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VFC OPERATIONS GUIDE

JULY 1, 2023 – JUNE 30, 2024

National Center for Immunization and Respiratory Diseases
Immunization Services Division

VFC Vaccines for Children

Table of Contents

About This Guide

The 2023 Vaccines for Children (VFC) Operations Guide:

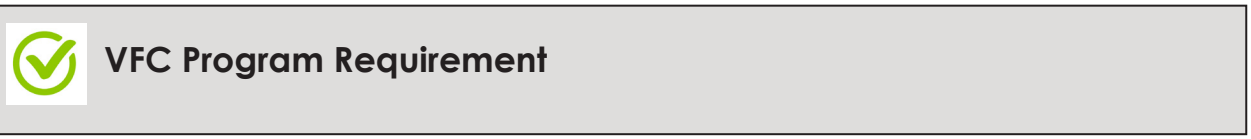
- Spans a valid budget period of July 1, 2023, through June 30, 2024
- Reflects current VFC program policies and processes
- Defines VFC requirements and outlines the steps or components necessary to meet the requirements
- Communicates VFC programmatic information to state, local, and territorial immunization programs efficiently and effectively

Design

Sections are color-coded for easy reference.

Table of Contents
About This Guide
Summary of 2023 VFC Program Requirements
VFC Program Overview
Module 1 – Patient Eligibility and Insurance Criteria
Module 2 – Recruiting and Enrolling Providers
Module 3 – Vaccine Management
Module 4 – Ensuring Provider Compliance
Module 5 – Fraud and Abuse
Module 6 – Program Operations
COVID-19 Addendum
Nirsevimab Addendum
Glossary
VFC Resources
Provider Type Definitions

VFC programmatic requirements for awardees are indicated by a grey box with a green check icon.



Important and supplemental information can be found in boxes throughout the guide.
Best practices are noted throughout the document. While not required, awardees are encouraged to implement these practices, where possible.

Terms Used in this Guide

For purposes of this guide:

- **Awardee** refers to immunization program staff responsible for implementation of the VFC program, which includes the VFC coordinator and the immunization program manager.
- **Facility** refers to a specific physical VFC provider location.
- **Medicaid-enrolled** and **Medicaid-eligible** are used interchangeably and 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 licensed to administer vaccines, as well as the staff within a provider location that stores and handles vaccines, orders and bills for vaccine administration, or screens 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 individuals who conduct VFC site visits on behalf of an immunization program.

Additional Resources

Additional resources to assist awardees are mentioned throughout this guide. Many of these resources are available through the Provider Education, Assessment, and Reporting (PEAR) system or the Immunization Services Division (ISD) Awardees SharePoint Portal. Awardees may request access through their assigned Immunization Operations and Services Branch (IOSB) project officer.

Future Changes to the Guide

Modules will be revised and replaced if information changes after the VFC Operations Guide is published. Unless otherwise noted, effective dates of any new requirements will be 90 days after notice of change. CDC will notify awardees by e-mail anytime changes are made.

Questions

Awardees with questions about the VFC Operations Guide may contact their Immunization Operations and Services Branch (IOSB) project officer.

Summary of 2023 VFC Program Requirements

	Requirement	Steps/Components
	Module 2 – Recruiting and Enrolling Providers	
M2	**Awardees must verify providers meet the eligibility criteria required for VFC program enrollment.**	VFC providers must: • Be licensed in the awardee's jurisdiction to administer vaccines to children aged 18 years and younger. • Be willing and able to follow all VFC program requirements, policies, and procedures, including participation in site visits and educational opportunities. • Have the capacity to order, receive, manage, store, and monitor the temperature of public vaccines. • Be open at least 4 consecutive hours on a day other than a Monday to receive VFC vaccines. • If notified by a state Medicaid agency that a provider is on the List of Excluded Individuals and Entities (LEIE), the provider location cannot be enrolled.
M2	**Awardees must use CDC's Provider Agreement for initial program enrollment, program reenrollment, and 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 behalf of the entity. • All licensed health care providers in an enrolled practice and their corresponding professional license numbers must be listed on the Provider Agreement. • If pharmacists are administering vaccines under the direct supervision of a physician, both the pharmacist and the physician must sign the Provider Agreement. • If there are community vaccinators enrolled or circumstances where the enrolled provider is not providing direct service and other parties are involved with administering vaccines, all parties involved with implementing the clinics must sign the Provider Agreement.

	Requirement	Steps/Components
	Module 2 – Recruiting and Enrolling Providers	
M2	**Awardees must collect a Provider Profile at initial program enrollment or reenrollment and every 12 months thereafter. In addition, awardees should obtain an updated form whenever provider ordering patterns indicate a change in populations served.**	
M2	**Awardees must advise providers on acceptable method(s) for documenting patient eligibility screening results, either using CDC's Patient Eligibility Screening Record or alternative awardee forms or guidance.**	
M2	**Awardees are responsible for reviewing key information of VFC provider locations at a minimum of every 12 months.**	Provider Review includes: • Collecting and validating Provider Profile data. • Verifying provider locations meet the awardee-defined annual training requirement.
M2	**Awardees are responsible for recertifying VFC provider locations at a minimum of every 24 months.**	Provider Recertification includes: • Verifying provider eligibility. • Collecting a signed Provider Agreement and ensuring it is complete and accurate. • Distributing the CDC Patient Eligibility Screening Record or awardee-developed written guidance to support eligibility screening and documentation.
M2	**If the Provider Agreement is terminated, the awardee is responsible for retrieving any unused VFC vaccine from the provider location within 30 days of termination.**	• Follow vaccine transport guidance outlined in CDC's *Vaccine Storage and Handling Toolkit* when retrieving unused VFC vaccines from the provider location.
M2	**When an immunization program is notified by the state Medicaid agency of a provider location with a staff member or subcontractor on the LEIE, the awardee is required to terminate the provider location from the VFC program immediately.**	

	Requirement	Steps/Components
	Module 3 – Vaccine Management	
M3	**Awardees must monitor provider practices to verify compliance with vaccine management guidelines in CDC's *Vaccine Storage and Handling Toolkit* and outlined in the current VFC Operations Guide.**	• Correct storage units. • Digital data loggers (DDLs) with continuous monitoring capabilities and a current Certificate of Calibration. • Receiving and documenting vaccines. • Daily monitoring and recording of unit temperatures, including responding to any temperature excursion. • Managing expired, spoiled, or wasted vaccine. • Vaccine handling and preparation. • Emergency situations.
M3	**Awardees must work with providers to develop vaccine management plans that include feasible standard operating procedures (SOPs) for routine and emergency vaccine management.**	• 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 how to handle a temperature excursion. • Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste. • Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disaster. • Plans must be updated annually or more frequently as needed.
M3	**Awardees must monitor vaccine orders to ensure providers are ordering vaccine in the appropriate amounts and properly maintaining their vaccine inventories.**	
M3	**Awardees can approve vaccine borrowing only when there are unforeseen delays or circumstances in vaccine supply and it will not impact a VFC-eligible child's ability to receive vaccine.**	The Vaccine Borrowing Report must be completed when either: • Privately purchased vaccine is administered to a VFC-eligible child, or • VFC vaccine is administered to a privately insured child.

	Requirement	Steps/Components
	Module 3 – Vaccine Management	
M3	**Awardees are required to approve, actively coordinate, and document the transfer of vaccine between VFC provider locations.**	Vaccine transfers can only occur: • With the approval and under direct guidance of the immunization program. • When a process is in place to ensure vaccine viability during transfer. • When temperature monitoring documentation validates the vaccine has not been exposed to a temperature excursion.
M3	**Awardees who wish to implement a vaccine ordering replacement model in their jurisdiction must submit a proposal to their IOSB project officer for CDC approval.**	Before submitting a proposal, awardees must make sure they can verify provider eligibility, oversee the vaccine replacement process, and ensure doses replaced directly reflect the VFC-eligible children served by the provider location. Vaccine replacement model proposals must meet the following criteria: • VFC screening and documentation for each vaccination encounter. • Awardee must have an immunization information system (IIS) that captures eligibility status at the dose level based on the required eligibility categories, and all doses-administered and eligibility data must be documented within 30 days. • Providers must submit replacement dose orders monthly. • Awardee must assess doses-administered data, replace vaccines according to data during the last 30 days, and ship directly to the provider location. • The total public vaccine inventory must be submitted to VTrckS with each vaccine order and must represent the public portion of the provider location's inventory on hand. • Public vaccine returns must be submitted to represent the public portion of the total vaccine returns.
M3	**If awardees establish a restitution policy, it must require providers to replace federal vaccine on a dose-for-dose basis (instead of financial payment). State vaccine may also be included at awardee discretion.**	Awardee restitution policies must state that providers are to replace vaccine on a dose-for-dose basis. This allows the restoration of doses to the VFC-entitled children for whom they are intended. Deviation from this method (e.g., purchasing equipment) may be considered if there are extenuating circumstances for an individual provider location. Awardees must submit written justification to VFC@cdc.gov and receive CDC approval prior to allowing restitution using any other method. Financial payment as a form of restitution is not allowed under any circumstances.

	Requirement	Steps/Components
	Module 4 – Ensuring Provider Compliance	
M4	**Awardees must use CDC's Provider Education, Assessment, and Reporting (PEAR) online system to record provider site visits and follow-up.**	Site visit data must be entered online into PEAR and submitted the same day. A hard copy process may be used only when there is no internet or computer access. In these cases, site visit data must be entered and submitted within 10 business days. Awardees are required to use PEAR to: • Enroll and unenroll provider locations. • Conduct and document all site visits. • Perform site visits using the appropriate Site Visit Reviewer Guide. • Document awardee 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 or its content must not be shared with providers at any time.
M4	**Awardees 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 and confirmation of provider understanding. • Confirmation the provider knows whom to contact if problems arise, especially with storage and handling issues. • Assessment of storage and handling equipment.
M4	**Awardees must conduct and record VFC compliance site visits covering areas of provider details, eligibility, documentation, storage and handling (per unit and sitewide), and inventory management with each VFC provider location every 24 months.**	Specific requirements are outlined under the categories of: • Provider details • Eligibility • Documentation • Storage and handling (per unit and sitewide) • Inventory The compliance visit must be conducted within 12 months of enrollment. Reviewers must educate the provider on VFC program requirements, including storage and handling.

	Requirement	Steps/Components
	Module 4 – Ensuring Provider Compliance	
M4	**A minimum of 5% of VFC provider locations must receive an unannounced storage and handling site visit during the cooperative agreement budget period using the VFC Storage and Handling Site Visit Guide, exactly as written.**	• Specific requirements outlined for storage and handling (per unit and sitewide). • Assess temperature monitoring. • Responses to temperature excursions.
M4	**Awardees 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, the vaccine coordinator and the backup vaccine coordinator at each provider facility must complete the required training. • VFC compliance site visits with an educational component meet annual training requirements. • Annual training may also be performed online, by webinar, or through an in-person, classroom-style presentation. • Provider location annual training must be documented in PEAR in the annual training module.
	Module 5 – Fraud and Abuse	
M5	**Awardee VFC program policies and procedures must address the prevention, detection, investigation, and resolution of VFC fraud and abuse allegations, as well as federal requirements regarding reporting of suspected fraud and abuse.**	Specific requirements related to: • Oversight personnel. • Personnel training. • Fraud and abuse monitoring. • 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	**All VFC program documentation must be maintained for a minimum of three years, or longer if required by state law.**	• This requirement applies even in the case of provider retirement or provider location closure.
M6	**Awardees must establish and implement policies and procedures for effective program operations, including staffing, staff training, program monitoring, and fraud and abuse.**	• Staffing • Staff training • Systems for program monitoring • Systems related to fraud and abuse
M6	**Awardees must establish and implement policies and procedures related to provider recruitment.**	Protocols must be established for: • Assessing vaccination access gaps for VFC-eligible children in their jurisdictions. • Performing targeted provider recruitment and enrollment to improve access to vaccination for VFC-eligible children.
M6	**Awardees must establish and implement policies and procedures for all aspects of the provider location enrollment process.**	Protocols must be established for: • Verifying provider eligibility to participate in the program. • Conducting an enrollment visit, including completion of the Provider Agreement, Provider Profile, and Patient Eligibility Screening document or similar guidance. • Entering enrollment visit data into PEAR.
M6	**Awardees must confirm 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.**	

	Requirement	Steps/Components
	Module 6 – Program Operations	
M6	**Awardees must establish and implement policies and procedures to validate provider compliance with:** • **Screening and documenting VFC eligibility at each vaccination encounter.** • **Administering VFC-funded vaccine only to children who are eligible for the program.** • **Screening patients for, documenting, and administering state vaccine, if applicable.** • **Complying with the immunization schedule, dosages, and contraindications recommended by ACIP.** • **Making available all appropriate vaccines for the population served.** • **Following vaccine billing and administration fee requirements.** • **Complying with the National Childhood Vaccine Injury Compensation Act.** • **Complying with VFC vaccine management requirements.** • **Maintaining all records for a minimum of three years, or longer if required by the state.**	Provider compliance is addressed through: • Compliance site visits. • Storage and handling visits. • Provider location training.
M6	**Awardee vaccine management and storage and handling policies and procedures must include standards necessary to prevent vaccine waste and ensure appropriate public vaccine stock is available by fund type.**	Areas to address include: • Storage and handling • Vaccine ordering • Vaccine loss and restitution • Vaccine borrowing • Vaccine transfer If applicable, awardees also need policies and procedures related to: • Implementing and monitoring a vaccine replacement model. • Temporary, Mobile, Off-Site, or Satellite Clinics oversight and management.

