment (e.g., doorless or vending-style units) with temperature monitoring capabilities. These units may monitor vaccine temperature as reliably as a DDL. However, some of these units may not be capable of digitally logging temperatures. 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)

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, award recipients, providers, or both must have the unit retested before it expires; this ensures that a valid DDL is available for required temperature monitoring. Backup DDLs are usually maintained on site.

Provider locations can use a different approach if they can obtain a backup DDL to meet the requirement for once-daily assessment and reporting. Award recipients must approve this approach. The provider location must also document the approach in its Vaccine Management Plan.

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.

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

> ***Temperature Excursion***
>
> A temperature excursion is any temperature outside of the recommended range found on a vaccine's package insert, for any duration of time.

Receiving and Documenting Vaccines

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 (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.

Vaccine Compromised During Shipment

If providers believe a vaccine shipment was compromised, they must immediately contact the award recipient. Based on the requirements of the award recipient, the provider should also contact:

- **Centralized distributor shipment:** Providers can contact centralized distribution immediately at 1-877-TEMP123 (1-877-836-7123). They must do this 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. An award recipient's budget may be reduced for this liability.

- **Direct shipment from manufacturer**: Providers should use the award recipient's guidance on whether to contact them or the vaccine manufacturer.

  Providers, award recipients, or both must contact the manufacturer directly with questions about storage temperature or temperature excursion for specific vaccines. Manufacturers have access to internal thermostability data on the impact of exposure to inappropriate temperatures or light for each vaccine lot.

  Providers must review and record minimum and maximum temperature readings at the beginning of the workday. Then, they must reset the minimum and maximum readings. This helps to identify temperature excursions quickly so that corrections can be made, preventing vaccine loss as a result.

CDC recommends that providers check the current temperature of the storage unit before accessing and administering vaccine from the unit.

When documenting a temperature reading, providers should include:

- At least one minimum and maximum temperature reading daily at the beginning of the workday
- The time and date of each reading
- The name or initials of the person who performed and recorded the reading

Providers have two options for documenting temperature readings:

Option 1: **Handwrite the temperature on a paper log.** Providers should post the log on the door of each vaccine storage unit, or nearby in an accessible and visible location. Providers can find a printable temperature log on the Immunization Action Coalition's website.

Option 2: Use a system for continuous temperature monitoring and recording. This allows providers to electronically document temperature readings. Award recipients have discretion to allow providers to use this option.

Award recipients should:

- Verify that the provider location's system for continuous temperature monitoring can perform the required activities.
- Understand how the provider location's system works, including how to read and interpret data. This allows award recipients to verify that the provider is meeting the VFC program's requirements for temperature documentation.

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.

- If a provider location uses paper logs, it must maintain those.
- If a provider location uses both electronic and printed logs (i.e., electronic copy and hard copy), it must maintain both log types.

If providers suspect that a temperature excursion has occurred, they should follow their vaccine management standard operating procedures (SOPs). Providers should also adjust the temperature to the appropriate range and notify the award recipient to determine whether the vaccine can still be used. Until this determination has been made, providers should label the vaccine as "Do Not Use" and store it under the correct temperature conditions. The vaccine may still be viable, so providers must not discard the vaccine, or remove it from proper storage conditions, until directed to do so by the award recipient.

Award recipients must provide guidance on documenting and reporting temperature excursions in the Vaccine Management Plan template. Doing so helps award recipients to best determine whether patients need to be revaccinated.

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 and record the incident, including the reason and number of doses lost, as instructed by the award recipient (Download the Vaccine Storage Troubleshooting Record).
- Return spoiled and expired vaccines within 6 months of the spoilage or expiration date. These vaccines, if necessary, will be accepted after 6 months, but this should be a rare situation. Providers should dispose of wasted vaccines according to state and local disposal requirements.

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. CDC recommends inspecting 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.

Readers can find more information on vaccine storage and handling in CDC's *Vaccine Storage and Handling Toolkit* and on CDC's vaccine administration website and educational materials.

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 ACIP-recommended vaccines for non-VFC-eligible patients if they do not plan to offer all ACIP-recommended 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 these two stocks of vaccines, unless the provider is in a universal purchase jurisdiction or approved to use a vaccine ordering replacement model.

Publicly purchased vaccines include vaccine supplied to the provider location to administer to children who are eligible for VFC or state-purchased vaccines. (If the award recipient purchases vaccines for Children's Health Insurance Program [CHIP] beneficiaries, then vaccines from this inventory may also be administered to those children). Providers in universal purchase jurisdictions will only have a single vaccine inventory for children.

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

- Fully insured children
- Children who are enrolled in the CHIP
- Other underinsured children (i.e., served by provider or facility that is not a federally qualified health center, rural health center, or deputized provider)

Privately purchased vaccine inventory also includes state-purchased vaccines that are used for insured patients when third party billing is performed.

Award recipients can find more guidance in the VFC CAMP Knowledge Center.

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.

Vaccine Borrowing

REQUIREMENT: Award recipients can 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.

CDC expects vaccine borrowing to be rare because provider locations should maintain adequate inventories of vaccine for both privately insured and VFC- or state-eligible children. VFC vaccines should never be used as a continuous replacement system for a provider location's inventory for privately purchased vaccine unless CDC and the award recipient have approved a vaccine ordering replacement model.

Award recipients should only approve vaccine borrowing for instances when:

- There is a lack of vaccine stock because of delayed or spoiled shipments. This bidirectional borrowing does not apply to influenza vaccine.
- Vaccine will expire soon and will be lost if not used. Provider locations with a small population of privately insured patients 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 incorrectly calculated ordering intervals, leading to a lack of either private or public vaccine stock.
- VFC stock for seasonal influenza vaccine is not yet available. Provider locations may use private stock, seasonal influenza vaccine for VFC-eligible children and replace it when VFC vaccine becomes available. This one-directional borrowing is unique to seasonal influenza 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.

Vaccine Borrowing Documentation

Vaccine Borrowing Report

Award recipients must complete the Vaccine Borrowing Report when either:

- A VFC-eligible child receives privately purchased vaccine
- A privately insured child receives VFC vaccine

Award recipients may report the information using CDC's template. They may also develop their own report as long as it contains all the CDC template's components. Award recipients can find CDC's template in the VFC CAMP Knowledge Center. See Module 6 – Program Operations for additional information.

Invoices

Providers may need to maintain invoices to validate that they used privately purchased vaccine to replenish borrowed VFC vaccine. The invoice date should correspond with the replacement date on the Vaccine Borrowing Report.

Award recipients must follow up with provider locations who borrow vaccines multiple times in a single year. Award recipients should assess the inventory management practices within the facility to determine whether changes can eliminate the frequent need to borrow. It is a recommended best practice that award recipients use IIS and/or other inventory systems to identify potential borrowing instances in advance of site visit discussions.

Vaccine Transfer

Proper vaccine inventory management at both the award recipient and provider level 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 award recipients about short-dated vaccine so they can coordinate a transfer. Note that transfers should be rare as long as provider locations are appropriately managing inventory.

REQUIREMENT: Award recipients must approve, coordinate, and document vaccine transfers between VFC provider locations.

Vaccine transfers can only occur:

- With the award recipient'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 award recipient 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 public (i.e., VFC, state) 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 award recipient.

Award recipients can find more information in the VFC CAMP Knowledge Center.

REQUIREMENT: If award recipients want to implement a replacement model for vaccine ordering in their jurisdiction, they must submit a proposal to the VFC functional mailbox at VFC@cdc.gov.

Before submitting a proposal, award recipients must make sure they can:

- Verify provider eligibility
- Oversee the process for vaccine replacement
- Ensure that replaced doses directly reflect the VFC-eligible children served by the provider location

Proposals for vaccine replacement models must meet the following criteria:

- Each vaccination encounter must include VFC screening and documentation of the patient's eligibility status for VFC and state vaccine.
- The award recipient must have an immunization information system (IIS). The IIS must capture eligibility status at the dose level based on the required eligibility categories, as outlined in Module 1 – Patient Eligibility and Insurance Criteria.
- The IIS must also document all doses administered and eligibility data within 30 days of the vaccination

encounter.

- The award recipient must assess doses-administered data and replace vaccines according to data from the last 30 days.
    - The proposal must include a sample of the data, report, or both that the award recipient will review monthly. The award recipient must include the following data:
        - Actual doses to be replaced, including total number of doses by eligibility as well as by vaccine type, brand, or presentation
        - Patient-level data validating that only doses used for VFC-eligible children are being replaced
- Providers must submit replacement dose orders monthly.
- The award recipient must ship replacement vaccine directly to the provider location. The award recipient should also consider that:
    - 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 clinics throughout the state.
- The award recipient must submit the total public vaccine inventory to VTrckS (either directly or via ExIS) with each vaccine order. The award recipient must represent the public portion of the provider location's inventory on hand.
    - To do this, the award recipient can apply the percentage of the provider location's VFC-eligible population from the VFC Provider Profile to the current vaccine inventory.
    - The award recipient cannot report a zero-amount based on the rationale that all doses on hand are considered private.
- The award recipient must submit public vaccine returns to represent the public portion of the total vaccine returns. To do this, award recipients can apply the percentage of VFC-eligible children in the provider location to the total amount of returned vaccines.

The award recipient may need to provide a demonstration of the system or process used to meet these requirements.

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, state vaccine, or both that were lost due to provider negligence.

CDC recommends that award recipients establish a restitution policy for federal vaccine doses (i.e., VFC, 317) that

are lost due to provider negligence. Award recipients have discretion over the restitution criteria.

Restitution policies should:

- Identify examples of typical situations that may require restitution
- Set reasonable loss thresholds for situations that require restitution
- Consider the size of loss, number of previous incidents involving the provider, and the provider location's response to education and corrective action plans when determining loss thresholds or doses to be replaced

Award recipients' restitution policies must state that 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. CDC does not allow financial payment as a form of restitution under any circumstances.

Providers must follow the award recipient's restitution policy, including:

- Only administering replaced doses to children who are eligible for VFC or state purchase vaccines, as applicable. These replaced doses must be based on the same proportion as the lost doses' original funding sources (i.e., VFC or state).
- Contacting the award recipient for guidance on handling any replaced vaccines that cannot be administered to the eligible population. These vaccine doses may be shipped directly to a local health department to be administered to VFC-eligible children. If a local health department is unavailable, another type of provider may receive the vaccines.
- Submitting 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 award recipient must negotiate an alternative replacement plan that should be met within six months.
- Providing required documentation related to restitution. This includes administering replacement doses to VFC-eligible or state-covered children (if applicable).

Temporary, Mobile, Off-Site, or Satellite Clinics

Some providers may conduct temporary, mobile, off-site, or satellite clinics. Award recipients may also collaborate with community vaccinators within their jurisdictions. These opportunities can improve access and vaccination coverage for VFC-eligible children. However, these situations require additional program oversight and vaccine accountability.

Mobile Clinics

Mobile clinics are movable units (e.g., trailers, buses) associated as extensions of existing providers. They allow access to health care services (e.g., immunization) and offer flexible and viable options for treating isolated and vulnerable groups as well as displaced populations

Mobile clinics are not the primary site for vaccine storage and administration. They should not be confused with mobile providers, who exclusively store and administer vaccines out of a mobile facility

These alternative provider locations must adhere to all general requirements for the 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" until they can gather further information on usability.

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

- Vaccine ordering:
  - CDC recommends that vaccines are delivered directly to provider facilities. However, this may not be possible for temporary, mobile, off-site, satellite and community vaccination clinics.
  - When direct delivery is not possible, vaccines must be ordered and shipped directly from CDC to a location within the award recipient's jurisdiction. This protects the cold chain and vaccine viability.
  - Providers may only administer vaccines within the jurisdiction.
- Records of vaccine transport:
  - These must detail the type of vaccine(s) as well as the quantity being transported.
  - Providers should maintain temperature monitoring for temporary, mobile, off-site, or satellite clinics.
- Provider forms:
  - Community vaccinators must sign a Provider Agreement and complete a Provider Profile. (See Module 2 for more information.)
  - Award recipients should work closely with these community vaccinators to develop the profile, since some VFC-eligible children may be served by other VFC provider locations in the area.

Vaccine Handling and Preparation for Temporary, Mobile, Off-Site, or Satellite Clinics

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

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

Module 4 – Ensuring Provider Compliance

Table of Contents

Overview

Providers enrolled in the Vaccines for Children (VFC) program carry out vital functions, including eligibility screening, vaccine storage and handling, and vaccine administration. It is essential for these providers to understand VFC requirements as well as how the program operates.

Site visits, training, and other oversight measures help maintain and improve a provider location's compliance with requirements for the VFC program. Site visits provide an opportunity to:

- Identify potential accountability issues with VFC vaccine
- Determine whether provider locations are storing, handling, and administering vaccines per the laws and policies governing the VFC program
- Educate providers on requirements for the VFC program

To review and evaluate the practices of VFC provider locations, award recipients must assess verbal, written, and visual information that they encounter during site visits. This allows them to determine whether providers are following the program requirements.

The goals of a site visit are to:

- Identify areas in which providers are doing well, as well as areas that need follow-up
- Identify educational needs of VFC providers to help them meet program requirements
- Insure that VFC-eligible children are receiving viable vaccine that is properly managed

Site visits also are critical opportunities to engage providers and develop and strengthen ongoing relationships.

To ensure the quality of VFC vaccine and the integrity of the VFC program, award recipients must:

- Conduct site visits for:
    - Enrollment
    - Compliance
    - Storage and handling (These can be scheduled or unannounced.)
- Develop and maintain VFC contacts as needed
- Conduct annual training for provider locations

Provider Education, Assessment, and Reporting (PEAR) System

The Provider Education, Assessment, and Reporting (PEAR) online system is an oversight management tool for award recipients and the Centers for Disease Control and Prevention (CDC). PEAR collects relevant VFC data to support overall program activities. The system can also track and generate detailed reports on site visits and annual training for provider locations.

VFC site visit reviewers use a series of questions in PEAR to conduct site visits. Each question is paired with future follow-up actions and minimum required on-site actions. PEAR allows reviewers to track follow-up progress and

REQUIREMENT: Award recipients must use CDC's Provider Education, Assessment, and Reporting (PEAR) system to record visits to provider sites as well as follow-up.

maintain VFC contact information.

During site visits where there is internet access, reviewers must enter site visit data into PEAR while at the provider location. They must also submit the data in PEAR on the same day.

CDC has identified valid reasons for delayed entry of site visit data into PEAR. These reasons are noted in the system. When one or more of these reasons applies, the reviewer may record site visit information on a copy of the VFC Site Visit Reviewer Guide while at the provider location. The reviewer may use either a printed or digital copy (e.g., Microsoft Word document, fillable PDF) of the guide. The reviewer must enter and submit the site visit data in PEAR within 10 business days of the site visit. To maintain data quality control during this process, CDC may request that reviewers upload printed documentation for site visits in PEAR.

Note: A reviewer may choose to use a printed copy of the guide for documentation but also enter and submit data into PEAR while at the provider location. In this situation, the reviewer should select that the site visit was "documented using PEAR" when entering the data into PEAR.

Award recipients must use PEAR to:

- Enroll and unenroll provider locations
- Conduct and document all site visits (i.e., enrollment, compliance, storage and handling)
- Perform site visits using the appropriate VFC Site Visit Reviewer Guide
- Document actions for award recipient or provider follow-up for compliance issues discovered during the site visit
- Record annual training for provider locations
- Monitor and evaluate program performance

Award recipients may use the pre-visit checklist in PEAR to prepare for a site visit. They may also use the PEAR training website train new staff.

See Module 6 – Program Operations for more information about PEAR.

VFC Site Visit Reviewer Guides

The VFC Site Visit Reviewer Guides help site visit reviewers effectively:

- Communicate the requirements of the VFC program
- Assess and verify provider compliance

There are two VFC Site Visit Reviewer Guides: one for compliance site visits and one for storage and handling site visits. Reviewers must administer these guides exactly as written.

Understanding the intent of each question in the Site Visit Reviewer Guides and the associated federal requirement is key to conducting high-quality site visits.

To ensure that they receive a realistic picture of how a provider location is implementing the VFC program, reviewers must not share these guides or their content with providers at any time.

Award recipients can find the Site Visit Reviewer Guides in PEAR.

Site Visits

VFC site visits are designed to allow reviewers to evaluate different aspects of provider compliance with, and understanding of, VFC requirements. There are three types of site visits:

- Enrollment
- Compliance
- Storage and handling (These can be scheduled or unannounced.)

Arranging a Site Visit

Award recipients' procedures for scheduling site visits should include:

- Identifying a contact person at the facility to discuss site visit requirements, and confirming their job title and phone number
- Arranging a mutually convenient date and time for the site visit
- Confirming the facility's address and location
- Discussing the estimated amount of time needed for the site visit, as well as who will need to be available to meet during the visit, with the office manager
- Outlining any information, equipment, and on-site equipment that the reviewer needs (e.g., workstation, power source)
- Sending a confirmation letter, e-mail, or fax to the contact person with the date and time of the site visit:
    - Award recipients should also send a summary of the site visit process
    - They can find a sample pre-visit letter for VFC compliance in PEAR
    - As a reminder, site reviewers must not share the VFC Compliance Site Visit Reviewer Guide or its contents with the provider:
        - The letter should only discuss the process for the site visit and any needed accommodations.
        - The letter should not preview information from the VFC Site Visit Reviewer Guides.
- Confirming the site visit one to two working days before the scheduled appointment
- Confirming that the provider location has VFC vaccine in inventory. If the provider location does not have VFC vaccine in stock for any reason, the award recipient needs to reschedule the site visit.

Reviewers do not need to use a pre-site visit protocol for unannounced storage and handling site visits. However, they should communicate the purpose and intent of the site visit when they arrive at the provider facility.

Before a site visit, award recipients should explain what items and documentation providers should have available. Award recipients should also specify the locations within the facility that the reviewer will need to access. At the least, this information should include:

- The need for a space to work, as well as a power source if the reviewer will use a laptop
- Patient records (Note that award recipients must notify the provider that a sampling of records will be reviewed during the site visit.)
- Current and previous temperature logs or data for at least the last three months
- Current and previous vaccine borrowing reports
- Access to all storage units in which VFC vaccine is stored
- Time with admitting and billing personnel to clarify the provider's processes for screening and billing
- Access to the circuit breaker, if applicable:
    - The award recipient should notify the provider that that maintenance staff may need to be available during the site visit to gain access to the circuit breaker.
    - Award recipients can find more information on circuit breaker labels, as well as comprehensive policy and standard operating procedures, in the VFC Compliance Site Visit Reviewer Guide.

Protocol for Site Visits

CDC recommends that award recipients conduct site visits for VFC compliance independently of site visits for the Immunization Quality Improvement for Providers (IQIP) program.

When award recipients perform combined visits, they must allot enough time to observe the provider's vaccination workflow and discuss implementing quality improvement (QI) strategies with appropriate staff.

Because shifting from a compliance-focused dialogue to one with a collaborative emphasis may be difficult, CDC recommends that award recipients perform the IQIP component of the visit before performing the VFC component.

Preparing for a Site Visit

When preparing for site visits, reviewers should consider the following questions and answers:

Question	Answer
What do I need to know?	• Data from previous site visit reports • Provider Profile • Vaccine returns and wastage • Vaccine ordering • Data from the immunization information system (IIS) that flag potential issues with inventory, borrowing, and screening
What do I need to bring with me?	• Screening form for VFC eligibility • Labels for storage and handling • Current vaccine information statements (VISs) or a list of VIS publication dates • Information on vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) • Training resources related to VFC requirements, • Etc.
What do I need to print?	• Demographic information for the provider location • VFC Site Visit Reviewer Guide • Acknowledgement of receipt • Follow-up plan • Provider Profile • Vaccine Management Plan template • Etc.

Award recipients can find CDC pre-visit checklists for reviewers in the Documents tab of PEAR. Award recipients may also wish to develop their own tools to help with reviewer preparation

Enrollment Site Visit

Before they can receive public vaccine, all new and reenrolling provider locations in the VFC program must receive a VFC enrollment site visit. They must also meet all CDC-defined criteria.

The enrollment site visit gives award recipients the opportunity to:

- Confirm that the provider can store and monitor vaccine supply according to the VFC program's requirements
- Supply appropriate resources
- Educate providers on carrying out the VFC program's requirements. This must include the requirements outlined in the CDC Provider Agreement, VFC Site Visit Reviewer Guides, and the current VFC Operations Guide.

Before they can receive VFC vaccine, providers must:

- Complete the Provider Agreement and Provider Profile
- Complete the enrollment site visit
- Receive training on how to implement VFC requirements
- Have appropriate equipment for storage and handling in place to store and monitor vaccine
- Be enrolled and active in the Vaccine Tracking System (VTrckS)

Beginning July 1, 2025, for the 2025–2026 budget period, award recipient may provide virtual enrollment as an option to all newly enrolled or re-enrolling providers at their discretion. Beginning July 1, 2026, award recipients must provide virtual enrollment as an option to such providers.

The enrollment site visit must include:

- Review of all VFC requirements as well as confirmation of provider understanding
- Confirmation that the provider knows whom to contact if problems arise, especially with storage and handling issues
- Assessment of storage and handling equipment

REQUIREMENT: Award recipients must conduct an enrollment site visit for all new and reenrolling VFC provider locations before they receive VFC vaccine.

Site reviewers must document all information about provider enrollment in PEAR.

Compliance Site Visits

Self-Assessment

To objectively address training deficits and areas of noncompliance, staff working in a provider location should not self-assess that location. For example, contracted local health department (LHD) staff should not assess their own clinic.

If a provider location's assigned reviewer works for that location, the VFC coordinator must conduct the site visit instead.

Compliance site visits allow reviewers to evaluate whether providers understand and are complying with

VFC requirements, including those outlined in the Provider Agreement. At this time, compliance visits must be conducted in-person by the award recipient staff.

REQUIREMENT: Award recipients must conduct and record VFC compliance site visits with each provider location every 24 months. These visits must cover the following areas: provider details, eligibility, documentation, inventory management, and storage and handling (per unit and sitewide).

Before they can receive their first compliance site visit, provider locations must:

- Be enrolled in the VFC program for at least 3 to 6 months
- Have experience ordering and administering VFC vaccines

CDC recommends that award recipients conduct the first compliance site visit within 3 to 6 months of the provider location's enrollment. **Award recipients must complete the first compliance site visit within 12 months of the provider location's enrollment, if the enrollment visit is conducted in-person. If the enrollment is conducted virtually, the compliance visit must be completed within 6 months of enrollment. All compliance visits must be conducted in-person.**

Verifying Provider Profiles, Vaccine Ordering Patterns, and Inventory

CDC strongly recommends that award recipients examine the Provider Profile before every site visit. Award recipients should review past vaccine orders to ensure that order volume is consistent with the Provider Profile. Provider locations should maintain enough inventory to prevent vaccine borrowing, loss, and waste. Reviewers should be ready to discuss any updates to the Provider Profile, if needed. The IIS can be a valuable resource for this work.

Reviewers must also review providers' vaccine borrowing activity. They must take corrective actions when they note excessive or inappropriate activities.

Reviewers should share the monetary value of the facility's inventory of VFC vaccines. This can help illustrate the need to store and manage the vaccine appropriately.

CDC also recommends that reviewers share any information on vaccine returns, wastage, or both from the last 12 months. Reviewers should discuss how inventory management and ordering practices may impact the provider location's vaccine loss. Such practices may involve rotating stock, as well as ordering appropriate quantities at appropriate frequencies to support the population defined in the Provider Profile.

Compliance Site Visit Assessment

Reviewers must ask questions **exactly as written** in the VFC Compliance Site Visit Reviewer Guide.
Reviewers must perform the following actions in each area:

Details about Provider Location:

- Confirm the signatures and information on the Provider Agreement.
- Verify the information in the Provider Profile. This includes visually inspecting the storage units to determine whether adequate stock is available for each population identified in the profile.
- Review and update key staff and other information about the provider location.