Vaccines for Children (VFC) Program Overview

Table of Contents

Overview

The Vaccines for Children (VFC) program was established by Congress in 1994 to increase access to vaccination for children who might not get vaccinated because of financial barriers. The VFC program 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 full information on patient eligibility, see Module 1 – Patient Eligibility and Insurance Criteria.

VFC Fast Facts

- VFC benefits an estimated 40 million children
- Approximately 38,000 enrolled health care provider sites
- 61 VFC state, local, and territorial immunization program awardees
- Approximately 72 million VFC vaccine doses distributed in 2022

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 61 state, local, and territorial immunization program awardees to implement and oversee the VFC program. These awardees 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 awardees enroll public and private health care provider locations into the VFC program to meet the immunization needs of VFC-eligible children in their respective jurisdictions.

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

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

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

VFC providers agree to follow all VFC requirements, which include screening patients for VFC eligibility at each immunization encounter and documenting their eligibility status. VFC-purchased vaccines can be administered only to children who are eligible.

Awardees monitor provider locations to ensure VFC compliance and provide guidance, with the goal of vaccinating more infants, children, and teens on schedule.

VFC Vaccines

Vaccines covered by the VFC program are recommended by ACIP to protect infants, children, and teenagers from 19 vaccine-preventable diseases.

ACIP is a federal advisory group of medical and public health experts that develops recommendations on the use of vaccines 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

NOTE: For the purposes of the VFC program, the term 'vaccine' is defined as any FDA-authorized or licensed, ACIP-recommended product for which ACIP approves a VFC resolution for inclusion in the VFC program.

Table: Diseases and ACIP-Recommended Vaccines Covered by the VFC Program

Disease	Vaccines and other immunizing agents	Disease	Vaccines and other immunizing agents
Chickenpox	Varicella, MMRV§	Measles	MMR,** MMRV§
COVID-19	Comirnaty®/Pfizer-BioNTech COVID-19 Vaccine, SPIKEVAX®/Moderna COVID-19 Vaccine , and Novavax COVID-19 Vaccine	Mpox	Jynneos
Dengue ł	Dengvaxia	Mumps	MMR,** MMRV§
Diphtheria	DTaP,* Td,** Tdap,* Kinrix, ¶ Quadracel,¶ Pentacel,§§ Pediarix,¶¶ Vaxelis §§§	Polio	IPV, Pentacel,§§ Pediarix,¶¶ Vaxelis §§§, Kinrix, Quadracel
Hib (Haemophilus influenzae type b)	Hib, Pentacel, Vaxelis §§§	Polio	IPV, Pentacel,§§ Pediarix,¶¶ Vaxelis §§§, Kinrix, Quadracel
Hepatitis A	HepA	Pneumococcal	PCV15, PCV20, and PPSV23
Hepatitis B	HepB, Pediarix,¶¶ Vaxelis §§§	Respiratory synctial virus (RSV)	Respiratory synctial virus (RSV) monoclonal antibody: nirsevimab Respiratory synctial virus (RSV) vaccine: Abrysvo maternal RSV vaccine
Human Papillomavirus (HPV)	HPV	Rotavirus	RV
Influenza (Flu)	IIV4 and LAIV4	Rubella	MMR,** MMRV§
Meningococcal	MenACWY, MenABCWY, MenB	Tetanus	DTaP,* Td,** Tdap,* Kinrix,¶ Quadracel,¶ Pentacel,§§ Pediarix,¶¶ Vaxelis §§§

ł Dengue vaccine is available only for endemic regions specified in current ACIP recommendations.

*DTaP and Tdap combine protection against diphtheria, tetanus, and pertussis.
**DT and Td combine protection against diphtheria and tetanus.
**MMR combines protection against measles, mumps, and rubella.
§MMRV is a combination vaccine containing MMR and varicella.
¶Kinrix and Quadracel are combination vaccines containing DTaP and IPV.
§§Pentacel is a combination vaccine containing DTaP, IPV, and Hib.
¶¶Pediarix is a combination vaccine containing DTaP, IPV, and HepB.
§§§Vaxelis is a combination vaccine containing DTaP, IPV, Hib, and HepB.
Source: Centers for Disease Control and Prevention (CDC)

VFC Program History

- Congress created the VFC program in response to the 1989–1991 measles outbreak in the United States, at a time when 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 Budget Reconciliation Act of 1993. It was established as a new entitlement program required to 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 by requiring each state to establish a program for pediatric vaccine distribution to registered provider locations. It provides authority for purchase of vaccines for administration to eligible children using federal Medicaid and state funds (including 317).
- 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 as a cooperative venture, jointly funded by the federal and state governments (including the District of Columbia and the territories) to assist states in furnishing 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 through the Centers for Medicare and Medicaid Services (CMS) to CDC.
- CDC awards VFC funding through a cooperative agreement to 61 state, local, and territorial immunization programs.

VFC Program Oversight

- The VFC program is administered at the national level by CDC through its National Center for Immunization and Respiratory Diseases (NCIRD).
- CDC is the lead agency responsible for VFC policy development and national program oversight.
- CDC's immunization program awardees manage and implement a VFC program in their state, city, or territory.
- NCIRD's Immunization Services Division (ISD) provides technical assistance to awardees.

Collaboration with VFC Partners

While CDC has the lead responsibility for policy development and implementation of the VFC program, it is important for awardees to 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. Therefore, awardees and state Medicaid agencies should collaborate on policies that affect the children or providers that participate in the program. Both state immunization and Medicaid programs are pivotal 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.

Successful implementation of the VFC program requires participation by and close collaboration with these programs and agencies:

- CDC
- CMS
- State Medicaid agencies
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- National, state, and local organizations representing the private health care sector
- State, local, and territorial health departments

ACIP and VFC Resolutions

ACIP has unique legal authority from Congress to provide recommendations for the VFC program. When recommending a new vaccine or a change in vaccine use, ACIP votes on a resolution to include the vaccine change in the VFC program. VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use.

Vaccines procured through the VFC program must be administered according to the guidelines outlined by ACIP in VFC resolutions. (VFC vaccines may also be administered in accordance with state school attendance laws.)

CDC establishes contracts for VFC vaccines only after 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 legislation that created the VFC program sets a limit on the dollar amount a provider can charge and be reimbursed for administering vaccines to VFC-eligible children. This means a provider may charge a patient any amount up to, but not exceeding, the regional vaccine administration fee cap. This cap varies from state to state and is based on a regional scale determined by CMS.

There is no lower limit, so providers have the option to charge what they feel is fair, including not charging a fee at all.

An initial Federal Register notice setting forth the interim maximum amounts a participating provider may charge for administering a vaccine to a VFC child was published on October 3, 1994. An updated fee schedule was published in November 2012.

A list of the maximum vaccine administration fees is located in the VFC library of the ISD Awardees SharePoint Portal.

Providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration. This policy does not apply to vaccine administration fees billed to Medicaid for children who meet the Medicaid eligibility criteria for the VFC program.

Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.

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

- Providers cannot deny access to federally purchased vaccines to an established patient whose parent is unable to pay the vaccine administration fee.
- Providers cannot charge a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the federal administration fee cap.
- For Medicaid VFC-eligible children, 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 in addition to the vaccine administration fee. This is not prohibited by the VFC statute.

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) is uninsured and, therefore, 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.

The CHIP program can be structured as an expansion of the state's Medicaid program, as a separate CHIP program, or as a combination of a Medicaid expansion program and a separate CHIP program.

Copies of the May 1998 letter to state Medicaid directors and the June 1999 letter from CMS and CDC, which provide clarification regarding immunization services and vaccine funding available for CHIP, can be found in the VFC library of the ISD Awardees SharePoint Portal. These letters outline how vaccinations are covered for each of the different types of CHIP plans. They also discuss how vaccines for the CHIP program can be purchased and utilized via the federal contract.

CHIP and VFC Eligibility

Children enrolled in a Medicaid expansion program are eligible for VFC vaccines.
Children enrolled in a separate CHIP are considered fully insured and are not eligible for VFC vaccines. The state CHIP is responsible for vaccine payment for its members, and awardees must guarantee the appropriate funding is in hand prior to placing vaccine orders for administration to CHIP members.

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Module 1 – Patient Eligibility and Insurance Criteria

Table of Contents

Overview

VFC providers agree to screen patients for program eligibility at each immunization encounter and document their eligibility status. VFC vaccines can be administered only 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 screening patients, providers should select and document the VFC eligibility category requiring the least out-of-pocket expense to the parent.

Awardees must ensure that providers fully understand the VFC eligibility categories and are meeting this basic program requirement of documenting VFC eligibility at each immunization visit.

Program Eligibility Criteria

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 the definition of at least one of the following criteria:

Table: VFC Eligibility Criteria for Patients

VFC Eligibility Criteria	Definition
American Indian or Alaska Native (AI/AN)	This population is defined by the Indian Health Care Improvement Act (25 U.S.C. 1603) (AI/AN children are VFC-eligible under any circumstance)
Medicaid-eligible	Children who are eligible for the Medicaid program (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably)
Uninsured	Children 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 there is a fixed dollar limit or cap for vaccines

American Indian or Alaska Native (AI/AN)

The American Indian or Alaska Native (AI/AN) population, for the purposes of the VFC program, is defined by the Indian Health Care Improvement Act [25 U.S.C. 1603].

AI/AN children are VFC-eligible under any circumstance. However, 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 cost less for the family. Depending on the facility where an AI/AN parent chooses to have their child vaccinated, the parent may be responsible for the vaccine administration fee if the vaccines are delivered through the VFC program. Therefore, if the child has private insurance (non-grandfathered plan under the Affordable Care Act (ACA) of 2010) or is enrolled in the CHIP program, it may result in fewer out-of-pocket costs for the child to receive vaccinations through these programs than through VFC, as there would be no cost-sharing. Likewise, if the AI/AN child is also Medicaid-eligible, Medicaid should be used for the administration fee because it will provide the least out-of-pocket expense.

Medicaid-Eligible

Under the legislation that created the VFC program, the term "Medicaid-eligible" is defined as a child entitled to medical assistance under a Medicaid state 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 considered VFC-eligible because of their Medicaid enrollment. However, their parents are not required to participate in the VFC program.

There are billing options for the parent and provider in this situation. The provider should choose the option that is most cost-effective for the family. The parent of a child with Medicaid as secondary insurance should never be billed for a vaccine or an administration fee.

Options include:

Option 1: The provider can administer VFC vaccines and bill Medicaid for the administration fee.

In most health care situations, Medicaid is considered 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 Medicaid-eligible VFC children. Medicaid must pay the VFC provider the administration fee because vaccinations are a component of the Medicaid Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program. However, once a claim is submitted to Medicaid, the state Medicaid agency has the option to seek reimbursement for the administration fee from the primary insurer.

Note: If the state Medicaid agency rejects a claim for a vaccine administration fee and states the claim must first be submitted to the primary insurer for payment, the provider should notify the awardee. The awardee should notify their Immunization Operations and Services Branch (IOSB) project officer so CDC can work with CMS to educate the state Medicaid agency and correct the situation.

Considerations regarding this option:

- Easiest way for a provider to use VFC vaccines and bill Medicaid for the administration fee
- No out-of-pocket costs to the parent for the vaccine or the administration fee

Option 2: The provider can administer private stock vaccines and bill the primary insurance carrier for both the cost of the vaccine and the administration fee.

If the primary insurer reimburses less than Medicaid for the vaccine administration fee, the provider can bill Medicaid for the balance, up to the amount Medicaid pays for the administration fee.

If the primary insurer denies payment of a vaccine and the administration fee, such as in cases where a deductible must be met, 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 (see Module 3 – Vaccine Management).

Considerations regarding this option:

- The provider may be reimbursed a higher dollar amount if privately purchased vaccine is administered and both the vaccine and the administration fee are billed to the primary insurer.

Medicaid as Secondary Insurance and High-Deductible Plans

If a child has Medicaid as secondary insurance and the primary insurance is a high-deductible insurance plan requiring the parent to pay out of pocket for vaccines, the child should be considered VFC-eligible if the family has not yet reached its deductible.