Patient Eligibility and Billing

- Review procedures, practices, and records to confirm that the provider:
  - Understands VFC eligibility criteria for patients
  - Is not billing for the cost of public vaccine purchased from the federal contract
  - Is not charging a vaccine administration fee that exceeds the fee

Resources to Bring to a Compliance Site Visit

When they conduct a compliance visit, reviewers should provide current immunization resources (or links to the resources). These may include:

- Vaccination brochures and educational materials for patients and providers
- A current list of vaccines available through the VFC program
- Educational materials and resources on all ACIP-recommended vaccines
- Educational materials on eligibility requirements for VFC
- CDC's VFC Patient Eligibility Screening Record (or awardee-created equivalent)
- Standards for Child and Adolescent Immunization Practices
- CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* (The Pink Book)
- A list of current VISs, along with their publication dates and instructions for use
- Monthly temperature logs for refrigerator and freezer temperature recordings, or other information on how to properly record and report temperatures
- "Do Not Disconnect" labels for storage unit outlets and circuit breakers
- Award recipient-specific information for the jurisdiction's Children's Health Insurance Program (CHIP)
- Information about upcoming CDC immunization trainings and online educational opportunities

- Is accepting reimbursement for the vaccine administration fee for VFC-eligible children enrolled in Medicaid or the contracted Medicaid health plans
- Is only issuing a single bill for the fee for vaccine
- Administration to a VFC-eligible child who is not enrolled in Medicaid. Providers must issue the bill within 90 days of administering vaccine to the patient
- Is not denying access to federally purchased vaccine to an established patient whose parent is unable to pay the administration fee. (This established patient rule does not apply to pharmacies, urgent care clinics, or school-located vaccination clinics). See Module 1 – Patient Eligibility and Insurance Criteria for more information.

Documentation

- Review procedures, practices, and records to confirm that the provider:
  - Is screening patients for VFC eligibility and documenting the results at each immunization encounter
  - Is screening for state vaccine eligibility and administering doses to identified children if applicable (This requirement is defined in the addendum to the Provider Agreement.)
  - Is making available the vaccines identified and agreed on in the Provider Agreement and Provider Profile based on the provider type and population served, including non-routine vaccines
  - Is ensuring that VFC-purchased vaccine is only administered to VFC-eligible children. This includes verifying insurance coverage for underinsured children.
    - If the provider location is a federally qualified health center (FQHC), a rural health center (RHC), or other deputized location, the provider must confirm that insurance coverage is verified before administering vaccine to an underinsured child.
    -
    - If the provider location is not an FQHC, RHC, or other deputized location, the provider must confirm referral to a qualified provider location.
  - Has enough vaccine inventory to vaccinate all children per their Provider Profile
  - Is retaining VFC-related documentation for three years or longer
  - Is following policies and procedures for vaccine borrowing. Reviewers should also assess whether the provider is borrowing excessively

Records Management

Providers must maintain all records related to the VFC program for at least 3 years, or longer if required by state law. Providers also must make these records available for review upon request.

VFC records include, but are not limited to:

- Documentation of VFC screening and eligibility
- Billing records
- Medical records that justify vaccine administration
- Ordering records for vaccines
- Purchase records for vaccines
- Other accountability records for vaccines (e.g., packing lists, borrowing forms, wastage reports)
- Documentation of storage unit temperature

- Is distributing current VISs* before administering each vaccine
- Is reporting vaccine adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Is reviewing the facility Vaccine Management Plan to ensure that it is complete and current

**Providers must present current VISs to patients at every vaccination before they administer the vaccine. Before administering VFC monoclonal antibody immunizing products (e.g. nirsevimab), providers should provide an Immunization Information Statement. Providers should not delay use of an ACIP-recommended vaccine because a VIS is unavailable. For any ACIP-recommended vaccine or immunization product that does not yet have a VIS or Immunization Information Statement available, a provider may use the manufacturer's package insert, written FAQs, or any other document to inform patients about the benefits and risks of that vaccine. Providers may also produce their own information materials for patients. Once a VIS is available, providers should use it. If the vaccine is under an Emergency Use Authorization (EUA), providers should make the EUA Fact Sheet for Recipients available for patients.*

Storage and Handling per Unit

- Verify that each individual storage unit:
  - Is approved based on VFC requirements
  - Contains a digital data logger (DDL) with the capability for continuous monitoring as well as a current, valid Certificate of Calibration Testing
  - Has the DDL and vaccines correctly placed and stored

    Note: Some provider locations may have purpose-built or pharmaceutical-grade equipment with the capacity for temperature monitoring. Reviewers should check with CDC to confirm whether these units meet VFC requirements.
- Review the provider location's documents related to:
  - Temperature monitoring
  - Responses to a temperature excursion within each storage unit. See Module 3 – Vaccine Management for more information.

Storage and Handling Sitewide

- Discuss the cost and quantity of vaccine that the provider location has ordered. This helps ensure that staff understand the VFC program's overall impact on their facility.
- Assess equipment and written procedures, records, and documents for vaccine procedures. This will confirm that the provider:
  - Has enough space to store all vaccine based on peak stock expectations
  - Is handling expired vaccine properly. This includes returning expired vaccine to the CDC central distributor within 6 months of expiration.
  - Has at least one backup DDL available on site. The backup must have a different calibration date than the other DDLs.
  - Correctly handles and prepares vaccine
  - Shares any data on vaccine returns or wastage from the last 12 months. See Module 3 – Vaccine Management for more information.
  - Is complying with any additional requirements for storage and handling:

- Per the award recipient
- Based on CDC's *Vaccine Storage and Handling Toolkit*

Inventory

- Review procedures, practices, and records to confirm that the provider:
  - Is ordering vaccine in the correct quantities to maintain appropriate vaccine inventories
  - Is complying with the child and adolescent immunization schedule as recommended by 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.
  - Maintains separate vaccine stock between public and private vaccine (for the vaccines the provider plans to offer their private population), if the provider is not in a universal state or under an approve vaccine ordering replacement model
    - 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 ACIP-recommended vaccines for privately insured patients if they do not plan to offer all ACIP-recommended 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 vaccinate with this product.
    - If a VFC provider does not carry private stock, they are not permitted to use VFC stock on non-VFC-eligible patients.

Storage and Handling Site Visit

Storage and handling site visits allow reviewers to assess a provider location's compliance with, and knowledge of, VFC requirements for vaccine storage and handling. Reviewers can also assess provider compliance of any award recipient-specific requirements. These requirements are based on recommendations and best practices outlined in CDC's *Vaccine Storage and Handling Toolkit*. These visits, like regular compliance visits, must be conducted in-person.

REQUIREMENT: At least 5% of VFC provider locations must receive an unannounced site visit on storage and handling during the cooperative agreement budget period.

Reviewers should perform unannounced storage and handling visits for provider locations based on:

- Previous compliance issues with storage and handling
- Time since the last site visit
- Close geographic proximity to provider locations that will receive a VFC compliance site visit during the year

Unannounced storage and handling site visits are separate from VFC compliance site visits and any associated follow-up contact.

Storage and Handling Site Visit Assessment

During storage and handling site visits, reviewers must assess individual storage units and DDLs based on VFC requirements and CDC's *Vaccine Storage and Handling Toolkit*. They must also assess overall operations for storage and handling operations. Reviewers must perform the following actions in two areas:

Storage and Handling per Unit

- Verify that each individual storage unit:
  - Is approved based on VFC requirements
  - Contains a digital data logger (DDL) with the capability for continuous monitoring as well as a current, valid Certificate of Calibration Testing
  - Has the DDL and vaccines correctly placed and stored

  Note: Some provider locations may have purpose-built or pharmaceutical-grade equipment with the capacity for temperature monitoring. Reviewers should check with CDC to confirm whether these units meet VFC requirements.
- Review the provider location's documents related to:
  - Temperature monitoring
  - Responses to a temperature excursion within each storage unit. See Module 3 – Vaccine Management for more information.

Storage and Handling Sitewide

- Discuss the cost and quantity of vaccine that the provider location has ordered. This helps ensure that staff understand the VFC program's overall impact on their facility.
- Assess equipment and written procedures, records, and documents for vaccine procedures. This will confirm that the provider:
  - Has enough space to store all vaccine based on peak stock expectations
  - Is handling expired vaccine properly. This includes returning expired vaccine to the CDC central distributor within six months of expiration.

Site Visits to CDC-Approved Depots and "Store Only" Facilities

CDC-Approved Depots

- Award recipients with CDC-approved depots must perform an announced storage and handling visit every 12 months. This ensures that provider locations are complying with storage and handling requirements.
- Award recipients do not have to perform compliance visits at these sites because the sites do not administer VFC vaccines to eligible children.

"Store Only" Facilities

- Award recipients should conduct storage and handling visits every 12 months for providers classified as "store only" facilities.

- Has at least one backup DDL available. The backup must have a different calibration date than the other DDLs.
- Correctly handles and prepares vaccine
- Shares any data on vaccine returns or wastage from the last 12 months. See Module 3 – Vaccine Management for more information.
- Is complying with any additional requirements for storage and handling:
  - Per the award recipient
  - Based on CDC's *Vaccine Storage and Handling Toolkit*

Discussion and Follow-Up on Site Visit Outcome

Discussion on Site Visit Outcome

At the end of a site visit, the reviewer must discuss the outcomes with appropriate provider staff. This discussion allows the reviewer to commend the provider for activities that are performed well and highlight findings that need follow-up.

To facilitate this discussion, the reviewer must present the Provider Follow-Up Plan for review. The Provider Follow-Up Plan is a summary document that includes review the provider location's documents related to:

- All relevant VFC requirements and recommendations that will be discussed
- An indication of whether the provider met the requirements
- Follow-up actions that the provider must complete, along with corresponding deadlines, for any compliance issues (if identified)

The Provider Follow-Up Plan can serve as an excellent checklist for providers to use to assess their location's compliance with VFC requirements between site visits.

After discussing outcomes and clearly outlining next steps, the reviewer and provider must sign the Acknowledgement of Receipt, even if no compliance issues were identified. The reviewer should upload the signed document in PEAR before marking the visit as complete.

The Acknowledgement of Receipt documents that:

- The site visit was completed.
- The provider and reviewer discussed the site visit outcomes.
- The provider understands the issues identified as compliance issues and the necessary follow-up actions for correction (if applicable).
- The provider and reviewer jointly agreed to the Provider Follow-Up Plan.

Award recipients can find the Provider Follow-Up Plan and Acknowledgment of Receipt in PEAR. Both the reviewer and the provider location must maintain copies of these signed documents for at least of three years.

Follow-Up

PEAR outlines the actions to perform during a site visit. The system also outlines the follow-up to perform at prescribed times after the site visit is completed. PEAR follow-up actions apply to all provider locations that experience a compliance issue for the first time.

Award recipients may add additional follow-up actions at any time in PEAR. However, they must add additional follow-up actions when the same issue has been identified during previous site visits. Award recipients' follow-up actions must be attached to the Provider Follow-Up Plan.

Award recipients must add a provider location to the PEAR Fraud and Abuse Module (see Module 5 – Fraud and Abuse) if:

- The provider location has a history of noncompliance on the same issue.
- The issue has serious consequences.

The PEAR Fraud and Abuse Module will help award recipients document details and monitor all actions taken to prevent noncompliance if a case warrants referral to the Centers for Medicare and Medicaid (CMS).

Additional Contact by Award Recipients

Award recipients may contact VFC providers outside of site visits for enrollment, compliance, and storage and handling. These contacts include any in-person, on-site, phone, or written interaction with a provider that is not related to a site visit, follow-up plan, vaccine ordering, or formal educational event. The award recipient has discretion to record these contacts in PEAR. Capturing notes from these interactions may be useful for future site visits and follow-up.

See Module 3 – Vaccine Management for more information.

Provider Location Training and Education

Award recipients must give providers annual education on requirements of the VFC program. This helps to ensure that providers continue to implement the program effectively. Education should focus on actions necessary to meet the components of the Provider Agreement and general VFC requirements.

REQUIREMENT: Award recipients must provide comprehensive training on VFC requirements to each VFC provider location every 12 months. The training must cover all VFC requirements in the Provider Agreement and the current VFC Operations Guide.

- At a minimum, each provider facility's primary and backup vaccine coordinators must complete the required training.
- VFC compliance site visits with an educational component meet annual training requirements. Award recipients must ensure that site visits with an educational component are scheduled with enough time to complete the site visit. They must also ensure that there is enough time for the education to cover components of VFC requirements in the Provider Agreement and the current VFC Operations Guide.
- Award recipients may also provide the annual training online, by webinar, or through an in-person, classroom-style presentation.
- Award recipients must document annual training for providers in the Annual Training Module in PEAR.

As they develop and conduct training, award recipients may

- Use their own training materials, as long as those materials address all requirements in the Provider Agreement and the VFC Operations Guide.
- Use CDC's *You Call the Shots (YCTS)* online modules on Vaccines for Children (VFC) and Storage and Handling to meet training requirements.
    - The modules can produce a Statement of Completion and continuing education (CE) credit if the user completes the posttest with a score of 80% or higher via the Training and Continuing Education Online (TCEO) system.
    - Two unsuccessful attempts will prompt TCEO to lock the user out of these *YCTS* modules. The user will still be able to access the modules via CDC TRAIN. They will also be able to receive a Statement of Completion to share with the award recipient.
    - Each module now has a Refresher Option. This new option is a pretest that will be available for providers who are familiar with VFC and requirements for vaccine storage and handling and have previously completed the full YCTS modules. The two Refresher Options (each with 25 questions) include content from the original *YTCS* modules.
        - Providers may choose to complete both Refresher Options or one Refresher Option and one original *YCTS* module.
        - Providers must score 80% or higher to receive a Statement of Completion that the award recipient can document in PEAR.
        - Providers cannot receive CE credit for completing either Refresher Option.

Providers' Responsibility to Train Staff

VFC providers must train their staff on proper procedures for vaccine storage and handling. Training should target staff who:

- Receive vaccine deliveries. Training should include how to open, record, and store vaccine shipments immediately.
- Handle or administer procedures for vaccine storage and handling
- Transport vaccine. Training should include routine, off-site, and emergency vaccine management.

Provider locations' Vaccine Management Plans should include documentation of staff training.

All training for provider locations must include relevant, state-specific requirements or information, if applicable. The Provider Agreement's educational components include the following areas and requirements:

Provider Profile:

- Submitting a Provider Profile that accurately reflects the populations that the provider serves and plans to vaccinate
- Updating a Provider Profile (i.e., when and how)

Patient Eligibility Screening and Documentation:

- Screening and documenting VFC eligibility before administering vaccines
- Screening and documenting children who are state-vaccine-eligible, if applicable
- Serving underinsured children:
    - If the provider location is an FQHC, RHC, or other deputized location, the provider can administer vaccine

to underinsured children.

- If the provider location is not an FQHC, RHC, or other deputized location, the provider must refer the patient to a qualified provider location.

Immunization Schedule, Dosages, and Contraindications:

- Accessing and using current ACIP recommendations and VFC resolutions
- Having a process for notifying staff of any changes to ACIP recommendations
- Making available the vaccines identified in the Provider Profile based on the provider type and population served, including non-routine vaccines if applicable
- Understanding state laws related to vaccination requirements and acceptable vaccine exemptions
- Using ACIP recommendations and vaccine package inserts to understand the contraindications for each type of vaccine available through the VFC program

Record Maintenance:

- Knowing which records the provider must maintain
- Maintaining VFC records for at least 3 years, or longer if required by state law (even in the event of provider retirement or closure of the provider location)

No Charge for Vaccines:

- Avoiding charging a patient for any publicly purchased vaccine
- Avoiding billing any individual or other third-party payer for the cost of VFC-supplied vaccine, or other vaccines purchased through CDC federal contracts

Administration Fees:

- Meeting administration fee billing requirements:
  - Administration fees are per vaccine and not per antigen.
  - Administration fees for VFC-eligible children who are not enrolled in Medicaid cannot exceed the regional Medicaid fee cap.
  - Providers should not deny access to vaccine if the VFC-eligible or state-eligible child's parent is unable to pay the administration fee. In these cases, providers should waive the administration fee.
  - Providers should only bill Medicaid for the administration fee for VFC-eligible children who are enrolled in Medicaid.
  - Provider locations may choose to bill for the vaccine administration fee of a VFC-eligible child who is not enrolled in Medicaid after the date of service. In these cases, providers should issue only a single bill to the patient within 90 days of administering vaccine.

Vaccine Access for Established Patients:

- Providing federally purchased vaccine to an established patient regardless of a parent's ability to pay the administration fee:
  - Exemptions to established patient criteria are specialty providers that must serve all

walk-in, VFC-eligible children, such as pharmacies, urgent care clinics, and school-located clinics. The exemptions also include FQHCs, RHCs, and deputized provider locations. See Module 1 – Patient Eligibility and Insurance Criteria for more information.

Compliance with the National Childhood Vaccine Injury Act (NCVIA):

- Following the record-keeping requirements for the NCVIA
- Obtaining and distributing the most current VISs for all vaccines included in the National Vaccine Injury Compensation Program or purchased through federal contracts
- Reporting adverse reactions to the Vaccine Adverse Event Reporting System (VAERS)
    - VFC providers should report all suspected adverse reactions to VAERS.
    - Providers should report suspected adverse reactions following co-administration of respiratory syncytial virus (RSV) monoclonal antibody products with any vaccine to VAERS.
    - Providers should report suspected adverse reactions following administration of RSV monoclonal antibody products without co-administration of any vaccine in MedWatch.

Vaccine Management:

- Following VFC requirements for storage and handling based on CDC's *Vaccine Storage and Handling Toolkit* (see Module 3 – Vaccine Management), including:
    - Ordering vaccine and maintaining appropriate inventories, including determining the appropriate order quantity and rotating vaccine
    - Using required equipment for storing vaccine in routine and emergency situations (providers should never use a dorm-style refrigerator)
    - Continuously monitoring all storage unit temperatures daily. Providers should also record storage unit temperatures daily.
    - Responding to actual or anticipated temperature excursions
    - Properly storing vaccine
    - Properly handling vaccine
    - Separating public and private vaccine stock
    - Maintaining and updating the Vaccine Management Plan, including routine and emergency plans (providers should also maintain and update documentation and reporting requirements)
    - Returning spoiled or expired public vaccine to CDC's centralized vaccine distributor within six months

Fraud and Abuse:

- Preventing fraud and abuse by sharing examples and potential consequences
- Discussing the restitution policy, if applicable

Site Visits and Other Educational Opportunities:

- Explaining the different types of VFC site visits
- Explaining educational opportunities and requirements

Termination:

- Sharing situations that would terminate the provider location's participation in the VFC program (see Module 2 – Recruiting and Enrolling Provider Locations)

Module 5 – Fraud and Abuse

Table of Contents

Overview

Federal fraud and abuse laws apply to award recipients' Vaccines for Children (VFC) programs. State fraud and abuse laws (e.g., related to insurance, consumer protection, or medical licensure) may also apply to portions of award recipients' VFC programs that involve state funds. 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
- Recipient practices that result in unnecessary cost to the Medicaid program.

Well-organized and properly administered programs for VFC accountability are the cornerstones for preventing potential fraud and abuse incidents. Award recipients should emphasize accountability measures through strong educational components carried out during the enrollment process for provider locations, as well as during any VFC site visit. Regularly communicating with providers can also reinforce training and further help prevent situations that may develop into fraud and abuse.

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.*

Fraud and Abuse Policies and Procedures

REQUIREMENT: Award recipients' policies and procedures for the VFC program must address prevention, detection, investigation, and resolution of VFC fraud and abuse allegations, as well as federal requirements regarding reporting of suspected fraud and abuse.

Oversight Personnel

Award recipients must identify a staff person to coordinate VFC fraud and abuse issues, along with at least two backups. These personnel must have the authority to:

- Determine if a situation:
  - Calls for educational intervention and follow-up
  - Requires immediate referral to the Medicaid Integrity Program and other mandated state agencies
- Take action to refer the case.

If a compliance issue appears intentional and the provider has received financial benefits from the behavior, the situation requires immediate referral to an outside agency for investigation of suspected VFC fraud and abuse.

Personnel Training

Award recipients must train all VFC staff, based on their job responsibilities and level of interaction with providers, on how to:

- Educate providers to prevent situations that could result in compliance issues with VFC requirements or VFC fraud and abuse.
- Identify situations that involve suspected compliance issues or fraud and abuse.
- Follow up on situations that involve suspected noncompliance or fraud and abuse.

Fraud and Abuse Monitoring

Analyzing VFC program information is key to identifying compliance issues and potential fraud and abuse patterns.

Program information that award recipients must monitor includes:

- The Provider Profile
- Ordering patterns (i.e., volume and frequency)
- Vaccine inventory and wastage
- Findings from VFC site visits
- Other accountability reports that are specific to the award recipient

Addressing Provider Noncompliance with VFC Requirements

Providers agree to comply with the requirements of the VFC program that are outlined in the Provider Agreement. Providers also discuss these requirements with the site reviewer during the enrollment site visit and subsequent visits.

The Centers for Disease Control and Prevention (CDC) encourages award recipients to provide routine

feedback to providers, based on information in the immunization information system (IIS) and other data sources at the award recipient level. This helps address potential noncompliance issues in a collaborative educational perspective early before it results in fraud and abuse incident. Repeated lack of adherence to the requirements, if not addressed, may lead to fraud and abuse charges for the provider. Noncompliance may occur due to an unintentional lack of understanding of program requirements, or the behavior may be intentional.

Failure to comply with VFC requirements is defined as follows:

> Any VFC provider or provider location that does not maintain the requirements—federal, state, or both—that are associated with implementing the Provider Agreement. This guide discusses the details of the federal requirements in Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance.
>
> The following personnel and entities may identify instances of suspected noncompliance or fraud and abuse:
>
> - VFC program staff
> - Provider location staff
> - A third party
>
> CDC's VFC Compliance Site Visit Reviewer Guide serves as a proxy measure for providers' compliance with the federal requirements for participation in the VFC program. The guide defines minimum follow-up requirements for any issue(s) identified during a site visit. If a compliance issue identified during a site visit has also occurred during one of the last two site visits, award recipients must add additional follow-up actions.
>
> Award recipients must enter information about noncompliance, fraud and abuse allegations, findings, and actions into the Provider Education, Assessment, and Reporting (PEAR) system's Fraud and Abuse Module. See Module 4 – Ensuring Provider Compliance for more information.

PEAR Fraud and Abuse Module

Award recipients must use the Fraud and Abuse Module in PEAR to monitor, document, and track actions related to VFC program fraud and abuse. Information supporting an allegation should be based on VFC site visits or reports and information from external sources. At a minimum, supporting information should include:

- The provider's name (and Medicaid provider ID, if known)
- The provider's address
- The source of the allegation
- The date that the allegation was reported to the award recipient
- A description of the suspected misconduct
- Specific VFC requirement(s) that were violated
- Descriptions and dates of the award recipient's response to the allegation (education, site visit, suspension, removal of vaccines, or other action(s) taken before disposition)
- The value of the vaccines involved, if applicable

- The outcome of educational intervention, if applicable
- Disposition of the case (e.g., closed, referred, entered into educational process) and the date of disposition

Award Recipient Investigation of Fraud and Abuse Allegations

Award recipients must investigate accusations of fraud and abuse to determine proper disposition. This investigation helps the award recipient's staff member who coordinates VFC fraud and abuse issues to determine the validity of the allegation and the proper course of action (i.e., educational intervention, corrective action, referral).

At a minimum, award recipient staff who coordinate VFC fraud and abuse issues should assess the following in their investigation:

- Is the allegation valid based on the data assessed?
- Does the compliance issue appear to be intentional or has the provider or provider location received financial benefits from their actions? If so, immediate referral may be warranted.
- Is the reporting source of the allegation an enforcement agency? If so, immediate referral may be warranted.
- Are there extenuating circumstances?
- Has there been previous noncompliance?
- How severe is the allegation?
- Is an educational intervention or corrective action warranted?
- Does this issue require referral?

Please review the VFC Fraud and Abuse Investigation Decision Aid in the appendices for further guidance on the appropriate fraud and abuse investigation steps.

Fraud and Abuse Referral and Reporting

Award recipients must refer all suspected cases of VFC fraud and abuse directly to the appropriate state Medicaid contact for "Program Integrity – Provider FWA (fraud, waste, and abuse)." The state Medicaid agency will conduct preliminary investigations. As warranted, the agency will refer appropriate cases to the state's Medicaid Fraud Control Unit following the federal regulatory scheme at 42 CFR § 455.15 and 42 CFR § 455.23. If award recipients are unable to reach a contact at the state or have questions about the fraud referral process, they should contact the Center for Program Integrity's (CPI) state liaison staff via the Medicaid Integrity Program website.