VFC vaccines should be administered, and the administration fee should be billed to Medicaid until the deductible is reached.

If a child does not have Medicaid as secondary insurance, the child is not VFC-eligible even if a child's family has a high-deductible plan.

Underinsured

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

- Doesn't cover any ACIP-recommended vaccines
- Doesn't cover all ACIP-recommended vaccines (underinsured for vaccines not covered), or
- Does cover ACIP-recommended vaccines but has a fixed dollar limit or cap for payment

The child is considered underinsured once the fixed dollar amount is reached.

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

Note: As required by the Affordable Care Act, insurance plans purchased through the Health Insurance Marketplace are required to cover ACIP-recommended vaccines (including seasonal flu vaccine) for children of all ages without charging a deductible, copayment, or billing coinsurance.

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

Underinsured children can receive VFC vaccines only at federally qualified health centers (FQHCs), rural health clinics (RHCs), or under an approved deputization agreement. 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 (BPHC) of the Health Resources and Services Administration (HRSA) to provide health care to a medically underserved population. FQHCs include community and migrant health centers, special health facilities such as those for the homeless and persons with acquired immunodeficiency syndrome (AIDS) that receive grants under the Public Health Service (PHS) Act, and "look-alikes," which meet the qualifications but do not actually receive grant funds. They also include health centers within public housing and Indian health centers.

What is an RHC?

An RHC is a clinic located in a Health Professional Shortage Area, a Medically Underserved Area, or a Governor-Designated Shortage Area. RHCs are required to be staffed by physician assistants, nurse practitioners, or certified nurse midwives at least half of the time that the clinic is open.

Table: Quick View of VFC Eligibility and Insurance Situations

Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Enrolled in Medicaid	Yes	Medicaid
Has private health insurance plan with Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit	No	Insured. This applies even when the primary insurer would deny reimbursement for the cost of the vaccine and its administration because the plan's deductible has not been met.
Has health insurance covering all vaccines, but has not yet met plan's deductible or paid for other services received at visit and has Medicaid as secondary insurance	Yes	Medicaid
Has health insurance covering all vaccines, but the plan has a fixed dollar limit or cap on amount that it will cover	Yes	• Insured until the fixed dollar limit is met • Underinsured after the fixed dollar limit is reached

Has an insurance plan that does not cover all ACIP-recommended vaccines	Yes	Underinsured. Child can only receive vaccines not covered by the plan.
Has health insurance, but plan does not cover any vaccines	Yes	Underinsured. With implementation of ACA, this situation should be rare.
Enrolled in a Health Care Sharing Ministry	Depends	• Uninsured unless plan is recognized as insurance by the state insurance department, regardless of vaccine coverage provided by the plan • Insured if plan is recognized by the state insurance department and covers vaccines • Underinsured if plan is recognized by the state insurance department and does not cover all ACIP-recommended vaccines
Enrolled in a Medicaid-expansion Children's Health Insurance Program (CHIP)	Yes	Medicaid
Enrolled in a separate Children's Health Insurance Program (CHIP)	No	Insured. The state CHIP program is responsible for vaccine payment for its members.
Has no health insurance coverage	Yes	Uninsured
Has private health insurance that covers all vaccinations and is AI/AN	Yes	AI/AN. However, provider should choose the eligibility category most cost-effective for the child and family.
Has Medicaid and is AI/AN	Yes	Medicaid or AI/AN. Provider should use Medicaid for the administration fee because this provides the least out-of-pocket expense for the family.

Special Circumstances

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

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. All children must be screened and their eligibility documented prior to administering VFC vaccines.

Bordering State

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

- Awardees should have memoranda of understanding (MOU) in place with neighboring states to ensure VFC-eligible children have access to VFC vaccines within their medical homes. (A sample MOU can be found in the VFC library of the ISD Awardees SharePoint Portal.)
- If a provider administers VFC vaccines to a Medicaid VFC-eligible child from a neighboring state, the provider must be Medicaid-enrolled for the child's state of residency in order to receive administration fee reimbursement from that Medicaid program.

Family Planning Clinics, Sexually Transmitted Disease (STD)/HIV Clinics, and Juvenile Detention Facilities

Family planning clinics, sexually transmitted disease (STD)/HIV clinics, and juvenile dentition facilities may have special VFC eligibility circumstances. A list of provider type definitions can be found under Provider Type Definitions.

Table: VFC Eligibility in Special Circumstances

Special Circumstance	Vaccination Service Location	Child's Insurance Status	VFC-Eligible?	VFC Eligibility Category
Seeking contraceptive, STD, or HIV services and wants to be vaccinated	School-located clinic, primary care provider, or urgent care center	For confidentiality reasons, does not want to use insurance	No, school-located clinics or any VFC-enrolled provider locations whose main services are primary or urgent care services are not defined as family planning clinics by CDC and cannot use the uninsured VFC eligibility category	Insured
Seeking contraceptive, STD, or HIV services and wants to be vaccinated	Family planning clinic or STD/HIV clinic	For confidentiality reasons, does not want to use insurance or insurance status is unknown	VFC-eligible at the awardee's discretion; however, eligibility must comply with the state's medical consent laws for minors	Uninsured
Incarcerated	Juvenile detention center or correctional facility	Lost access to health insurance due to incarceration	Yes	Uninsured

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Module 2 – Recruiting and Enrolling Provider Locations

Table of Contents

Overview

Health care providers who vaccinate children are critical to extending the reach of the VFC program. These providers increase the potential number of children vaccinated in an awardee's jurisdiction and allow VFC-eligible children to stay in their medical homes.

Awardees are responsible for:

- Assessing vaccination access gaps for VFC-eligible children in their jurisdictions
- Recruiting and enrolling providers in the VFC program to increase access to vaccines
- Educating providers on VFC program requirements and proper vaccine storage and handling
- Monitoring VFC-enrolled provider locations for correct implementation of VFC requirements

Eligibility

Requirement: Awardees must verify providers meet the eligibility criteria required for VFC program enrollment.

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

- Be licensed in the awardee's jurisdiction to administer vaccines to children aged 18 years and younger
- Be willing and able to follow all VFC program requirements, policies, and procedures, including participation in site visits and educational opportunities
- Have the capacity to order, receive, manage, store, and monitor the temperature of public vaccines
- Be open at least four consecutive hours on a day other than a Monday to receive VFC vaccines to accommodate shipment delivery window.

If the awardee has been notified by the state Medicaid agency that a provider is on the Office of Inspector General's (OIG) List of Excluded Individuals and Entities (LEIE), that provider location is not eligible 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), IHS health professionals who are assigned or detailed to tribes or tribal organizations under the Intergovernmental Personnel Act (IPA) or Memorandum of Agreement (MOA) are not required to be licensed in the state in which they are assigned or detailed.

Awardees are still required to validate the medical licenses of these IHS providers with out-of-state credentials.

Recruitment

Awardees must periodically assess to see if their VFC-eligible population has adequate access to vaccines. Awardees must prioritize the recruitment of additional provider locations to address any gaps in access, especially those areas where there is low vaccination coverage.

To identify new potential VFC providers, awardees can collaborate with medical societies, state licensing boards, the state Medicaid agency, and the Indian Health Service (IHS), including IHS/tribal/urban health facilities for awardees with federally recognized tribes. These entities may assist awardees by identifying providers who vaccinate children but are not enrolled in VFC.

Prioritizing Potential Provider Locations for VFC Enrollment

Prioritization criteria should include:

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

Additional criteria to consider:

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

Awardees are responsible for addressing provider recruitment for their jurisdictions.

For more information, see Module 6 – Program Operations.

Who Can Be a VFC Provider?

Health care provider locations serving 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/centers)
- OB/GYNs
- Pharmacists*
- Specialty provider practices
- Urgent Care Centers*
- School-located vaccination clinics*
- Providers serving adolescents in nontraditional environments (such as long-term juvenile correctional facilities, family planning, and sexually transmitted disease/HIV clinics)

*These providers must agree to vaccinate all "walk-in" VFC-eligible children, in addition to meeting all general VFC requirements.

Specialty Providers

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.

Awardees have the option to allow specialty providers to administer only vaccines recommended for the specific populations the providers serve.

Pharmacists

Pharmacists 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.

Pharmacists must agree to vaccinate all "walk-in" VFC-eligible children, in addition to meeting all other general VFC requirements.

At the discretion of the awardee, enrolled provider locations such as pharmacies and off-site vaccination clinics may offer only influenza and/or COVID-19 vaccine.

Enrollment

Once a provider has agreed to participate in the VFC program, awardees are required to verify the provider's eligibility to participate. This is done through the collection of enrollment forms and by conducting an enrollment site visit.

Enrollment Forms

Three forms are involved in the provider enrollment process:

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

Information about the enrollment forms can be found in the VFC library of the ISD Awardees SharePoint Portal.

1. Provider Agreement

CDC-developed contract between the provider location and the awardee outlining VFC program requirements the providers must comply with to receive publicly funded vaccines.

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

  These requests must pertain to the following policies:

  - FQHC or RHC delegation of authority (awardee must have an approved deputization agreement in place)
  - Pharmacies, urgent care, or school-based vaccination clinics as VFC provider locations
  - VTrckS (for awardees requiring provider direct entry in VTrckS; not applicable to ExIS awardees)
  - Vaccine restitution (for federal and/or state vaccines)
  - Immunization information system (IIS) (include proposed language to be included on the Provider Agreement)
  - Non-VFC-eligible vaccine inventory
  - Store, administer, and distribute vaccines (for provider locations with state/local territorial immunization program approval to store and distribute publicly funded vaccines)

  These requests must be submitted on the Awardee Provider Agreement Application to the assigned IOSB project officer.

  CDC will use the submitted information to develop the final, approved Provider Agreement for awardee use.

  Once approved by CDC, awardees 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

When signing the Provider Agreement, the following apply:

- All VFC provider locations in an awardee'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 behalf of the entity. That provider will be held accountable for the entire location's compliance, including site visit participation and educational requirements.
- All licensed health care providers in an enrolled practice and their corresponding professional license numbers must be listed on the Provider Agreement.
- 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.
- In jurisdictions where there are community vaccinators enrolled or circumstances where the enrolled provider location is not providing direct service and other parties are involved with administering vaccines, all parties involved with implementing the clinics (i.e., the community vaccinator, physician, medical director, and other groups that are directly administering the vaccines) must sign the Provider Agreement. In this situation, there must also be an agreement attached to the CDC Provider Agreement detailing the responsibilities of each party involved.

If the status of the individual signing the Provider Agreement changes, the provider must notify the awardee.

The Provider Agreement must be signed at least every 24 months as part of the VFC program provider recertification process.

State Vaccine Eligibility

Awardees with a finance policy designating 317 and/or state funds to purchase vaccines for non-VFC-eligible children must clearly define these criteria for providers as "state-vaccine-eligible" in an addendum to the Provider Agreement. These awardees must confirm providers are screening for this state vaccine eligibility category and administering doses to qualified children.

2. Provider Profile

Captures the number of VFC-eligible children and non-VFC-eligible children served by a VFC provider location. Information represents populations served by the practice or facility during the most recent 12 months.

- Helps awardees determine how much VFC vaccine to supply each provider location
- Awardees can use the Provider Profile to compare projected vaccine needs with actual vaccine orders and inventory.
- Helps determine amounts of vaccines by fund type to distribute to provider locations
- The Provider Profile must be updated every 12 months, or more frequently if the provider reports a change in patient population during the enrollment year, or if 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 awardee use. Each version illustrates a different vaccine purchase policy and different categories of non-VFC-eligible children.
- Awardees can determine the Provider Profile information on behalf of a provider location if the awardee has the capacity to collect, manage, and incorporate data on the provider location's patient population, specifically noting patients' VFC eligibility status and age groups.

Requirement: Awardees must collect a Provider Profile at initial program enrollment or reenrollment and every 12 months thereafter. In addition, awardees should obtain an updated form whenever provider location ordering patterns indicate a change in populations served.

3. Patient Eligibility Screening Record

Guides VFC eligibility screening and offers a location to document each child's eligibility category.

- A CDC-developed Patient Eligibility Screening Record is available for awardee use.
- Awardees can develop their own form or written guidance as long as it includes the ability to document patient eligibility and all eligibility categories.
- Including a form or written guidance with enrollment materials reinforces the eligibility screening and documentation requirement.

Requirement: Awardees must advise providers on an acceptable method(s) for documenting patient eligibility screening results, either by using CDC's Patient Eligibility Screening Record or alternative awardee forms or guidance.

Electronic Enrollment Forms

Awardees may allow VFC providers to complete and sign enrollment and recertification paperwork through an electronic system. The awardee'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
- Utilizes an electronic signature as acknowledgement of understanding and agreement to maintain the requirements of the VFC program
- Explains that receipt of VFC vaccines after the electronic signature date is additional acknowledgement of the Provider Agreement terms

Enrollment Site Visits

The purpose of the enrollment site visit is to:

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

The enrollment site visit must be completed before a provider location can receive VFC vaccines.

See Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance for additional information on VFC vaccine management and site visits.

Enrollment site visits must be performed independently from compliance site visits, and the VFC Compliance Site Visit Reviewer Guide must not be administered during enrollment site visits.

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

- Educate the provider on successfully implementing VFC requirements, including proper vaccine management and review of a vaccine management template
- Verify 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 vaccine coordinator for each facility
- Complete the enrollment site visit
- Enter enrollment site visit data into the Provider Education, Assessment, and Reporting (PEAR) online system
- Activate the provider location in VTrckS

Reenrollment, Recertification,and Review

Reenrollment

In situations where provider locations leave the VFC program but later want to be reenrolled, awardees must complete all steps for a newly enrolling provider location. This includes all education and documentation requirements, as well as an enrollment site visit. Awardees should be able to track if providers leave the program but later want to be re-enrolled to determine if there has been a history of unresolved non-compliance or mandatory exclusion (i.e, included on LEIE). However, terminated providers should be eligible to reenroll if they are no longer on the LEIE list and have addressed all past VFC program noncompliance.

Provider Recertification (Every 24 Months)

Current VFC provider locations must be recertified to remain in the program.

Requirement: Awardees are responsible for recertifying VFC provider locations at a minimum of every 24 months.

Awardees may recertify all provider locations in the same year or, to better manage workload, 50% of provider locations each year. Timing of recertification is at the awardee's discretion, as long as all provider locations are recertified at a minimum of every 24 months.

Recertifying provider locations includes the following activities conducted by the awardee:

- Verifying provider eligibility (licensure in the jurisdiction)
- Collecting a signed Provider Agreement and ensuring it is complete and accurate
- Distributing the CDC Patient Eligibility Screening Record or awardee-developed written guidance to support eligibility screening and documentation

Provider Review (Every 12 Months)

Key information for current VFC provider locations must be reviewed and updated to remain in the program.

Requirement: Awardees are responsible for reviewing key information for VFC provider locations at a minimum of every 12 months.

Provider Location Training Requirements

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

VFC programmatic training

This training covers all VFC program requirements, including those in the Provider Agreement. The awardee-coordinated training should be conducted every 12 months. At a minimum, the vaccine coordinator and backup coordinator must complete this annual training.

Vaccine management training

Awardees provide vaccine management training at the enrollment site visit. After the initial enrollment training, providers are responsible for annual training on proper storage and handling procedures for all staff involved in the receipt, management, administration, or transport of vaccines. Vaccine management training should also be covered in the awardee-defined annual training (see Module 4 – Ensuring Provider Compliance).

Timing of review is at the awardee's discretion, as long as all provider locations are reviewed at a minimum of every 12 months.

Reviewing provider locations includes the following activities conducted by the awardee:

- Collecting and validating Provider Profile data
- Verifying provider locations meet the awardee-defined annual training requirement

Termination

Either the awardee or provider may terminate the VFC Provider Agreement at any time. Termination must occur if:

- 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.
- The awardee is notified by the state Medicaid agency that a provider is on the LEIE.

Examples of circumstances where a provider location has not ordered vaccine in the past 12 months, but termination may not be warranted include:

- The provider location is a specialty provider (who only needs small quantities of vaccine).
- The provider location is a store-only location (stores and distributes but does not administer vaccine).

Beginning July 1, 2023, awardees will be required to document the reason for unenrollment and who initiated the unenrollment in PEAR.

The awardee must follow vaccine transport guidance 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 awardee is responsible for retrieving any unused VFC vaccines from the provider within 30 days of termination.

List of Excluded Individuals and Entities (LEIE)

The 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, and default on Health Education Assistance Loans.

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. Awardees should work with the state Medicaid agency to develop procedures so that the agency notifies the immunization program routinely regarding 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 an immunization program is notified by the state Medicaid agency of a provider with a staff member or subcontractor on the List of Excluded Individuals and Entities (LEIE), the awardee is required to terminate the provider location from the VFC program immediately.

Module 3 – Vaccine Management

Table of Contents

Overview

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

Awardees are responsible for:

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

Vaccine Coordinators

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

The vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining the Vaccine Management Plan
- Monitoring storage and handling and vaccine administration practices in the facility
- Overseeing vaccine ordering and notifying the awardee if vaccines will expire before they are administered
- Ensuring and documenting annual vaccine management training for designated staff, as well as training new staff upon hire. Providers should be instructed to contact the immunization program, if needed, to provide training for new vaccine coordinators
- Participating in and documenting completion of annual training on VFC requirements
- Storing all required documentation for three years, or longer if required by state statutes or rules, even in the case of provider retirement or provider location closure

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

VFC providers are required to notify the awardee whenever there is a change in vaccine coordinator staff.

Storage and Handling

All VFC vaccine storage and handling requirements and recommendations are in place to ensure the vaccine cold chain is maintained. The cold chain begins at the manufacturing plant, includes delivery to and storage at the provider location, and ends with administration of vaccine to the patient. Too much exposure to heat, cold, or light at any step in the cold chain can result in a loss of vaccine potency. Once potency is lost, it cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced even further. With loss of potency, vaccines become useless and are unable to provide immunity for the

vaccinated individual.

CDC's *Vaccine Storage and Handling Toolkit* provides guidance on safe and effective vaccine management practices for all health care providers. Though VFC providers are required by the VFC program to implement only certain recommendations and best practice guidance, awardees should strongly encourage providers to adopt all recommendations and best practices in the toolkit. Following the toolkit's guidance can minimize financial burden for providers due to vaccine loss and prevent the need for revaccination. The result is maximum vaccine effectiveness and patient protection.

Requirement: Awardees must monitor provider location practices to verify compliance with vaccine management guidelines in CDC's Vaccine Storage and Handling Toolkit and outlined in the current VFC Operations Guide.

VFC Storage and Handling Equipment Requirements

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

- Storage units that maintain correct temperatures at all times
- Refrigerator temperature between 2°C and 8°C (36°F and 46°F)
- Freezer temperature between -50°C and -15°C (-58°F and +5°F); 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 continuous monitoring capabilities and a current and valid Certificate of Calibration Testing for each unit, as well as at least one backup

Storage Unit Best Practices

To protect the viability of vaccines:

- Never store food or beverages in a unit with vaccines.
- Do not store vaccines in the deli, fruit, or vegetable bins (remove bins if possible), in the doors or on the floor of the unit, or under or near cooling vents.
- Place water bottles throughout units—against walls, in the back, on the floor, and in the doors—to help stabilize temperatures.
- Place vaccines and diluents in the center of the unit, two to three inches away from walls, ceiling, floor, and door.
- Store vaccines in their original packaging with lids closed until ready for administration.

Refrigerator and Freezer Units

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

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

- Purpose-built or pharmaceutical/medical-grade units, including doorless and vending-style units
- Stand-alone refrigerator and freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit
- Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines—a separate stand-alone freezer should then be used to store frozen vaccines.*

***Any currently enrolled provider who is currently using both compartments of a household combination unit that is consistently maintaining the required temperature ranges may continue to do so. If temperature excursions occur that can't be attributed to another cause (e.g., power outage), the provider must adhere to this requirement to**

discontinue use, even if it requires the purchase of a separate freezer unit. Any newly enrolling providers after July 1, 2024, will not be allowed to use the freezer compartment of a household combination unit. The use of dormitory or bar-style refrigerator/freezers is prohibited at all times for VFC program provider locations.

These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment.

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

Providers must also protect the power source for all storage equipment, usually by means of "Do Not Disconnect" warning labels at the electrical outlet and circuit breaker.

Doorless/Vending-Style Units

Doorless/vending-style units that are assessed should be identified as such for the type of unit and purpose built for the grade. If you are a VFC provider, your immunization program determines which purpose-built units meet VFC program requirements. Please refer to CDC's *Vaccines Storage and Handling Toolkit* for more information on purpose-built units.

*Digital Data Loggers (DDLs)**

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

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

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

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

Additional recommended DDL features include:

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

Certificates of Calibration Testing must include:

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

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

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

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

VFC Storage and Handling Best Practices

VFC provider locations are required to establish storage and handling policies and procedures in their Vaccine Management Plans, based on the recommendations and best practices in CDC's *Vaccine Storage and Handling Toolkit*. These procedures should be easily accessible and kept near vaccine storage units.

Storage and handling policies and procedures must address:

- Receiving and documenting vaccine shipments, including whom to contact with a problem related to a shipment
- Daily monitoring and recording of storage unit temperatures, including responding to any temperature excursion
- Managing expired, spoiled, or wasted vaccine
- Vaccine handling and preparation
- Emergency situations

Temperature Excursion

A temperature excursion is any temperatures outside of the recommended range found on the package insert for any duration of time.

Receiving and Documenting Vaccines

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

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

Vaccine Compromised During Shipment

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

- Centralized distributor shipment: Contact centralized distribution immediately at 1-877-TEMP123 (1-877-836-7123). This must be done the same day vaccines arrive. Not doing it the same day results in CDC liability for vaccine replacement, regardless of the cause of the temperature excursion. (In the future, an awardee's budget may be decremented for this liability.)
- Direct shipment from manufacturer: Contact the awardee or vaccine manufacturer based on awardee guidance.

Providers and/or awardees must contact the manufacturer directly with questions about storage temperature or temperature excursion for specific vaccines. Manufacturers have access to internal thermostability data concerning the impact of exposures to inappropriate temperatures or light for each vaccine lot.

Daily Temperature Monitoring and Recording

Provider locations are required to have protocols for reviewing and recording the minimum and maximum (min/max) temperature readings in vaccine storage units daily. They should also have procedures for training appropriate staff to document, assess, and interpret temperature monitoring data.

CDC requires reviewing and recording min/max temperature readings at the beginning of the workday, then resetting the min/max reading. This helps to identify temperature excursions quickly so corrections can be made to prevent vaccine loss. CDC also recommends checking the current temperature of the storage unit prior to accessing and administering vaccine.

Information to include when documenting a temperature reading:

- At least one min/max temperature reading per day at the beginning of the workday
- Time and date of each reading
- Name or initials of the person who assessed and recorded the reading

Providers have two options for documenting temperature readings:

Option 1: Handwrite the temperature on a paper log. The log should be posted on each vaccine storage unit door or nearby in a readily accessible and visible location.

A printable temperature log can be found on the Immunization Action Coalition's website.

Option 2: Use a continuous temperature monitoring and recording system that allows providers to electronically document temperature readings. This option is at the awardee's discretion.

Awardees should:

- Verify that the provider location's continuous temperature monitoring system can perform the required activities.
- Understand how the provider location's system works, including how to read and interpret data to validate temperature documentation requirements are met.

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

If a temperature excursion is suspected, providers should follow their vaccine management plan SOPs, including adjusting temperature to the appropriate range and notifying the awardee to determine whether the vaccine can still be used. Until this determination can be made, vaccine should be labeled "Do Not Use" and stored under correct temperature storage conditions, if possible. The vaccine may still be viable; therefore, vaccine must not be discarded or removed from proper storage conditions until the provider is directed to do so by the awardee.

Awardees must provide guidance in the Vaccine Management Plan template on how to document and report an incident so that awardees can best provide guidance on whether patients will 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 stores viable vaccines.
- Label vaccines "Do Not Use."
- Report and record the incident, including the reason and number of doses lost, as instructed by the awardee (download the Vaccine Storage Troubleshooting Record).
- Return spoiled and expired vaccines within six months of the spoilage or expiration date. These vaccines, if necessary, will be accepted after six months, but this should be a rare situation. Wasted vaccines should be disposed of following state and local disposal requirements.

Vaccine Handling and Preparation

Proper vaccine handling and preparation are equally as important as storing vaccines properly.
Providers should follow best practices, including:

- Vaccines should be prepared immediately prior to administration.

Types of Vaccine Loss

- **Expired or spoiled vaccine:** Nonviable vaccine in its original container (vial or syringe) that is able to 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 is unable to be returned for excise tax credit. This includes vaccine in an open vial, drawn into a syringe, or compromised because its container was dropped or broken.
- **Lost or unaccountable vaccine:** Vaccine for which the physical vaccine vial or syringe is missing.

- Prepare vaccines in a designated, clean medication area, away from any space where potentially contaminated items are placed.
- Always check expiration dates prior to preparing the vaccine. Never administer expired vaccines.
- Reconstitute lyophilized vaccine with the diluent that came with the vaccine—nothing else.
- A single-dose vial contains **one** dose and should only be used for **one** patient.
- A separate, sterile needle and syringe should be used for each injection.
- Discard any predrawn doses no later than the end of the workday or per the manufacturer's package insert (if sooner).