Award recipients should make referrals within 10 working days from the assessment and determination of possible fraud and abuse. They should include the following information:

- Contact information for their staff member who coordinates VFC fraud and abuse issues
- The provider's name, Medicaid provider ID (if known), address, and provider type (e.g., private provider)
- The source of the complaint (e.g., provider location, VFC staff, anonymous caller)
- The date on which the award recipient received information that the provider might be putting the VFC

program at risk of loss due to fraud and abuse

- A detailed description of the suspected misconduct and actions taken by the program to confirm the behavior. This should include:
    - A complete description of the alleged behavior (including specific Medicaid statutes and rules or VFC program requirements violated)
    - The persons involved
    - Contact information, if available
    - The value of the vaccine involved, when available
- All available communication between the VFC program and the provider location concerning the suspected misconduct. This includes:
    - The signed enrollment forms for the provider location
    - Education given to the provider because of previous compliance problems
    - Any general communication with the provider location about implementing the VFC program

The award recipient should concurrently make a referral to any other state agency as mandated by state law.

The award recipient should also send a copy of the referral to their assigned Immunization Operations and Services Branch (IOSB) project officer.

Private Insurers

While not required, award recipients should develop communication procedures with private insurance entities that may be affected by VFC fraud and abuse. This enables bidirectional communication regarding instances of suspected fraud, abuse, or both.

Module 6 – Program Operations

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Overview

Award recipients' strong program operations are essential to the success of the Vaccines for Children (VFC) program. Award recipients must ensure that their program and all VFC providers within their jurisdictions, adhere to VFC requirements. Award recipients must establish, implement, and monitor operational policies and procedures. They must also follow the Centers for Disease Control and Prevention's (CDC) requirements and guidance. These actions ensure that they—and providers in their jurisdictions—comply with all aspects of the VFC program.

Award recipients must have written policies and procedures to govern the VFC program. These policies and procedures should be specific, providing enough detail that new hires can follow protocols with minimal supervision or clarification.

The immunization program manager and VFC coordinator should review policies and procedures annually. They should also certify that the policies and procedures are up to date and align with CDC requirements. The policies and procedures must be available to CDC upon request.

Award recipients must have operational policies and procedures related to:

- Program operations
- Provider recruitment
- Enrollment of provider locations
- Provider compliance
- Vaccine management

REQUIREMENT: Award recipients must maintain all VFC program documentation for at least 3 years, or longer if required by state law.

Record Retention

Award recipients must retain all VFC program documentation for at least 3 years, including provider- and award recipient-level documents. Award recipients may store these records digitally or electronically. Award recipients should store and maintain documentation in a location and manner that allows multiple staff to access the information and provide it to CDC upon request, even if the award recipient's staff experiences turnover.

Program Operations

REQUIREMENT: Award recipients must establish and use policies and procedures for effective program operations. These policies and procedures must address staffing, staff training, systems for program monitoring, and systems related to fraud and abuse.

Award Recipient Staff

Award recipients must designate enough staff, including a VFC coordinator, to oversee and implement the VFC program. Award recipients must notify their Immunization Operations and Services Branch (IOSB) project officer and VFC@cdc.gov any time that their VFC coordinator changes role, including when staff are temporarily serving in the role. Award recipients must confirm that their staff is knowledgeable about vaccine ordering, inventory, and storage and handling, as well as VFC program components.

Staff Training

Award recipients must provide annual training for staff involved with implementing and managing the VFC program. Training on VFC program policies and procedures is an essential component of quality assurance.

Award recipients must also have a process for circulating updated versions of the VFC Program Operations Guide and

training materials, as well as VFC information and programmatic updates, to all VFC staff. Award recipients should clearly and promptly communicate information about changes or revisions impacting the VFC program to staff. These communications should include how the award recipient's program has incorporated the changes.

Site Visit Reviewer Training

Award recipients must offer annual training developed for reviewers. The annual training must cover:

- All requirements of the VFC program, including those for eligibility screening and documentation
- The purpose of VFC site visits
- The sampling methodology used for chart selection during site visits for VFC compliance
- Proper storage and handling of vaccines, as outlined in CDC's Vaccine Storage and Handling Toolkit
- Administering the VFC Site Visit Reviewer Guides through the Provider Education, Assessment, and Reporting (PEAR) system
- The rationale behind the questions in the VFC Site Visit Reviewer Guide
- Documentation required after completing a site visit
- Required follow-up with the provider location after a site visit
- Conducting the educational component of a site visit to a VFC provider location
- Basic competencies for site visits, including skills required to prepare and report findings and feedback from a site visit

Award recipients can find the following resources on PEAR's help page:

- Training materials and resources related to performing site visits
- Background information on the rationale behind site visit questions

Skills for Successful Site Visits

Award recipients should emphasize interpersonal skills and behaviors during staff training.

- **Organization** – Prepare for the site visit by knowing where to go and when to arrive. Have identification and provide business cards. Being organized allows a reviewer to be seen as professional—and an effective immunization resource.
- **Knowledge** – Explain the rationale behind all VFC requirements to help providers understand the program as well as any necessary follow-up actions. Have a clear and accurate understanding of the immunization schedule, recommended vaccines, and storage and handling practices.
- **Observation** – What is seen can be more important than what is said. Visually confirm answers to questions where applicable. Use observations to back up findings about the facility's strengths and opportunities for improvement.
- **Critical Thinking** – Use listening and observational skills to determine how information fits with official answers. Expect the unexpected and try to be flexible in addressing these situations.
- **Ask Questions** – Questions should assess the provider's understanding of the program and allow them to describe their practices. Ask open-ended (not leading) questions based on observations. Ask follow-up questions when answers are vague or incomplete.
    - Ask: What is the vaccine administration fee charged to VFC-eligible patients who are not enrolled in Medicaid?
    - Don't ask: Do you charge more than X dollars for the vaccine administration fee for VFC-eligible patients who are not enrolled in Medicaid
- **Offer Constructive Criticism** – Effectively share and address negative findings, making sure to be nonjudgmental. Share strengths of the practice and how the provider might use these to correct noncompliant behavior.

As part of training, CDC requires that VFC coordinators (or their designees) observe a compliance site visit with each reviewer annually. This provides an opportunity for the VFC coordinator to assess how the reviewer conducts site visits. It also provides insight into the reviewer's level of understanding of the program. The VFC coordinator can then provide

more training opportunities for the site reviewer, if needed.

Award recipients should document each observation in the reviewer's training file. They can find a sample VFC Reviewer Supervisory Visit Observation Tool in the VFC Cooperative Agreement Management Platform (CAMP) Knowledge Center.

The immunization program manager must document that site visit reviewers have completed annual training.

Award recipients can find information about requirements for vaccine management, site visits for provider locations, and provider training in Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance.

New Site Visit Reviewer Hires

Newly hired site visit reviewers must:

- Shadow an experienced reviewer on a VFC compliance site visit as part of their training
- Have the VFC coordinator (or their designee) accompany them on at least one VFC site visit before conducting site visits independently (the VFC coordinator should provide guidance as well as suggestions for improvement)

Operational Policies and Procedures

Fraud and Abuse

Award recipients must write and implement a comprehensive policy regarding VFC fraud and abuse. At a minimum, the policy must address the components outlined in Module 5 – Fraud and Abuse. These include:

- Oversight personnel
- Personnel training
- Fraud and abuse monitoring
- Referral and reporting
- Procedures for entering allegations in PEAR's Fraud and Abuse Module

Award recipients should review the policy annually to verify that it is current with VFC requirements, CDC guidance, and federal and state laws.

Provider Recruitment

REQUIREMENT: Award recipients must establish and use policies and procedures related to provider recruitment.

Award recipients must establish protocols for:

- Assessing gaps in vaccine access for VFC-eligible children in their jurisdictions
- Recruiting and enrolling providers to improve vaccine access for VFC-eligible children

Award recipients must recruit providers in their jurisdictions based on need assessments.

See Module 2 – Provider Recruitment and Enrollment for information on types of VFC providers and recruitment criteria.

Provider Location Enrollment

REQUIREMENT: Award recipients must establish and use policies and procedures for all aspects of the enrollment process for provider locations.

Award recipients must establish protocols for:

- Verifying provider eligibility to participate in the program
- Conducting an enrollment visit, including completion of the Provider Agreement, the Provider Profile, and the document for Patient Eligibility Screening (or similar guidance)
- Entering data for the enrollment visit into PEAR

All provider locations that leave the VFC program and request to return must fulfill all enrollment requirements. These include participating in the enrollment site visit.

See Module 2 – Provider Recruitment and Enrollment for more information.

Deputization (FQHCs and RHCs)

REQUIREMENT: Award recipients must confirm that CDC-approved, deputized provider locations have a signed memorandum of understanding (MOU) between a federally qualified health center (FQHC) or rural health clinic (RHC) and the state or local immunization program allowing them to serve underinsured VFC-eligible children.

Underinsured children who are eligible for VFC can only receive VFC vaccine from a federally qualified health center (FQHC) or rural health clinic (RHC). Some VFC provider locations may be deputized by an FQHC or RHC to allow them to administer vaccines to this patient population. The deputization designation applies almost exclusively to public health clinics.

As part of the memorandum of understanding (MOU), provider locations agree to:

- Screen and document VFC eligibility status at every immunization encounter.
- Vaccinate all VFC-eligible underinsured children presenting for vaccination services, even if they receive primary care from another provider.
- Apply the definition of "underinsured" as described in Module 1 – Patient Eligibility and Insurance Criteria.
- Collect and report data on underinsured usage using an acceptable method identified in the CDC VFC Deputization Guidance and MOU Template.

Beginning in Budget Period 2025–2026, award recipients with deputized provider locations in their jurisdictions are strongly encouraged to submit the following documents every 24 months via the optional Award Recipient Deputization module in PEAR:

- VFC Awardee Deputization Agreement Form
- MOU
- Accompanying List of Deputized Provider Locations

If the population of deputized providers changes outside of the data request window (i.e., deputized provider locations are added or removed), award recipients should submit a "Deputization Change Request" form to their IOSB project officer for approval. Award recipients can find Deputization Agreement forms and supplemental materials in the VFC library of the VFC CAMP Knowledge Center. Utilization of the PEAR Award Recipient Deputization module will be a requirement starting July 2026.

Provider Annual Review

Provider locations must undergo annual review to remain in the VFC program. Award recipients must have policies and procedures that govern the annual review of providers every 12 months. These policies and procedures must address how the award recipient will:

- Collect and validate Provider Profile data
- Verify that provider locations meet the annual training requirement defined by the award recipient

Provider Biannual Recertification

Provider locations must be recertified every 24 months to remain in the VFC program. Award recipients must have policies and procedures that govern provider recertification every 24 months. These policies and procedures must address how the award recipient will:

- Verify provider eligibility (licensure in the jurisdiction)
- Collect a signed Provider Agreement and ensure that it is complete and accurate
- Distribute the CDC Patient Eligibility Screening Record or award recipient-developed written guidance to support eligibility screening and documentation

See Module 2 – Provider Recruitment and Enrollment for more information.

Provider Compliance

REQUIREMENT: Award recipients must establish and implement policies and procedures to validate provider compliance with:

- **Screening and documenting VFC eligibility for each vaccination encounter**
- **Administering VFC-funded vaccine only to children who are eligible for the program**
- **Screening patients for state vaccine and, if applicable, documenting and administering state vaccine**
- **Complying with the immunization schedule, dosages, and contraindications recommended by the Advisory Committee on Immunization Practices (ACIP)**
- **Making available all appropriate routine vaccines for VFC and other populations planning to vaccinate**
- **Following requirements for vaccine billing and administration fees**
- **Complying with the National Childhood Vaccine Injury Compensation Act**
- **Complying with management requirements for VFC vaccine**
- **Maintaining all records for at least three years, or longer if required by the state**

Refer to information throughout this guide for provider-specific responsibilities.