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

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

Emergency Situations

Provider locations should plan ahead for emergency situations such as power outages, natural disasters, and equipment failure. This information should be incorporated into a Vaccine Management Plan so providers can follow the protocol for protecting vaccines, including possible transport methods and alternative storage locations. Provider locations should keep on hand or have ready access to the supplies needed for emergency transport. Alternative storage locations should be inspected prior to an emergency to validate that proper vaccine storage conditions can be maintained.

In large clinics, generators and a security system to alert appropriate staff in the event of a power outage may be feasible. If used, generators should be tested quarterly and serviced annually based on manufacturer specifications for testing procedures and maintenance schedules.

Additional information on vaccine storage and handling can be found in CDC's *Vaccine Storage and Handling Toolkit* and on CDC's vaccine administration website and educational materials.

Vaccine Management Plans

Requirement: Awardees must work with providers to develop vaccine management plans that 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 and up-to-date SOPs for routine and emergency vaccine management. Awardees should provide a Vaccine Management Plan template to assist provider locations, although provider locations can develop their own. Provider-developed plans must be reviewed and approved by awardees.

Vaccine Management Plans must address:

- Contact information for current primary and backup vaccine coordinators
- Provider staff roles and responsibilities

- Documented training related to vaccine management
- Proper storage and handling practices, including how to handle a temperature excursion
- Procedures for vaccine ordering, receiving, inventory control, stock rotation, and handling vaccine loss and waste
- Procedures for emergency situations, including transport, equipment malfunction, power failure, and natural disaster

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

Vaccine Management Training

Vaccine management training first occurs during provider enrollment and includes a review of the key components of a Vaccine Management Plan. Thereafter, provider locations are required to receive training annually. See Module 4 – Ensuring Provider Compliance.

The vaccine coordinator and backup coordinator must be fully trained in routine and emergency standard operating procedures for vaccine shipments, storage and handling, transport, and 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: Awardees must monitor vaccine orders to ensure providers are ordering vaccine in the appropriate amounts and properly maintaining their vaccine inventories.

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

Provider locations must submit their total vaccine inventory amounts (i.e., number of doses physically on hand) with each vaccine order. CDC recommends 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 the amount of vaccine loss should an incident occur during shipment or in the vaccine storage unit.

Also important to the vaccine ordering process is the provider location's ability to immediately store vaccine after receipt. 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 and submit updates to awardees. Awardees use the profile data to monitor vaccine orders to ensure provider locations are not inadvertently over-ordering, stockpiling, or building inventory, which can put vaccine at risk for waste or indicate fraud or abuse.

Some providers access VTrckS to order vaccines. Awardees must monitor these provider locations for compliance with the guidelines outlined in the Centralized Vaccine Distribution Guide, found on the ISD Awardees SharePoint Portal.

Provider Profile Estimates

Awardees are required to assess if the patient population estimates reported in a Provider Profile reasonably matches a provider location's vaccine ordering patterns. To accomplish this, awardees can compare:

- Patient population estimates with the birth cohort for the state or jurisdiction. Determine if the estimate relative to the birth cohort is an amount that makes sense for the community the provider location serves.
- Provider location vaccine orders with the Provider Profile population estimate. For example, if a Provider Profile estimates serving 100 patients under 1 year of age during a 12-month period, compare the amount of DTaP doses ordered against this 100-patient estimate (3 doses per eligible child, 300 doses during the year, or 75 doses quarterly).
- Doses administered as reported in an IIS with the quantity of vaccines ordered. This can help show whether doses ordered are being correctly administered to eligible populations and whether quantities ordered are appropriate amounts for eligible populations shown in the Provider Profile.
- In instances where comparisons show significant discrepancies from Provider Profile estimates, awardees should consult with the provider to determine reasons for the differences. The Provider Profile may need to be updated.

Vaccine Inventory Accountability

Separating Pediatric Vaccine Stock

Provider locations are required to have two separate vaccine inventories: one for publicly purchased vaccines and one for privately purchased vaccines.

Note: For providers that serve any non-VFC eligible population according to their provider profile, they must maintain a separate vaccine inventory to vaccinate their non-VFC-eligible population. Non-VFC-eligible populations include:

1. Fully insured children
2. Other underinsured children (served by a provider/facility that is not a FQHC/RHC or a deputized provider)
3. Enrolled in CHIP

Publicly purchased vaccine inventory includes publicly purchased vaccines supplied to the provider location for administration to VFC, 317, state-vaccine-eligible, and CHIP children (if the awardee purchases vaccines for the CHIP program). Universal purchase states will only have this type of vaccine inventory.

Privately purchased vaccine inventory includes vaccines purchased for the provider location's privately insured children. This includes state-purchased vaccines that are used for insured patients when third-party billing is performed.

Provider locations approved to use the vaccine ordering replacement model do not have to maintain separate stocks of public and private vaccines (i.e., they can have a co-mingled vaccine inventory with "virtual" doses attributable to the public and private portions of inventory).

For additional guidance on separating stock, see "Separating and Storing Your Vaccine Stock" in the VFC library of the ISD Awardees SharePoint Portal.

Vaccine Borrowing

Requirement: Awardees can approve vaccine borrowing only when there are unforeseen delays or circumstances in vaccine supply and it will not impact a VFC-eligible child's ability to receive vaccine.

CDC's expectation is that vaccine borrowing will 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 privately purchased vaccine inventory unless CDC and the awardee have approved a vaccine ordering replacement model.

Borrowing is approved only 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 privately insured patient population can use this option to administer short-dated, privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated, VFC dose.
- New staff calculated ordering intervals incorrectly, leading to a lack of either private or public vaccine stock.
- VFC seasonal influenza vaccine stock 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

A Vaccine Borrowing Report must be completed when either:

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

Awardees may report the information using CDC's template or by developing their own as long as it contains all the components of the CDC template. The template can be found on the ISD Awardees SharePoint Portal.

See Module 6 – Program Operations for additional information.

Invoices

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

Awardees must follow up with provider locations who borrow vaccines multiple times in a single year. Awardees should assess the inventory management practices within the facility to determine whether changes can eliminate the frequent need to borrow.

Vaccine Transfer

Proper vaccine inventory management at both the awardee 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 soon-to-expire vaccine stock. Where practical, and as long as the cold chain is maintained, transfer of short-dated vaccine can occur between VFC provider locations to avoid wasting vaccine. Providers must notify awardees of short-dated vaccine so that a transfer can be coordinated. This should be a rare practice if provider locations are appropriately managing inventory.

Requirement: Awardees are required to approve, actively coordinate, and document the transfer of vaccines between VFC provider locations.

Vaccine transfers can only occur:

- With the approval and under direct guidance of the immunization program
- 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 and valid Certificate of Calibration Testing for temperature monitoring during transport, as well as other appropriate equipment
- When temperature monitoring documentation validates 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 and, as doses are used for VFC-eligible children, those doses are replaced on a regular basis by the awardee. The model is intended to allow providers such as but not limited to large health systems and hospitals to use their private funds to establish an initial vaccine stock for use in providing vaccination services to all the patients they serve. Provider locations approved to implement a vaccine ordering replacement model are required to meet all VFC requirements, including operating within the NCIRD Policy for Grantee-Supported Vaccine Depots (as stated in the Centralized Vaccine Distribution Guide), following proper storage and handling practices, and receiving required VFC program site visits.

Eligible provider locations must have the financial means to maintain a vaccine inventory at all times that is sufficient to cover both their private and public (i.e., VFC, 317, and/or state) patients. However, having financial means alone is not sufficient for approval. In addition, providers must be able to show they have an electronic process for recording dose-level patient eligibility for each vaccination encounter and can submit this information to the awardee.

The awardee must also have the capacity to verify provider location eligibility, oversee the vaccine ordering replacement model, and ensure that doses replaced directly reflect the VFC-eligible children served by the provider location.

Additional information may be found in the document, "VFC Program Vaccine Replacement Policy–FAQ," posted in the VFC library on the ISD Awardees SharePoint Portal.

Requirement: Awardees who wish to implement a vaccine ordering replacement model in their jurisdiction must submit a proposal to their IOSB project officer for CDC approval.

Before submitting a vaccine ordering replacement model proposal to CDC, awardees must make sure they have the capacity to verify provider eligibility, oversee the vaccine ordering replacement process, and ensure doses replaced directly reflect the VFC-eligible children served by the provider location.

Vaccine ordering replacement model proposals must meet the following criteria:

- VFC screening and documentation of federal and state vaccine eligibility status must be performed for each vaccination encounter.
- Awardee must have an electronic system such as an immunization information system (IIS) that captures eligibility status at the dose level, based on the required eligibility categories as outlined in Module 1 – Patient Eligibility and Insurance Criteria.
- All doses administered and the dose-level eligibility of the child on the date of service must be documented within 30 days of administration using the awardee-identified IIS or other electronic system.
- To accomplish dose-for-dose replacement, the awardee must assess doses-administered data and replace vaccines according to the data recorded during the last 30 days. A sample of the data and/or report that will be reviewed monthly by the awardee must be included with the vaccine replacement model proposal.
- Data to review:
    - Actual doses to be replaced, including total number of doses by vaccine type/brand/ presentation and eligibility
    - Patient-level data validating that only doses used for VFC-eligible children are being replaced
- Awardee must require provider replacement dose orders to be submitted monthly.
- Awardee must ship replacement doses directly to the provider location. Additional considerations:
    - Large health care systems that use a centralized pharmacy may only have vaccine shipped to the pharmacy for redistribution to the clinic(s) 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 total public vaccine inventory amount must be submitted to VTrckS (directly or via ExIS) with each vaccine order and must represent the public portion of the provider location's inventory on hand. It is not acceptable to report a zero amount based on the rationale that all doses on hand are considered private. One option for accomplishing this is to apply the percentage of the provider location's VFC-eligible population from the VFC Provider Profile to the current vaccine inventory.
- Similar to inventory, public vaccine returns must be submitted to represent the public portion of the total vaccine returns. This can be accomplished by applying the percentage of VFC-eligible children in the provider location to the total amount of returned vaccines.

A demonstration of the system or process used by the awardee may be required to support a submitted proposal.

CDC does not allow inclusion of influenza vaccine in a vaccine ordering replacement model.

It is recommended that provider locations using the vaccine ordering replacement model identify and separate VFC replacement doses. However, provider locations do not have to maintain separate stocks of public and private vaccines (i.e., 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 vaccine doses (i.e., VFC and/or state) that were lost due to provider negligence.

CDC recommends awardees establish a restitution policy for federal vaccine doses (VFC and 317) that are lost due to provider negligence. Restitution criteria are at the discretion of awardees.

Restitution policies should:

- Identify examples of typical situations that may require restitution.
- Set reasonable loss thresholds for when restitution is required.
- 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.

Requirement: If awardees establish a restitution policy, it must require providers to replace federal vaccines on a dose-for-dose basis (instead of financial payment). State vaccine may also be included at awardee discretion.

Awardee restitution policies must state that providers are to replace vaccine on a dose-for-dose basis. This allows the restoration of doses to the VFC-entitled children for whom they are intended. Deviation from this method (e.g., purchasing equipment) may be considered if there are extenuating circumstances for an individual provider location. Awardees must submit written justification to VFC@cdc.gov and receive CDC approval prior to allowing restitution using any method other than dose-for-dose replacement. Financial payment as a form of restitution is not allowed under any circumstances.

Providers must follow the awardee's restitution policy, including:

- Administering replaced doses only to VFC- and/or 317-eligible children, based on the same proportion as the original funding sources (VFC and/or 317) for the lost doses
- Contacting the awardee for how to handle any replaced vaccines that cannot be administered to the eligible population—these vaccine doses may be shipped directly to a local health department for administration to VFC-eligible children (if a local health department is unavailable, another provider type may receive the vaccines)
- Submitting a receipt for vaccine purchase reflecting the dose-for-dose replacement within 90 days of vaccine loss—if the provider location cannot achieve this within 90 days, the awardee must negotiate an alternative replacement plan that should be met within six months
- Providing required documentation related to restitution, including the administration of replacement doses to VFC- or 317-eligible children or state-covered children (if applicable)

Temporary, Mobile, Off-Site, or Satellite Clinics

Some providers may conduct temporary, mobile, off-site, or satellite clinics, and awardees may collaborate with community vaccinators within their jurisdictions, too. 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 (i.e., trailers, buses, etc.) 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 These units are not the primary site for vaccine storage and administration—they are not to be confused with mobile providers who exclusively store and administer vaccines out of a mobile facility.

Not only are these alternative provider locations required to adhere to all general program requirements, including screening and documenting VFC eligibility, they must maintain enhanced storage and handling practices, including:

- The number of VFC vaccines transported to a temporary, mobile, off-site, or satellite clinic should be based on anticipated number of VFC-eligible children to be served.
- Vaccines may be transported—not shipped—to a clinic site using vaccine transportation procedures outlined in CDC's *Vaccine Storage and Handling Toolkit*. This includes transporting vaccines to and from the site at appropriate temperatures and using appropriate equipment, as well as 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 appropriate temperature throughout the clinic day.
- Temperature data must be reviewed and documented every hour during the clinic using a DDL with a digital display and probe in buffered material.
- At the end of the clinic day, temperature data must be assessed prior to placing vaccines back into storage units to prevent administration of vaccines that may have been compromised.

If at any time, vaccines are exposed to temperature excursions, they must be labeled "do not use" until further information can be gathered on usability.

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

- Vaccine ordering—while CDC recommends vaccines be delivered directly to provider facilities, this may not be possible for temporary, mobile, off-site, satellite and community vaccination clinics. To protect the cold chain and vaccine viability, vaccines must be ordered and shipped directly from CDC to a location within the awardee's jurisdiction when direct delivery is not possible. Vaccines may also only be administered within the jurisdiction.
- Vaccine transport records that detail the type of vaccine(s), quantity being transported, and temperature monitoring should be maintained by providers for temporary, mobile, offsite, or satellite clinics.
- Provider forms—following VFC operations guidance, community vaccinators must sign a Provider Agreement (see Module 2 for more information) and complete a Provider Profile. Awardees should work

closely with these community vaccinators in development of the profile, since some VFC-eligible children may be served by other VFC provider locations in the area.

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

CDC recommendations and best practices for vaccine handling during a temporary, mobile, off-site, or satellite clinic include:

- Do not draw up vaccines before arriving at the clinic site. Drawing up doses days or even hours before a clinic is not acceptable. CDC strongly recommends not pre-drawing doses before they are needed.
- Use manufacturer-filled syringes, if possible, as an alternative to predrawing vaccines.
- Each person administering vaccines should pre-draw no more than one multidose vial (MDV) at one time.
- Monitor patient flow to avoid drawing up unnecessary doses.
- Discard any remaining vaccine in pre-drawn syringes at the end of the workday.

Additional information on handling and preparing vaccine can be found in CDC's *Vaccine Storage and Handling Toolkit* and on CDC's vaccine administration website.

Module 4 – Ensuring Provider Compliance

Table of Contents

Overview

VFC providers perform vital functions of the VFC program, including eligibility screening, vaccine storage and handling, and vaccine administration. It is essential for these providers to have a clear understanding of VFC requirements and how the program operates. Site visits, training, and other oversight measures help maintain and improve a provider location's compliance with VFC program requirements. Site visits provide an opportunity to identify potential accountability issues with VFC vaccine and determine whether vaccines are stored, handled, and administered in accordance with the laws and policies governing the VFC program. Site visits also provide an opportunity to educate providers on VFC program requirements.

Reviewing and evaluating VFC provider location practices involves assessing verbal, written, and visual information encountered during site visits to determine if providers are following the program requirements.

Site visit goals are to:

- Identify areas where providers are doing well and areas needing additional follow-up.
- Identify educational needs of VFC providers to help them meet program requirements.
- Ensure VFC-eligible children are receiving properly managed and viable vaccine.

Additionally, site visits 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, awardees do the following:

- Conduct Enrollment site visits
- Conduct Compliance site visits
- Conduct Storage and handling site visits (scheduled or unannounced)
- Develop and maintain VFC contacts, as needed
- Conduct annual provider location training

Provider Education, Assessment, and Reporting (PEAR) System

CDC's Provider Education, Assessment, and Reporting (PEAR) online system serves as an oversight management tool for awardees and CDC. The system collects relevant VFC data to support overall program activities and can track and generate detailed reports on site visits and annual provider location training. 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 maintain VFC contact information.

Requirement: Awardees must use CDC's Provider Education, Assessment, and Reporting (PEAR) online system to record provider site visits and follow-up.

During site visits where there is internet access, site visit data must be entered online into PEAR while at the provider location and submitted the same day. The reviewer may record site visit information on a hard or soft (e.g., MS word, fillable PDF) copy VFC Site Visit Reviewer Guide while at the provider location and enter data into PEAR at a later time for reasons identified by CDC as valid (noted in PEAR). In this situation, the reviewer must submit the site visit data into PEAR within 10 business days. In an effort to maintain data quality control during this process, select paper site visits must be uploaded in PEAR upon the request of CDC.

Note: If documenting on hard copy but also entering data into PEAR while at the provider location, the reviewer should select that the site visit was "documented using PEAR" when entering the site visit data into PEAR.

Awardees are required to use PEAR to:

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

PEAR may also be used to prepare for a site visit (using a previsit checklist) and to train new awardee staff (using the PEAR training website).

See Module 6 – Program Operations for more on PEAR.

VFC Site Visit Reviewer Guides

Located in PEAR, VFC Site Visit Reviewer Guides are designed to help site visit reviewers effectively communicate VFC program requirements and 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. Both of these guides must be administered 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 reviewers are receiving a realistic picture of how a provider location is implementing the VFC program, these guides and their content must not be shared with providers at any time.

Site Visit Reviewer Guides can be found in PEAR.

Site Visits

Multiple types of VFC site visits are designed to evaluate different aspects of provider compliance with and understanding of VFC requirements:

- Enrollment site visit
- Compliance site visit
- Storage and handling site visit (scheduled and unannounced)

Arranging a Site Visit

For enrollment, compliance, and scheduled storage and handling site visits, scheduling procedures 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 facility address and location
- Discussing with the office manager the estimated amount of time needed for the site visit and who will need to be available to meet during the site visit
- Outlining what provider location information you will need, equipment you will need access to, and any reviewer on-site needs, such as a workstation or power source
- Sending a confirmation letter, e-mail, or fax to the contact person with the date and time of the site visit, as well as a summary of the site visit process (a sample VFC compliance pre-visit letter is located in PEAR) Note: The VFC Compliance Site Visit Reviewer Guide or its contents must not be shared with the provider.

Therefore, the letter should only discuss the process and accommodations needed. It 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 the provider location has VFC vaccine in inventory **(If, for any reason, the provider location does not have VFC vaccine in stock, the compliance site visit will need to be rescheduled.)**

While there is no need to use a pre-site visit protocol for unannounced storage and handling site visits, reviewers should communicate the purpose and intent of the site visit when they arrive at the provider facility.

Explain in advance what items and documentation providers should have available, and specify which locations within the facility the reviewer will need to access. This information, as well as other items deemed necessary by the awardee, should include:

- The need for a space to work and a power source if a laptop is used
- Patient records (provider must be informed that a sampling of records will be reviewed during the site visit)
- Current and previous temperature logs or data for a minimum of the last three months
- Current and previous vaccine borrowing reports
- Access to all vaccine storage units where VFC vaccine is stored
- Access to the circuit breaker, if applicable—the provider should be informed that maintenance staff may need to be available during the site visit to gain access to the circuit breaker (see the VFC Compliance Site Visit Reviewer Guide for more information on circuit breaker labels and comprehensive policy and standard operating procedures in lieu of labels)
- Time with admitting and billing personnel to clarify screening and billing processes

Site Visit Protocol

CDC recommends conducting VFC compliance site visits independently from COVID-19 vaccination program and IQIP visits. When awardees must perform combined visits, it is imperative enough time be allotted to fully observe provider vaccination workflow and engage appropriate staff in discussion of QI strategy implementation. Because it may be difficult to shift from a compliance-focused dialogue to one with a collaborative emphasis, CDC recommends awardees perform the IQIP component of the visit prior to the VFC component.

Preparing for a Site Visit

When preparing for site visits, reviewers should consider:

- What do I need to know? (Data from previous site visit reports, the Provider Profile, vaccine returns and wastage, vaccine ordering, etc.)
- What do I need to bring with me? (VFC eligibility screening form, storage and handling labels, current VISs or VIS publication date list, information on ACIP-recommended vaccines, training resources related to VFC requirements, etc.)
- What do I need to print? (Provider location demographic information, Site Visit Reviewer Guide, acknowledgement of receipt, follow-up plan, Provider Profile, Vaccine Management Plan template, etc.)

Awardees will find CDC previsit checklists for reviewers in PEAR (Documents tab). Awardees may also wish to develop their own tools to assist with reviewer preparation.

Enrollment Site Visit

All new and reenrolling provider locations in the VFC program must receive a VFC enrollment site visit and meet all CDC-defined criteria prior to receiving public vaccine. The purpose of the enrollment site visit is to educate providers on implementing VFC program requirements and supply appropriate resources, as well as to confirm the provider can store and monitor vaccine supply according to program requirements. Provider education must include requirements outlined in the CDC Provider Agreement, VFC Site Visit Reviewer Guides, and the current VFC Operations Guide.

The enrollment site visit must include:

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

Before receiving VFC vaccine, providers must:

- Complete the Provider Agreement and Provider Profile.
- Successfully complete the enrollment site visit.
- Receive training on how to implement VFC requirements.
- Have appropriate storage and handling equipment in place to store and monitor vaccine.
- Be enrolled and active in VTrckS.

Requirement: Awardees must conduct an enrollment site visit for all new and reenrolling VFC providers before they can receive VFC vaccine.

Provider enrollment information must be documented in PEAR.

Compliance Site Visit

Self-Assessment

In order to address training deficits and areas of noncompliance objectively, a location should not be self-assessed by staff working in that location (e.g., contracted LHD staff assessing their own clinic). The VFC coordinator must conduct the site visit if the assigned reviewer works for that provider location.

The purpose of the compliance site visit is for reviewers to evaluate whether providers are complying with and understanding VFC requirements, including those outlined in the Provider Agreement.

Requirement: Awardees must conduct and record VFC compliance site visits, covering areas of provider details, eligibility, documentation, storage and handling (per unit and sitewide), and inventory management with each VFC provider every 24 months.

Before receiving their first compliance site visit, provider locations must be enrolled in the VFC program for at least three to six months and have experience ordering and administering VFC vaccines. CDC recommends the site visit occur at the three- to six-month time frame. **Regardless, the compliance site visit must be completed within 12 months of enrollment.**

Verifying Provider Profiles, Vaccine Ordering Patterns, and Inventory

It is strongly recommended that awardees carefully examine the Provider Profile before every site visit. Review past vaccine orders to ensure order volume is consistent with the Provider Profile. Providers locations should maintain sufficient inventory to prevent vaccine borrowing, loss, and waste. Reviewers should be prepared to discuss any updates to the Provider Profile, if needed.

Reviewers must also review providers' vaccine borrowing activity. Corrective actions must be taken when excessive or inappropriate activities are noted.
Sharing with the provider the monetary amount the facility's VFC vaccine inventory is worth can help to further illustrate the need to store and manage the vaccine appropriately.

CDC also recommends sharing any vaccine returns and/or wastage information during the last 12 months. Reviewers should discuss how inventory management and ordering practices may be impacting the provider location's vaccine loss.

These practices may involve stock rotation, as well as ordering appropriate quantities at appropriate frequencies to support the provider location 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.

Specific information for reviewers to assess in each area includes:

Provider Location Details

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

Patient Eligibility and Billing

Review procedures, practices, and records to confirm provider understanding and implementation of:

- VFC eligibility criteria for patients
- Not billing for the cost of public vaccine purchased from the federal contract
- Not charging a vaccine administration fee to non-Medicaid VFC-eligible children that exceeds the federal administration fee cap
- Accepting the vaccine administration fee reimbursement for Medicaid VFC-eligible children or the contracted Medicaid health plans
- Provider locations that choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.
- Not denying access to federally purchased vaccine to an established patient whose parent is unable to pay the

Resources to Bring to a Compliance Site Visit

Reviewers should provide current immunization resources (or links to resources) when conducting a compliance site visit.