Compliance Site Visits

At a minimum, award recipients' policies and procedures for VFC compliance site visits must address procedures for:

- Identifying and selecting provider locations to receive a VFC compliance site visit
- Scheduling site visits
- Preparing for site visits
- Ensuring sections 1–6 of the CDC VFC Compliance Site Visit Reviewer Guide, exactly as written. Award recipients must also note that neither this guide nor any of the information contained in it should be shared with staff at provider locations.
- Evaluating a provider location's vaccine management practices and implementation of VFC program requirements. These are outlined in Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance.
- Ensuring all spoiled and expired vaccine returns are entered, as well as correction of any discrepancies between returns entered and vaccines shipped to the centralized distributor
- Collecting, monitoring, and reporting to CDC on the total number of publicly purchased vaccine doses ordered by vaccine type that expired, were spoiled, or were otherwise wasted due to improper vaccine storage and handling by VFC providers
- Providing formal education and training on VFC requirements, as outlined in Module 4 – Ensuring Provider Compliance
- Documenting, reviewing, and reporting on-site findings and results in PEAR. If possible, award recipients should enter the data on the day of the site visit.
- Following-up on-site actions defined by CDC. Award recipients should also implement future follow-up actions, including adding and adhering to award recipient-defined actions for provider locations with the same or similar compliance issues during the past two site visits.
- Requiring the VFC coordinator, immunization program manager, or both to review provider locations that have been visited, as well as the site visits' summary data

Award recipients must conduct a compliance site visit at provider locations every 24 months. This is a minimum-level requirement.

CDC strongly encourages award recipients to conduct site visits for VFC compliance independently of visits for immunization quality improvement. This allows enough time and focus for requirements of the VFC program, or for improving processes related to program implementation. On the other hand, award recipients may combine site visits for VFC and Adult/317 discretionary funded programs if the provider participates in both.

All completed VFC compliance site visits must be reviewed by the VFC coordinator, immunization program manager, or a designee. The staff member who completes the review must document it in PEAR using the site visit sign-off functionality.

Also, the VFC coordinator or immunization program manager must regularly review summary data from completed site visits. Reviewing summary data from site visits helps to identify trends across multiple provider facilities as well as training gaps for the site visit reviewer. Identified issues should be carefully reviewed and addressed in program planning.

Award recipients must provide site visit reviewers with the following:

- The most current CDC VFC Program Operations Guide
- Access to PEAR
- Access to the internet and a laptop for site visits
- Digital data loggers (DDLs) to check temperatures of storage units when applicable. These must have:
  - The capability for continuous monitoring
  - A buffered probe
  - A current, valid Certificate of Calibration Testing

Instead of using their own DDL, CDC recommends that reviewers use the provider location's DDL to assess and record the storage unit's minimum and maximum temperatures, as long as:

- The provider location's DDL has a current, valid Certificate of Calibration Testing
- The thermometer or probe is properly placed in the storage unit

Updates for Providers

Award recipients must promptly notify providers when changes or updates are made to:

- Requirements for the VFC program
- Recommendations of the Advisory Committee on Immunization Practices (ACIP)
- Best practices and recommendations for storage and handling

Storage and Handling Site Visits

At a minimum, award recipients' policies and procedures for storage and handling site visits must address:

- How to schedule routine site visits for storage and handling
- How to prepare for storage and handling site visits
- How to conduct storage and handling site visits using PEAR
- How to document, review, and report results of storage and handling site visits

- How to identify and select provider locations that should receive an unannounced storage and handling
- Site visit based on:
    - The provider location's history of compliance issues with storage and handling
    - Time since the last site visit
    - Geographic distance from provider locations that will receive a VFC compliance site visit during the year
- Scheduling requirements for routine storage and handling site visits
- Requirements for site visit preparation
- How to administer the CDC Storage and Handling Site Visit Reviewer Guide, exactly as written
- How to evaluate a provider location's practices for vaccine storage and handling, as outlined in Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance
- How to provide formal education and training on VFC requirements related to storage and handling, as outlined in Module 4 – Ensuring Provider Compliance
- How to document, review, and report findings and results from site visits on-site visit findings and results in PEAR. If possible, award recipients should enter the data on the day of the site visit.
- Following-up on CDC-defined on-site actions. Award recipients should also implement future follow-up actions, including adding and adhering to award recipient-defined actions for provider locations with the same or similar compliance issues during the past two site visits.

CDC encourages award recipients to conduct as many storage and handling site visits as needed. However, five percent (5%) of provider locations must receive unannounced storage and handling site visits during each budget period.

Provider Location Training

Award recipients' policies and procedures must address annual training of staff at VFC provider locations. The annual training must meet all requirements of the VFC program based on the Provider Agreement and current VFC Program Operations Guide.

Module 4 – Ensuring Provider Compliance outlines the training components.

Award recipients should review storage and handling practices contained in CDC's *Vaccine Storage and Handling Toolkit* and the VFC Program Operations Guide annually. This allows them to verify that their annual training's information is correct.

Vaccine Management Policies and Procedures

REQUIREMENT: Award recipients' policies and procedures for vaccine management as well as storage and handling must include standards necessary to prevent vaccine waste and ensure that appropriate public vaccine stock is available by fund type.

Award recipients' policies and procedures for vaccine management must address:

- Storage and handling
- Vaccine ordering

- Vaccine loss and returns
- Vaccine restitution
- Vaccine borrowing
- Vaccine transfer

If applicable, award recipients also need policies and procedures for:

- Implementing and monitoring a vaccine ordering replacement model
- Overseeing and managing temporary, mobile, off-site, satellite and community vaccination clinics
- Making non-routine VFC vaccines (e.g. COVID-19, Mpox, PPSV23) available to VFC-eligible children, if not stocked routinely by a VFC provider).

To help providers with proper vaccine management, award recipients must also develop a Vaccine Management Plan template for VFC provider locations to use. The template must address the plan components detailed in Module 3 – Vaccine Management.

Storage and Handling

Award recipients must establish policies regarding timelines for digital data logger (DDL) calibration testing.

Temperature monitoring devices experience drift over time, which affects accuracy. The frequency of calibration testing varies by manufacturer, make, and model, but calibration testing every two to three years is standard. CDC recommends doing calibration every 2 to 3 years from the date the Certificate of Calibration Testing was issued or in accordance with the manufacturer's recommended timeline.

CDC also recognizes that ice melting point testing can meet the standard for calibration testing; however, the award recipient must provide significant oversight to implement such testing. Award recipients interested in using this method must contact their IOSB project officer to learn more about the process as well as oversight requirements.

If calibration testing indicates that a DDL is no longer accurate within ±0.5°C (±1°F), the DDL must be replaced. CDC does not recommend adjusting such a DDL.

Devices purchased by award recipients must be tested every two to three years.

Vaccine Ordering

Award recipients must implement policies and procedures that include timely review and approval of VFC provider locations' vaccine orders.

Before distributing vaccines, award recipients must have policies and procedures for evaluating the orders' appropriateness. These include comparing the ordering information and Provider Profile data to:

- Check for any issues with the provider location's inventory management that could cause:
    - Stockpiling or over-ordering (these actions can put vaccines at risk for waste or indicate fraud or abuse)
    - Under-ordering (this action can prevent vaccines from being available for eligible children)
- Verify that the amount of public vaccine to be distributed to the provider location is appropriate for the number of VFC-eligible children (and state-eligible children, if applicable) served by that location.

See Module 3 – Vaccine Management for more information.

Stocking COVID-19 and Non-Routine Vaccines

Non-routine vaccines include, but are not limited to:

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

Stocking non-routine, VFC-covered vaccines (including the COVID-19 vaccine) at all times may not be a viable option for a provider facility. Award recipients should support providers by sharing alternative options to making these vaccines available to VFC-eligible children, including:

- Maintaining a limited amount of stock at provider facilities that serve a large volume of VFC-eligible children
- Establishing methods for providers to order non-routine vaccines as needed
- Establishing a process in which local health departments serve as referral locations and "safety nets" for access to non-routine vaccines

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.

Award recipients' policies and procedures for vaccine ordering and monitoring must require provider locations to submit vaccine inventory amounts with each order. This allows award recipients to verify that the provider location is not inadvertently stockpiling or building up excessive inventory, which could put VFC vaccine at risk.

Award Recipient Restitution

Award recipients must develop and implement policies and procedures to ensure that approved provider vaccine orders contain appropriate quantities for the provider location relative to the eligible patient population(s) represented in the Provider Profile. Failure to comply with this requirement may result in the administration of VFC vaccines to ineligible children. If this occurs, award recipients may be required to purchase replacement doses of VFC vaccine. As with provider restitution, **dose for dose replacement is required**.

Award recipient restitution also requires award recipients to track and monitor replacement doses of vaccine from bulk-order purchase through the shipment from the centralized distributor to providers to administration to VFC-eligible patients. Additional details about awardee restitution are situational. CDC will discuss these directly with an award recipient should the need arise.

Vaccine Purchase Policy

Vaccine purchase policy, also known as "vaccine supply policy," determines:

- Which vaccines an award recipient will purchase
- Which funding source(s) the award recipient will use
- Which populations will be eligible to receive the vaccines

Types of vaccine purchase policies include:

Universal

Through a combination of VFC and state funding, the award recipient supplies all ACIP-recommended pediatric vaccines to public and private VFC-enrolled provider locations to vaccinate all children in the award recipient's jurisdiction.

Universal Select

Through a combination of VFC and state funding, the award recipient supplies all but a few ACIP-recommended pediatric vaccines to public and private VFC-enrolled provider locations to vaccinate all children in the award recipient's jurisdiction.

VFC and Underinsured

Through a combination of VFC, and state funds (if applicable), the award recipient supplies all ACIP-recommended pediatric vaccines to public and private VFC-enrolled provider locations to vaccinate only VFC-eligible and underinsured children.

VFC and Underinsured Select

Through a combination of VFC and state funds (if applicable), the award recipient supplies all but a few routinely recommended pediatric vaccines to public and private VFC-enrolled provider locations to vaccinate only VFC and underinsured children. Under this policy, the award recipient limits the supply of certain vaccines to only VFC-eligible children in both public and private settings.

VFC-Only Supply

Through VFC funds, the award recipient supplies all routinely recommended pediatric vaccines to private VFC-enrolled provider locations to vaccinate only VFC-eligible children.

Private provider locations do not receive state-funded vaccine for underinsured children. However, underinsured children may be served in public clinics using VFC, state, or local funds, or through some combination of those fund types.

VFC-Only and Universal Hepatitis B Birth Dose

Private provider locations do not receive state-funded vaccine for children who are ineligible for VFC. These children may be served in public clinics using state funds.

In some cases, VFC-only states may provide state-funded hepatitis B vaccine to public or private hospitals to administer the birth dose of hepatitis B vaccine before hospital discharge. In these instances, VFC supports the hepatitis B birth dose for VFC-eligible newborns. Providers should administer state-purchased vaccine to

newborns for whom the birth dose is covered under bundled billing or global billing for all neonatal services (i.e., no routine services are individually billed).

Other

Any purchase policy not described above, such as the combination of two or more of the above policies.

Vaccine Loss

Award recipients must monitor provider compliance with policies for vaccine loss, as outlined in Module 3 – Vaccine Management. These include dose-for-dose replacement and timely return of wasted vaccine. Award recipients' policies regarding vaccine loss should include using the Vaccine Tracking System (VTrckS) to:

- Enter all returns for spoiled and expired vaccine. Award recipients should also correct any discrepancies between the returns entered and the vaccines shipped to the centralized distributor.
- Collect and monitor information on the total number of publicly purchased vaccine doses ordered by vaccine type. Award recipients should also report this information to CDC.
- Collect, monitor, and report to CDC the number of publicly purchased (i.e., VFC, state) doses by vaccine type that expired, were spoiled, or were otherwise wasted due to improper storage and handling by VFC providers.

Award recipients can find more information on the return process in VTrckS in the Centralized Vaccine Distribution Guide, which is available in the VFC Cooperative Agreement Management Platform (CAMP) Knowledge Center.

Policies regarding vaccine loss should also include using PEAR to annually report details of vaccine storage and handling incidents by:

- Identifying the aggregate number of incidents and total number of expired and wasted vaccines by VTrckS category for storage and handling incidents
- Identifying the aggregate number of vaccines wasted for reasons other than storage and handling incidents, based on VTrckS category (e.g., broken vials or vaccines that were drawn into a syringe but not used).

Restitution Policy

Award recipients' restitution policies must state that providers are to replace vaccine on a dose-for-dose basis. This allows doses to be restored to the VFC-entitled children for whom they are intended. Financial payment as a form of restitution is not allowed under any circumstances.