Resources may include items such as:

- Vaccination brochures and educational materials for patients and providers
- Current list of vaccines available through the VFC program
- Educational materials and resources on all ACIP-recommended vaccines
- Educational materials on VFC eligibility requirements
- 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)
- List of current vaccine information statements (VISs) and 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" stickers for storage unit outlets and circuit breakers
- Awardee-specific information for the jurisdiction's Children's Health Insurance Program (CHIP)
- Information about upcoming CDC immunization trainings and online educational opportunities

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 provider understanding and implementation of:

- Properly screening patients for VFC eligibility and documenting the results at each immunization encounter
- If applicable, screening for state vaccine eligibility and administering doses to identified children, as defined in the addendum to the Provider Agreement
- Making available the vaccines identified and agreed upon in the Provider Agreement and Provider Profile based on the provider type and population served, including non-routine vaccines
- Ensuring VFC-purchased vaccine is only administered to VFC-eligible children, including verifying insurance coverage for underinsured children:
    - If an FQHC/RHC or other deputized provider location, confirm insurance coverage is verified before administering vaccine to an underinsured child.
    - If not an FQHC/RHC or other deputized provider location, confirm referring to a qualified provider location.
- Having sufficient vaccine inventory to vaccinate all children
- Retaining VFC-related documentation for three years (or more)
- Borrowing policies and procedures, including assessment of whether the provider is borrowing excessively
- Distributing current vaccine information statements (VISs) prior to administration of each vaccine
- Reporting vaccine adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Reviewing the facility Vaccine Management Plan to ensure it is complete and current

Records Management

Providers must maintain all records related to the VFC program for a minimum of three years, or longer if required by state law, and make these records available for review upon request. VFC records include, but are not limited to:

- VFC screening and eligibility documentation
- Billing records
- Medical records that verify administration of vaccine
- Vaccine ordering records
- Vaccine purchase and other accountability records (packing lists, borrowing forms, wastage reports, etc.)
- Storage unit temperature documentation

Storage and Handling per Unit

Assess that each individual storage unit:

- Is an approved storage unit based on VFC requirements

- Contains a DDL with continuous monitoring capability and a current and valid Certificate of Calibration Testing
- Has vaccines and DDL placed correctly in the unit

Some provider locations may have purpose-built or pharmaceutical-grade equipment with temperature monitoring capacity. Check with CDC on whether these units meet VFC requirements.

Also, review provider location documents related to:

- Temperature monitoring
- Responses to a temperature excursion within the unit (see Module 3 – Vaccine Management for more information)

Storage and Handling Sitewide

Discuss the cost and quantity of vaccine ordered by the provider location so staff understands the overall impact of the VFC program on their facility.

Assess vaccine storage equipment and written procedures, records, and documents to confirm provider understanding and implementation of:

- Sufficient space to store all vaccine based on peak stock expectations
- Handling expired vaccine, including returning it to the CDC central distributor within six months of expiration
- Having at least one backup DDL readily available with a different calibration date
- Correct vaccine handling and preparation
- Any additional storage and handling requirements as required by the awardee and based on CDC's *Vaccine Storage and Handling Toolkit*
    - Sharing any vaccine returns or wastage data during the last 12 months

See Module 3 – Vaccine Management for more information.

Inventory

Review procedures, practices, and records to confirm provider understanding and implementation of:

- Ordering vaccine in correct quantities to maintain appropriate vaccine inventories
- Complying with the childhood immunization schedule as recommended by ACIP unless:
    - The provider deems 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.
- Separation of vaccine stock between private and public vaccine

Storage and Handling Site Visit

The purpose of a storage and handling site visit is for a reviewer to assess a provider location's compliance with and knowledge of VFC storage and handling requirements, as well as any awardee-specific requirements. These requirements are based on recommendations and best practices outlined in CDC's *Vaccine Storage and Handling Toolkit*.

Requirement: A minimum of 5% of VFC providers must receive an unannounced storage and handling site visit during the cooperative agreement budget period using the VFC Storage and Handling Site Visit Reviewer Guide exactly as written. Awardees with less than 20 provider locations should conduct a minimum of one unannounced storage and handling visit.

Provider locations who receive unannounced storage and handling site visits should be selected based on:

- Previous storage and handling compliance issues
- Time since 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.

Site Visits to CDC-Approved Depots

- Awardees with CDC-approved depots are required to perform an announced storage and handling visit every 12 months to ensure compliance with storage and handling requirements.
- Compliance visits are not required since these sites do not administer VFC vaccines to eligible children.

Storage and Handling Site Visit Assessment

During storage and handling site visits, reviewers assess individual storage units and DDLs, as well as overall storage and handling operations, based on VFC requirements and CDC's *Vaccine Storage and Handling Toolkit*.

Storage and Handling per Unit

Assess that each individual storage unit:

- Is an approved vaccine storage unit based on VFC requirements
- Contains a DDL with continuous monitoring capability and a current and valid Certificate of Calibration Testing
- Has vaccine and DDL placed correctly in the unit

Some provider locations may have purpose-built or pharmaceutical-grade equipment with temperature monitoring capacity. Check with CDC on whether these units meet VFC requirements.

Also review provider location documents related to:

- Temperature monitoring

- Responses to a temperature excursion within the unit (see Module 3 – Vaccine Management for more information)

Storage and Handling Sitewide

Discuss the cost and quantity of vaccine ordered by the provider location so staff understands the overall impact of the VFC program on their facility.

Assess vaccine storage equipment and written procedures, records, and documents to confirm provider understanding and implementation of:

- Sufficient space to store all vaccine based on peak stock expectations
- Handling expired vaccine, including returning it to the CDC central distributor within six months of expiration
- Having at least one backup DDL readily available with a different calibration date
- Correct vaccine handling and preparation
- Any additional storage and handling requirements as required by the awardee and based on CDC's *Vaccine Storage and Handling Toolkit*

Site Visit Outcome Discussion and Follow-Up

Site Visit Outcome Discussion

At the conclusion of a site visit, the reviewer must discuss the outcomes with appropriate provider staff. This discussion serves the dual purposes of commending the provider for activities being performed well and highlighting site visit findings that require or recommend follow-up for the provider facility. To aid in this discussion, the reviewer must present the Provider Follow-Up Plan for review. The Provider Follow-Up Plan is a summary document that includes:

- All relevant VFC requirements and recommendations discussed
- An indication of whether requirements were met
- Follow-up actions and corresponding deadlines required of the provider for any compliance issues (if identified)

The 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.

Once outcomes have been discussed and next steps clearly outlined, the reviewer and provider must sign the Acknowledgement of Receipt, even if no compliance issues were identified. The signed document should be uploaded in PEAR before marking the visit 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.

The Provider Follow-Up Plan and Acknowledgment of Receipt are located in PEAR. Both the reviewer and the provider location must maintain copies of these signed documents for a minimum of three years.

Follow-Up

PEAR outlines the actions to perform during a site visit, as well as 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.

Awardees may add additional follow-up actions at any time in PEAR. However, awardees are required to add additional follow-up actions when the same issue has been identified during prior site visits. Awardee follow-up actions must be attached to the Provider Follow-up Plan.

Provider locations must be added 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, or
- The issue has serious consequences.

The PEAR Fraud and Abuse Module will assist with documenting details and monitoring all actions taken to prevent noncompliance should a case warrant referral to CMS.

Additional Awardee Contact

Awardees may contact VFC providers outside of the enrollment, compliance, and storage and handling site visits. These contacts include any in-person, on-site, phone, or written interaction with a provider not related to a site visit, follow-up plan, vaccine ordering, or formal educational event. Recording these contacts in PEAR is at the awardee's discretion, but 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

Awardees must annually educate providers on VFC program requirements to ensure effective program implementation continues. Education should focus on actions necessary to meet the components of the Provider Agreement and general VFC requirements.

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

- At a minimum, the vaccine coordinator and the backup vaccine coordinator at each provider facility must complete the required training.
- VFC compliance site visits with an educational component meet annual training requirements. Awardees must ensure that site visits with an educational component are scheduled with enough time to complete the site visit, and to provide education covering all components of VFC requirements in the Provider Agreement and the current VFC Operations Guide.
- Annual training may also be performed online, by webinar, or through an in-person, classroom-style presentation.
- Annual provider training must be documented in PEAR in the annual training module.

In developing and conducting educational training, awardees may:

- Use their own training materials, as long as all requirements in the Provider Agreement and the VFC Operations Guide are addressed.

- Use CDC's *You Call the Shots (YCTS)* online courses on VFC Requirements and Storage and Handling to meet training requirements.

    - The modules can produce a certificate of completion and continuing education if the user successfully completes the posttest with a score of 80% or higher via the Training and Continuing Education Online (TCEO) system.

    - If the user is unsuccessful after two attempts, they will be locked out of these *YCTS* modules in TCEO. The user will still be able to access these modules via CDC TRAIN and receive a certificate of completion to share with the awardee.

All provider location training must include relevant, state-specific requirements or information, if applicable.

Educational components of the Provider Agreement include:

Provider Responsibility to Train Staff

VFC providers are also responsible for training their staff on proper vaccine storage and handling procedures. Trainings should target:

- Staff receiving vaccine deliveries—how to open, record, and store vaccine shipments immediately
- Staff handling or administering vaccine storage and handling procedures
- Staff transporting vaccine off-site—routine and emergency vaccine management

Provider location Vaccine Management Plans should include documentation of staff training.

Provider Profile

- How to submit a Provider Profile that accurately reflects populations served
- When and how to update a Provider Profile

Patient Eligibility Screening and Documentation

- Properly screening and documenting VFC eligibility prior to administering vaccines
- Properly screening and documenting children who are state-vaccine-eligible, if applicable
- Serving underinsured children
    - If an FQHC/RHC or other deputized provider location, administers vaccine to underinsured children
    - If not an FQHC/RHC or other deputized provider location, refer to a qualified provider location

Immunization Schedule, Dosages, and Contraindications

- Accessing and utilizing current ACIP recommendations and VFC resolutions
- Having a process for informing 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 contraindications for each vaccine type available through the VFC program

Record Maintenance

- Knowing which records must be maintained
- Maintaining VFC records for a minimum of three years, or longer if required by state law (even in the case of provider retirement or provider location closure).

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 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 non-Medicaid VFC-eligible children cannot exceed the regional Medicaid fee cap.
    - Waive the administration fee and not deny access to vaccine if the VFC-eligible or state-eligible child's parent is unable to pay the administration fee.
    - Bill only Medicaid for the administration fee for VFC-eligible children enrolled in Medicaid.
    - Provider locations who choose to bill for the vaccine administration fee of a non-Medicaid VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.

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, school-located clinics, as well as FQHCs, RHCs, and deputized provider locations (see Module 1 – Patient Eligibility and Insurance Criteria).

Compliance with the National Childhood Vaccine Injury Act (NCVIA)

- Obtaining and distributing the most current vaccine information statements for all vaccines included in the National Vaccine Injury Compensation Program or purchased through federal contracts
- Following the record-keeping requirements for the NCVIA
- Reporting adverse reactions to VAERS

Vaccine Management

- Following VFC storage and handling requirements based on CDC's *Vaccine Storage and Handling Toolkit* (see Module 3 – Vaccine Management), including:
    - Ordering vaccine and maintaining appropriate inventories, including determining appropriate order quantity and rotating vaccine

- Utilizing required equipment for storing vaccine in routine and emergency situations, including never using a dorm-style refrigerator
- Continuous monitoring and recording of all storage unit temperatures on a daily basis
- 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, as well as documentation and reporting requirements
- Returning spoiled or expired public vaccine within six months to CDC's centralized vaccine distributor

Fraud and Abuse

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

Site Visits and Other Educational Opportunities

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

Termination

- Sharing situations that would terminate 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 awardee VFC programs. State fraud and abuse laws (e.g., related to insurance, consumer protection, or medical licensure) may also be applicable for portions of awardee VFC programs involving state funds. The terms "fraud" and "abuse" related to VFC are consistent with the definitions in Medicaid regulations (42 CFR § 445.2).

Fraud

An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state laws.

Abuse

Provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient), or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.

Well-organized and correctly administered VFC accountability programs are the cornerstones for preventing potential fraud and abuse incidents. Accountability measures should be emphasized through strong educational components carried out during the provider location enrollment process, as well as during any VFC site visit. Additionally, regular communication with providers can also reinforce training and further help prevent situations that may develop into fraud and abuse.

*Fraud and Abuse Examples**

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

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

Fraud and Abuse Policies and Procedures

Requirement: Awardee VFC program policies and procedures must address the 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

Awardees must identify a VFC fraud and abuse coordinator and at least two backups with authority to:

- Determine if a situation calls for educational intervention and follow-up, or if it requires immediate referral to the Medicaid Integrity Group 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

Awardees 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 involving suspected compliance issues or fraud and abuse.
- Follow up on situations involving suspected noncompliance or fraud and abuse.

Fraud and Abuse Monitoring

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

Program information that must be monitored includes:

- Provider Profile
- Ordering patterns (i.e., volume and frequency)
- Vaccine inventory and wastage
- VFC site visit findings
- Other awardee-specific accountability reports

Addressing Provider Noncompliance with VFC Requirements

Providers agree to comply with the VFC program requirements outlined in the Provider Agreement and discussed during the enrollment and subsequent site visits. Lack of adherence could lead to fraud and abuse charges for the provider. This 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:

- Any VFC provider/provider location that does not maintain the federal and/or state requirements associated with implementation of the Provider Agreement. The details of federal requirements are discussed throughout this operations guide, primarily in Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance.

Instances of suspected noncompliance or fraud and abuse may be identified by:

- VFC program staff
- Provider location staff
- A third party

CDC's VFC Compliance Site Visit Reviewer Guide serves as a proxy measure for compliance with federal requirements that providers agree to meet as program participants. 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, awardees must add additional follow-up actions. Information about noncompliance, fraud and abuse allegations, findings, and actions must be entered into the PEAR Fraud and Abuse Module (see Module 4 – Ensuring Provider Compliance).