Award recipients with a restitution policy must monitor the use of replacement doses in a provider's facility to verify that these doses are used only for eligible children. They must also verify that the doses are allocated proportionally to the original funding source (i.e., VFC, state). They can do so by developing and using a paper or electronic form for provider locations. The form should track private replacement doses purchased through final administration to an eligible child. Award recipients should reach out to their IOSB Project Officer to receive a copy of the Vaccine Restitution Reporting Template.

See Module 3 – Vaccine Management for more information on restitution.

Vaccine Borrowing

Award recipients can establish policies and procedures to approve vaccine borrowing under certain, rare conditions. They must define the circumstances and conditions for borrowing. Award recipients may use CDC's vaccine borrowing report template or develop their own. At a minimum, the report should contain the following

information:

- The type of vaccine borrowed
- The stock type used (i.e., VFC, private)
- The patient's name
- The patient's date of birth
- The date on which the provider administered the borrowed dose
- The reason why the provider did not use the appropriate stock type
- The date on which the provider replaced the vaccine

Award recipients must monitor and verify replacement for vaccine borrowing using invoices or other appropriate means. Award recipients must also have procedures for addressing provider locations that have multiple instances of borrowing throughout the year.

See Module 3 – Vaccine Management for more information.

Vaccine Transfer

Vaccines may only be transferred between provider locations with approval from the award recipient. Award recipients' policies and procedures must address coordinating and documenting transfers. The award recipient must enter transfer information into VTrckS. During transport, vaccine handling must adhere to the requirements detailed in Module 3 – Vaccine Management.

See Module 3 - Vaccine Management for more information.

Vaccine Ordering Replacement Model

Award recipients must have CDC approval before they implement a vaccine ordering replacement model. Award recipients' proposals must meet the criteria outlined in Module 3 – Vaccine Management.

Temporary, Mobile, Off-site, Satellite and Community Vaccination Clinics

Community vaccinators and VFC providers who conduct temporary, mobile, off-site, or satellite clinics must adhere to all general requirements of the VFC program. It is important that they screen patients and document VFC eligibility. These alternative provider locations must also meet enhanced storage and handling requirements, meaning that award recipients have more oversight responsibilities. These enhanced requirements include:

- Adhering to current policies for CDC depots, as described in the Companion Guide Supplemental Documents and Resources (award recipients can find the Companion Guide Supplemental Documents and Resources in the VFC CAMP Knowledge Center)
- Requesting, reviewing, and approving vaccination procedures for temporary, mobile, off-site, satellite, and community vaccination clinics, including procedures for vaccine transport and temperature monitoring
- Maintaining a current list of clinic dates and locations, as well as vaccine amounts being transported for each clinic by vaccine fund type

Award recipients must also work with community vaccinators to validate that the Provider Profile correctly reflects need for VFC vaccine. The Provider Profile must also consider the overlap of VFC-eligible children who

may also be served by other VFC provider locations in the area.

See Module 3 – Vaccine Management for requirements and recommendations for temporary, mobile, off-site, satellite and community vaccination clinics.

VFC Management Systems and Resources

CDC provides a variety of systems, tools, and resources for collecting and evaluating. Award recipients can find links to these resources:

- In this guide's VFC Resources section and throughout
- In the Strengthening Vaccine-Preventable Disease Prevention and Response Companion Guide (CG)
- In the VFC CAMP Knowledge Center.

CDC recommends using the following to assess program performance:

- PEAR
- Satisfaction surveys for VFC providers
- CDC program evaluation resources

Using information from these sources helps award recipients to identify program successes and areas for improvement, including additional training needs.

Examples of Questions for Data Analysis

- Do the data reflect program expectations and realities?
- Is the information consistent with what is known about the populations being served in that area (e.g., birth cohorts, doses required for specific vaccines)?
- Do the data reflect compliance with program policies?
- Does anything seem unusual, surprising, or incompatible with other data?
- Do the data significantly differ from previously reported data? If so, can the reason for the change be identified?

PEAR Data

The VFC coordinator and other award recipient staff may use PEAR dashboards and reports to monitor issues and trends at the provider location and program levels.

Reviewing findings from problem analyses, along with non-compliant responses to questions, can help identify a need for program changes. It can also help identify a need to address systemic compliance issues.

A noncompliant response to the same questions over time poses a serious threat to the integrity of the VFC program.

Award recipients should also review follow-up actions in PEAR that are overdue or have not been implemented. This information can indicate:

- A lack of follow up by staff
- A lack of structure for implementing follow-up actions at the award recipient level
- Underreporting of follow-up actions by staff
- A combination of these circumstances

Helpful PEAR Reports and Dashboards for Program Monitoring

- Program Overview Dashboard
- Provider Noncompliance Analysis Report
- Storage and Handling or Certificate of Calibration Testing
- VFC and Vaccine Accountability Metrics (VVAM) Interim Progress Report
- Follow-Up Action Details Report
- Question Summary Report

Consult Quick Tips: Pear Reports for Awardees for additional information on all PEAR reports available for award recipients to use.

Award recipients can assess provider compliance in key areas through routine monitoring and detailed reports. For example, running borrowing reports can help determine if providers are experiencing issues with inventory management.

Provider Satisfaction Surveys

VFC provider satisfaction is key to an effective program. Routinely conducting satisfaction surveys of enrolled providers and following up on results by potentially implementing policy or procedural changes, as indicated, is an important approach to program improvement.

Program Evaluation Resources

Award recipients are encouraged to conduct program evaluation on various aspects of their programs, including the VFC program. Program evaluation is important to inform decisions, act on findings, and drive continuous program improvement. CDC has many useful resources on w to conduct program evaluation, which can be found here: CDC Approach to Program Evaluation | Program Evaluation | CDC.

Award recipients are required to implement and evaluate interventions to raise vaccination coverage in selected populations of focus. A program evaluation of an intervention related to the VFC program may satisfy this requirement. Additional information and resources are available in the Knowledge Center in VFC CAMP.

Award recipients may contact their IOSB project officer with questions or to request program evaluation- technical assistance.

Glossary

Abuse (related to Fraud)

Practices of providers or provider locations that are inconsistent with sound fiscal, business, or medical practices, and that result in an unnecessary cost to the Medicaid program. Also includes:

- Actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient;
- Actions that result in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care; and
- Program recipient practices that result in unnecessary cost to the Medicaid program.

Advisory Committee on Immunization Practices (ACIP)

For more information, see General Committee-Related Information | ACIP | CDC

Affordable Care Act

For more information, see About the ACA | HHS.gov

American Indian or Alaska Native (AI/AN)

As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603):

- "Indians" or "Indian," unless otherwise designated, means any person who is a member of an Indian tribe, as defined in subsection (d) of this section, except that, for the purpose of sections 1612 and 1613 of this title, such terms shall mean any individual who (1) irrespective of whether he or she lives on or near a reservation, is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member, or (2) is an Eskimo or Aleut or other Alaska Native, or (3) is considered by the Secretary of the Interior to be an Indian for any purpose, or (4) is determined to be an Indian under regulations promulgated by the Secretary.
- (d) "Indian tribe" means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or group or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) [43 U.S.C. 1601 et seq.], which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

CDC-Approved Depot

A site that receives, stores, and distributes VFC vaccines but does not administer vaccines to eligible children. CDC has only approved these sites for the following award recipients:

- Alaska
- American Samoa
- Guam
- Commonwealth of the Northern Mariana Islands

Deputization Agreement

A formal agreement through a memorandum of understanding (MOU), whereby federally qualified health centers (FQHCs) or rural health clinics (RHCs) delegate their VFC authority for vaccinating underinsured children to other VFC-enrolled provider locations. These locations are usually public health department clinics, which then vaccinate underinsured children as agents of the FQHC/RHC.

Department of Health and Human Services, Office of Inspector General (OIG)

Office mandated to protect the integrity of DHHS programs and their beneficiaries by identifying, communicating, and correcting waste, fraud, or abuse within DHHS programs. The OIG maintains the List of Excluded Individuals and Entities (LEIE).

Expiration Date

The last date on which a vaccine may be used. Expired vaccine includes vaccine that is past the manufacturer expiration date on the vial or expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

Fraud (related to Abuse)

An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself, or to another person. Includes any act that constitutes fraud under applicable federal or state law.

Health Care Sharing Ministries (HCSMs)

Nonprofit alternatives to purchasing health insurance from private, for-profit insurers. Generally, HCSMs are organizations whose members share a common belief system and "share" the cost of their members' medical care.

Insurance

A plan that is:

- Regulated by a state's insurance commissioner
- Subject to the Employee Retirement Income Security Act of 1974 (ERISA)
- Both of these conditions

NOTE: ERISA is a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry. This provides protection for individuals enrolled in these plans.

List of Excluded Individuals and Entities (LEIE)

Providers on the LEIE are excluded from participating in federally funded health care programs because of issues that include:

- Program-related fraud
- Patient abuse
- Licensing board actions
- Default on Health Education Assistance Loans

This list is maintained by the OIG of DHHS. The Centers for Medicare and Medicaid (CMS) requires state Medicaid agencies to use the LEIE to identify ineligible Medicaid providers. Since the VFC program falls under the auspices of CMS, provider locations with providers on the list are not eligible to enroll, reenroll, or otherwise participate in the VFC program in any way.

Maximum Regional Charge (see Vaccine Administration Fee) Office of Management and Budget (OMB)

Office that assists the president in overseeing preparation of the federal budget and supervising its administration in Executive Branch agencies. OMB evaluates the effectiveness of agency programs, policies, and procedures.

Provider Recertification

Award recipients must recertify provider locations that are currently enrolled in the VFC program at least every 24 months. To recertify a VFC provider location, awardee recipients must:

- Verify provider eligibility (i.e., licensure in the jurisdiction).
- Collect a signed Provider Agreement and ensure that it is complete and accurate.
- Distribute the Patient Eligibility Screening Record or written guidance to support eligibility screening and documentation.

Note: "Recertifying" provider locations and "reenrolling" provider locations are separate. They are not interchangeable terms.

Provider Review

Award recipients must review key information for currently enrolled provider locations at least every 12 months. To review a VFC provider location, award recipients must

- Collect and validate profile data.
- Verify that provider locations meet the annual training requirement defined by the award recipient.

Reenroll

Award recipients must officially reenroll previously enrolled provider locations who left the VFC program and are returning to it. Award recipients must conduct an enrollment site visit and training for provider locations that are new to or reenrolling in the VFC program.

Note: "Recertifying" provider locations and "reenrolling" provider locations are separate. They are not interchangeable terms.

Ship (Shipping)

Shipping, as compared to transport, typically involves longer distances and more time to move vaccine between locations. This often refers to the process of moving vaccine using a large shipping service, requiring adherence to shipping standards that go beyond CDC's guidance for vaccine transport.

CDC does not recommend that award recipients ship vaccines because of the potential risks to the cold chain and the vaccine's viability.

Specialty Provider

A provider that only serves:

- A defined population due to the practice specialty (e.g., obstetrician/gynecologist [OB/GYN], sexually transmitted disease [STD], family planning)
- A specific age group within the general population of children ages 0–18 years

Local health departments and pediatricians are not considered specialty providers. The award recipient has the authority to designate VFC providers as specialty providers. At the award recipient's discretion, certain enrolled providers such as pharmacies or community vaccinators may offer a limited selection of vaccines.

Transport (Transporting)

Transport involves moving vaccine over a short time and distance between provider locations. Transport is typically performed by award recipient staff or providers using private vehicles or courier services, over the course of less than eight hours. CDC expects vaccine transport to be rare.

Vaccine Funding Source

One of three types of funding that award recipients use to purchase vaccines. These are:

- VFC funds: Federal entitlement funds used to purchase vaccines to administer to VFC- eligible children
- Section 317 discretionary funds: Federal funds provided through an annual appropriation that support 66 state and local award recipient immunization programs. Federal 317 funds also support the purchase of vaccines for certain eligible populations, though in general, they should be prioritized for eligible adult populations. VFC-eligible children are not eligible for discretionary 317 purchased vaccines, except in rare circumstances as outlined in "General Use of Vaccines Purchased with 317 Discretionary Funds," a document located in the VFC CAMP Knowledge Center.
- State funds: State-contributed funds used to purchase vaccine for children who are not VFC-eligible or to support immunization program operations.

Vaccine Administration Fee (also known as Maximum Regional Charge)

The amount that a VFC-enrolled provider location can charge for each vaccine administered to a VFC-eligible child who is not enrolled in Medicaid. This is also known as the administration fee or "admin fee".

State Medicaid agencies have the authority to reimburse at a lower level than the set vaccine administration fee. CMS set and adjust these maximum regional charges.

VFC-ACIP Resolutions

For more information, please see VFC resolutions.

VFC Program Eligibility Categories

VFC-eligible

A child who is 18 years of age or younger and meets one or more of the following criteria:

- American Indian or Alaska Native (AI/AN)
- Medicaid-eligible or enrolled in Medicaid
- Uninsured
- Underinsured (has health insurance, but the insurance plan does not include any ACIP-recommended vaccines; only includes selected ACIP-recommended vaccines; has a fixed dollar limit, or cap, for vaccines; or does not provide first dollar coverage for vaccines)

Uninsured

A child who has no health insurance coverage.

Underinsured

A child who has health insurance, but whose insurance plan:

- Does not include any ACIP-recommended vaccines
- Only includes selected ACIP-recommended vaccines
- Coverage has a fixed dollar limit (or cap) for vaccines
- Does not provide first dollar coverage for vaccines

An underinsured child is VFC-eligible only for the vaccines that are not covered.

Underinsured children are only eligible to receive VFC vaccine through:

- An FQHC
- An RHC
- A VFC provider under an approved deputization agreement

Fully insured (not eligible)

A child with insurance that covers the cost of vaccine, even if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the child's family has not yet met the plan's deductible. This child is not eligible for the VFC program.

VFC Resources:
Where to Find Them and How to Use Them

Location Key		
● CDC's website	✚ VFC CAMP Knowledge Center	
■ Other website	◆ PEAR	■ CDC's Pink Book

Document/System	Location	Award Recipient Use	Provider Use
VFC PROGRAM OVERVIEW			
VFC Operations Guide: July 1, 2025–June 30, 2026	✚ ●	X	
VFC Statute 42 U.S.C. and CMS Policy Letters	✚	X	
Maximum Vaccine Administration Fees for Children Who are Not Eligible for Medicaid	✚	X	
What's New (for PEAR system updates)	◆	X	
MODULE 1 – PATIENT ELIGIBILITY AND INSURANCE CRITERIA			
Indian Health Care Improvement Act	■	X	
VFC FAQs	✚	X	
MODULE 2 – RECRUITING AND ENROLLING PROVIDERS			
Awardee Provider Agreement Application	✚	X	X
Enrollment Forms Overview	✚	X	X
Provider Profiles (Universal, Universal Select, VFC Underinsured, VFC-Only)	✚	X	X
Patient Eligibility Screening Record	✚	X	X
Office of Inspector General List of Excluded Providers	■	X	
You Call the Shots Online Training Courses	●	X	X
MODULE 3 – VACCINE MANAGEMENT			
CDC's *Vaccine Storage and Handling Toolkit*	■ ●	X	X
Centralized Vaccine Distribution Guide	✚	X	
Vaccine Borrowing Form	✚	X	X
Vaccine Borrowing Form – Example	✚	X	
Separating VFC Stock Visual Aids (color and grayscale)	✚	X	X

Immunization Action Coalition Temperature Logs	■	X	X
Vaccine Storage Troubleshooting Record	■	X	X
Checklist for Certificate of Calibration/Testing Reports	✚	X	X
Sample Form – Vaccine Restitution Report	✚	X	X
VFC Replacement Policy FAQ	✚	X	
Purpose-Built Vaccine Storage Units	✚ ◆	X	
CDC's Vaccine Tracking System (VTrckS)	●	X	X
MODULE 4 – ENSURING PROVIDER COMPLIANCE			
PEAR User Manual	◆	X	
Pre-Visit Checklists	◆	X	
PEAR Site Visit Reviewer Guides	◆	X	
Provider Acknowledgement of Receipt	◆		X
Reviewer Follow-Up Plans	◆	X	
Provider Follow-Up Plans	◆		X
Interim Communication Letters	◆		X
MODULE 5 – FRAUD AND ABUSE			
VFC Fraud and Abuse Investigation Decision Aid	✚ ◆	X	
MODULE 6 – PROGRAM OPERATIONS			
NCIRD Policy Regarding Grantee-Supported Vaccine Depots	✚	X	
Quick Tips: PEAR Reports for Awardees	◆	X	
Sample VFC Provider Satisfaction Survey	✚	X	
Sample Border State Memorandum of Understanding – VFC	✚	X	
VFC Reviewer Supervisory Visit Observation Tool	✚	X	

Definitions of Provider Types

Note: Providers and award recipients can find these definitions on the Provider Profile Form. Award recipients also can find these definitions in the Glossary section of the Provider Education, Assessment, and Reporting (PEAR) system's User Manual.

Behavioral Health Clinic

Locations that provide counseling, behavioral therapy, medication, case management, and other types of services to persons with behavioral health disorders. This provider type is used for behavioral health treatment centers where on-site vaccination services are provided.

Birthing Hospital or Birthing Center

Birthing centers or birthing hospitals where on-site vaccination services are provided. A birthing hospital or birthing center is defined as a facility with:

- More than one birth within the past year (January 1 - December 31 of the past year) or
- At least one registered maternity bed.

Community Vaccinator

Community-wide vaccinators that are external to health departments and conduct vaccination clinics in satellite, temporary, or off-site locations exclusively.

Correctional Facility

Correctional facilities where juveniles are confined and on- site vaccination services are provided. Unlike juvenile detention centers, correctional facilities are long- term in nature; youths are confined in secure correctional facilities for periods generally ranging from a few months to a year or more.

Family Planning Clinic (non-health department)

Clinics that provide contraceptive services for clients who want:

- Pregnancy prevention and birth spacing services
- Pregnancy testing and counseling
- Assistance to achieve pregnancy
- Basic infertility services
- Sexually transmitted disease (STD) services, including human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS)
- Other preconception health services (e.g., screening for obesity, smoking, mental health)

This provider type is used for family planning clinics where vaccination services are provided.

Note: Non-health department clinics that only offer STD/HIV screening and treatment services should be categorized as "STD/HIV Clinic (non-health department)."

Federally Qualified Health Center

Community-based health care providers that:

- Offer primary care services in underserved areas
- Meet the criteria for "Federally Qualified Health Center (FQHC)" certification as set by the Centers for Medicare and Medicaid Services (CMS) (Section 1861(aa)(4)(B) and section 1905(l)(2)(B) of the Social Security Act)

FQHCs include HRSA Health Center Program award recipients and HRSA Health Center Program look-alikes, which are health centers that meet Health Center Program requirements but do not receive federal award funding.

Note: Certain tribal organizations are also FQHCs. However, for tribal or urban Indian health clinics enrolled as FQHCs, use the "Indian Health Service, Tribal, or Urban Clinic" designation.

The FQHC provider type includes any satellite, temporary, or off-site locations where the provider of record (i.e., FQHC personnel) is administering vaccine.

Hospital

All hospitals, except for birthing hospitals, where on-site vaccination services are provided.
Note: For birthing hospitals, use the "Birthing Hospital or Birthing Center" designation.

Indian Health Service, Tribal, or Urban Clinic

Indian Health Service (IHS), Tribal, or Urban Indian Health Program facilities that provide vaccination services. Urban Indian Health Centers are also designated FQHCs and provide comprehensive primary care and related services to American Indians and Alaska Natives. Alaska Village Clinics should be included in this provider type.

Juvenile Detention Center

Juvenile detention centers where on-site vaccination services are provided. Juvenile detention is defined as the temporary and safe custody of juveniles who are accused of conduct subject to the jurisdiction of the court, and who require a restricted environment for their own or the community's protection while pending legal action.

Migrant Health Center

Centers that provide health services, including on-site vaccination services, to migratory and seasonal agricultural workers and their families.

Mobile Provider

Providers who exclusively store and administer vaccines out of a mobile facility. This designation should not be used for providers who have a mobile unit associated with their facility but do not use the unit as the primary site for administering vaccines.

Pharmacy

Stand-alone retail pharmacies (e.g., CVS, Duane Reade, Walgreens) or retail pharmacies within a hospital or health system where on-site vaccination services are provided. This category also includes retail pharmacies that conduct community vaccination clinics at off-site or mobile locations.

Private Practice (e.g., family practice, pediatric, primary care)

Private practice locations, including solo, group, or health maintenance organization (HMO) practitioners, where vaccination services are provided.

Note: This definition includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., provider location personnel) is administering vaccine.

Private Practice (e.g., family practice, pediatric, primary care) as agent for FQHC/RHC-deputized

A deputized provider has been delegated by an FQHC or RHC as an agent to vaccinate underinsured children. This provider type is used for deputized private practices, including solo, group, or HMO practitioners, that provide vaccination services.

Note: This definition includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., deputized private practice personnel) is administering vaccine.

Public Health Department Clinic (state/local)

State or local public health department clinics that provide vaccination services. This category includes:

- Public health department-run STD/HIV clinics
- Family planning clinics
- Teen health centers

Note: This definition includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., deputized private practice personnel) is administering vaccine.

Public Health Department Clinic (state/local) as agent for FQHC/RHC-deputized

A deputized provider has been delegated by an FQHC or RHC as an agent to vaccinate underinsured children. This provider type is used for deputized state or local public health department clinics that provide vaccination services.

Note: This definition includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., deputized public health clinic personnel) is administering vaccine.

Refugee Health Clinic

Clinics that are designated to improve the health care and monitor medical conditions of refugees who have relocated to the United States. This provider type is used for refugee health clinics that provide vaccination services.

Note: Vaccination services may be provided in a location within a physical facility with a refugee health clinic, but vaccines are not administered by refugee health staff. In these cases, select the category of the provider with oversight of vaccination services.

Residential/Congregate Care Facility

Out-of-home settings, including group homes, childcare institutions, congregate foster care facilities, where on-site vaccination services are provided.

Note: If children in these settings receive vaccinations from a mobile provider or community vaccinator, then that provider type should be used.

Retail Health Clinic

Health clinics located within grocery, drug, or retail stores that provide on-site vaccination services. Retail health clinics generally provide a focused range of protocol-driven healthcare services, such as the treatment of minor illnesses or injuries and vaccination services (e.g., Minute Clinic, Take Care Clinic).

Rural Health Clinic

Clinics that are located in a:

- Non-urbanized Health Professional Shortage Area
- Medically Underserved Area
- Governor-designated and secretary-certified shortage area

This provider type is used for rural health clinics that provide vaccination services.

School-Based Clinic (permanent clinic location)

Permanent school-based clinics that provide vaccination services through grade 12.

Note: For non-permanent school-based clinics, use the "Community Vaccinator" designation. The "School-Based Clinic" (permanent clinic location) designation includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., school-based clinic personnel) is administering vaccine.

Specialty Provider

For purposes of the VFC program, "specialty providers" are defined as providers who offer limited care:

- In a specialized environment or
- For a specific age group within the general population of children aged 0–18 years (e.g., birthing hospitals, birthing centers)

Award recipients can allow specialty providers to administer only vaccines recommended for the specific populations that the providers serve.

Student Health Services

Permanent school-based clinics that provide vaccination services for college or university students (e.g., Job Corps).

Teen Health Center (non-health department)

Teen health centers that are not public health department-sponsored but that provide on-site vaccination services.

Urgent/Immediate Care Center

Locations that provide immediate medical outpatient care for treating acute and chronic illness and injury. This provider type should be used for urgent care centers or walk-in clinics where on-site vaccination services are provided.

Women, Infants, and Children (WIC) Clinic

Locations that serve low-income pregnant, postpartum, and breastfeeding women; infants; and children up to age 5 who are at nutritional risk by providing:

- Nutritious foods to supplement diets
- Information on healthy eating, including breastfeeding promotion and support
- Referrals to health care

This provider type is used for WIC clinics that also provide vaccination services.

Note: Vaccination services may be provided in a location within a physical facility with a WIC clinic, but vaccines are not administered
by WIC staff. In these cases, select the category of the provider with oversight of vaccination services.

Other

Any provider type not captured in one of the other provider type options (e.g., CVS Minute Clinic, Walgreens Take-Care Clinic).