PEAR Fraud and Abuse Module

Awardees 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. Information should include (at a minimum):

- Provider's name (Medicaid ID, if known)
- Address
- Source of allegation
- Date allegation reported to immunization program
- Description of suspected misconduct
- Specific VFC requirement(s) violated
- Descriptions and dates of the awardee's response to the allegation (education, site visit, suspension, removal of vaccines, or other action taken prior to disposition)
- Value of vaccines involved, if applicable
- Outcome of educational intervention, if applicable
- Disposition of case (closed, referred, entered into educational process) and date of disposition

Please review the PEAR User Manual for additional details about the module.

Awardee Investigation of Fraud and Abuse Allegations

Awardees must investigate accusations of fraud and abuse to determine proper disposition. This investigation is meant to help the awardee fraud and abuse coordinator determine the validity of the allegation and the proper course of action (i.e., educational intervention, corrective action, or referral).

At a minimum, fraud and abuse coordinators 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.
- Consider extenuating circumstances, severity of the allegation, and/or previous noncompliance.
- Is an educational intervention/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

Awardees 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 CMS State Directory is located on the ISD SharePoint site.) The state Medicaid agency will conduct preliminary investigations and, as warranted, 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 awardees are unable to reach a contact at the state or have questions about the fraud referral process, contact the Center for Program Integrity's (CPI) state liaison staff electronically at Medicaid Integrity Program website.

Referrals should be made within 10 working days from the assessment and determination of possible fraud and abuse, and the following information should be included:

- Contact information for VFC fraud and abuse coordinator
- Provider name, Medicaid provider ID (if known), address, and provider type (e.g., private provider)
- Source of complaint (e.g., provider location, VFC staff, anonymous caller)
- Date the awardee received information that the provider might be putting the VFC program at risk of loss due to fraud and abuse
- Specific, detailed description of suspected misconduct and actions taken by program to confirm behavior (i.e., complete description of alleged behavior [including specific Medicaid statutes and rules or VFC program requirements violated], persons involved, contact information if available, and value of vaccine involved, when available)
- All available communication between the VFC program and the provider location concerning the suspected misconduct (this includes the signed provider location enrollment forms, education given to the provider as a result of previous compliance problems, and any general provider location communication about program implementation)

The awardee should concurrently make a referral to any other state agency as mandated by state law. A copy should also be sent to the IOSB project officer.

Private Insurers

While not required as part of fraud and abuse procedures, awardees 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 and/or abuse.

Fraud and Abuse Hotline

Although not required as part of fraud and abuse procedures, awardees should consider establishing and promoting a VFC fraud and abuse hotline or other method of communication for the general public to report suspected cases.

Module 6 – Program Operations

Table of Contents

Overview

Strong awardee program operations are essential to the success of the VFC program. Awardees are tasked with ensuring VFC requirements are adhered to within the awardee's program and among VFC providers within their jurisdictions. Establishment, implementation, and monitoring of operational policies and procedures, along with following CDC requirements and guidance, are necessary to ensure awardee and provider actions are in compliance with all aspects of the VFC program.

Awardees must have written policies and procedures to govern the VFC program. These policies and procedures should be specific and provide enough detail so that new hires can easily follow protocols with minimal supervision or clarification.

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

Operational policies and procedures are required in the areas of:

- Program operations
- Provider recruitment
- Provider location enrollment
- Provider compliance
- Vaccine management

Requirement: All VFC program documentation must be maintained for a minimum of three years, or longer if required by state law.

Record Retention

Awardees must retain all VFC program documentation for a minimum of three years, including provider- and awardee-level documents. Digital or electronic storage of records is allowable. Documentation should be stored and maintained in a location and manner such that multiple staff can access the information and provide it to CDC upon request, even if the awardee staff leaves the program.

Program Operations

Requirement: Awardees must establish and implement policies and procedures for effective program operations, including staffing, staff training, program monitoring, and fraud and abuse.

Awardee Staff

Awardees must designate sufficient staff, including a VFC coordinator, to oversee and implement the VFC program. Awardees must notify their IOSB project officer and VFC@cdc.gov any time there is a change in the individual filling this role, including staff who may be in the role temporarily. Awardees must confirm staff is knowledgeable about vaccine ordering, inventory, and storage and handling, as well as VFC program components.

Staff Training

Awardees are required to provide annual training for staff involved with implementation and management of the VFC program. Training in VFC program policies and procedures is an essential component of quality assurance.

Awardees must also have a process in place to circulate to all VFC staff updated versions of the VFC Program Operations Guide and training materials, as well as VFC information and programmatic updates. Information about changes or revisions impacting the VFC program should be clearly and promptly communicated to staff, including how the changes have been incorporated into the awardee program.

Site Visit Reviewer Training

Awardees must offer annual training specifically developed for reviewers.

Training must cover:

- All VFC program requirements, including eligibility screening and documentation
- Purpose of VFC site visits
- Sampling methodology used for chart selection during VFC compliance site visits
- Proper vaccine storage and handling as outlined in CDC's *Vaccine Storage and Handling Toolkit*
- Correctly administering the VFC Site Visit Reviewer Guides through PEAR
- Rationale behind the VFC Site Visit Reviewer Guide questions
- Documentation required after completing a site visit
- Required follow-up with the provider location after a site visit
- Conducting the VFC provider location educational component of a site visit
- Basic site visit competencies, including skills required to effectively prepare and report feedback from and findings of a site visit

Training materials and resources related to performing site visits and background information on the rationale behind site visit questions can be found on the PEAR system help page.

As part of training, it is recommended that VFC coordinators (or designees) must observe a compliance site visit with each reviewer on an annual basis. This provides an opportunity to assess how the reviewer conducts site visits and the reviewer's level of understanding of the program. Beginning in July 2024, this annual observation will be a requirement. Based on findings, the VFC coordinator can provide additional training opportunities, if needed. Each observation should be documented in the reviewer's training file. A sample VFC Reviewer Supervisory Visit Observation Tool is located on the ISD Awardees SharePoint Portal.

Skills for Successful Site Visits

Interpersonal skills and behaviors should be emphasized 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 and any follow-up actions needed. 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 provider 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 non-Medicaid VFC-eligible patients?*
    - Don't ask: *Do you charge more than X dollars for the vaccine administration fee for non- Medicaid VFC-eligible patients?*
- Offer constructive criticism – Effectively share and address negative findings, making sure to be nonjudgmental. Share strengths of the practice and how these might be used to correct noncompliant behavior.

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

Information about vaccine management requirements and provider location site visits and training can be found 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 designee) accompany them on at least one VFC site visit before conducting independent site visits. The VFC coordinator should provide guidance and suggestions for improvement.

Operational Policies and Procedures

Fraud and Abuse

Awardees are required to implement a comprehensive, written VFC fraud and abuse policy. The policy must address, at a minimum, the components outlined in Module 5 – Fraud and Abuse, including:

- Oversight personnel
- Personnel training
- Fraud and abuse monitoring
- Referral and reporting
- Entering allegations in the PEAR Fraud and Abuse Module

The policy should be reviewed annually to verify it is current with VFC requirements, CDC guidance, and federal and state laws.

Provider Recruitment

Requirement: Awardees must establish and implement policies and procedures related to provider recruitment.

Protocols must be established for:

- Assessing vaccination access gaps for VFC-eligible children in their jurisdictions
- Performing targeted provider recruitment and enrollment to improve access to vaccination for VFC-eligible children

Awardees are responsible for provider recruitment in their jurisdictions based on assessments of need.

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

Provider Location Enrollment

Requirement: Awardees must establish and implement policies and procedures for all aspects of the provider location enrollment process.

Protocols must be established for:

- Verifying provider location eligibility to participate in the program
- Conducting an enrollment site visit, including completion of the Provider Agreement and Provider Profile
- Entering enrollment site visit data into PEAR

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

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

Deputization (FQHCs and RHCs)

Requirement: Awardees must confirm CDC-approved, deputized providers 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 VFC-eligible children can receive VFC vaccine only from an FQHC or RHC. Some VFC provider locations may be deputized by an FQHC or RHC to allow them to administer vaccines to this population. The deputization designation applies almost exclusively to public health clinics.

As part of the 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 receiving primary care from another provider.
- Apply the definition of "underinsured" as described in Module 1 – Patient Eligibility and Insurance Criteria.
- Collect and report underinsured usage data using an acceptable method identified in the CDC VFC Deputization Guidance and MOU Template.

Beginning in 2023, awardees with deputized provider locations in their jurisdictions will be requested to submit a VFC Deputization Agreement Form and accompanying List of Deputized Provider Locations every 24 months so that CDC can maintain an accurate listing of deputized VFC provider locations.

Provider Annual Review

Provider locations must go through annual review to remain in the program. Awardees must have policies and procedures governing the annual review of providers every 12 months. These policies and procedures must address how the awardee will:

- Collect and validate Provider Profile data.
- Verify provider locations meet the awardee-defined annual training requirement.

Provider Biannual Recertification

Provider locations must be recertified every 24 months to remain in the program. Awardees must have policies and procedures governing the recertification of providers every 24 months. These policies and procedures must address how the awardee will:

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

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

Provider Compliance

Requirement: Awardees must establish and implement policies and procedures to validate provider compliance with:

- **Screening and documenting VFC eligibility at each vaccination encounter**
- **Administering VFC-funded vaccine only to children who are eligible for the program**
- **Screening patients for, documenting, and administering state vaccine, if applicable**
- **Complying with the immunization schedule, dosages, and contraindications recommended by ACIP**
- **Making available all appropriate vaccines for the population served**
- **Following vaccine billing and administration fee requirements**
- **Complying with the National Childhood Vaccine Injury Compensation Act**
- **Complying with VFC vaccine management requirements**
- **Maintaining all records for a minimum of three years, or longer if required by the state**

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

Compliance Site Visits

Policies and procedures for VFC compliance site visits must, at a minimum, address:

- How provider locations are identified and selected to receive a VFC compliance site visit
- Site visit scheduling requirements
- Site visit preparation requirements
- Administering sections 1–6 of the CDC VFC Compliance Site Visit Reviewer Guide, exactly as written, noting neither this guide nor any of the information contained in it should be shared with provider location staff
- Evaluating a provider location's vaccine management practices and implementation of VFC program

- 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, including same-day data entry, if possible
- Following CDC-defined, on-site actions and implementing future follow-up actions, including adding and adhering to awardee-defined actions for provider locations with the same or similar compliance issues during the past two site visits
- VFC coordinator and/or program manager review of provider locations visited and summary data

CDC requires that provider locations receive a compliance site visit every 24 months. This is a minimum-level requirement. Awardees who wish to conduct compliance site visits more frequently are encouraged to do so.

CDC strongly encourages awardees to conduct VFC-compliance-related site visits separately from immunization quality improvement visits. This allows for adequate time and focus on VFC program requirements or process improvement.

All completed VFC compliance site visits must be reviewed by the VFC coordinator, immunization program manager, or a designee. Each review must be documented in PEAR using the site visit sign-off functionality by the VFC coordinator, immunization program manager, or their designee.

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

Awardees must provide site visit reviewers with:

- The most current CDC VFC Program Operations Guide
- Access to the PEAR system
- Access to the internet and a laptop for site visits
- DDLs with continuous monitoring capability, a buffered probe, and a current and valid Certificate of Calibration to check temperatures of storage units when applicable

Rather than using the site visit reviewer's DDL, CDC recommends the reviewer assess and record the provider location's storage unit min/max temperatures using the provider's DDL **if** it has a current and valid Certificate of Calibration Testing **and** the thermometer/probe is properly placed in the storage unit.

Provider Updates

Awardees are required to promptly notify providers when changes or updates are made to VFC program requirements, ACIP recommendations, or storage and handling best practices and recommendations.

Storage and Handling Site Visits

Policies and procedures for storage and handling site visits must address how to:

- Schedule routine storage and handling site visits.
- Prepare for storage and handling site visits.

- Conduct storage and handling site visits using PEAR.
- Document, review, and report results of storage and handling site visits.

Policies and procedures for storage and handling site visits must, at a minimum, address:

- How to identify and select provider locations that should receive an unannounced storage and handling site visit based on:
    - Provider location history with storage and handling compliance issues
    - Time since the last site visit
    - Geographic distance from provider locations that will receive a VFC compliance site visit during the year
- Routine storage and handling site visit scheduling requirements
- Site visit preparation requirements
- Administering the CDC Storage and Handling Site Visit Reviewer Guide, exactly as written
- Evaluating a provider location's vaccine storage and handling practices outlined in Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance
- Providing formal education and training on VFC requirements related to storage and handling as outlined in Module 4 – Ensuring Provider Compliance
- Documenting, reviewing, and reporting on-site visit findings and results in PEAR, including same-day data entry, if possible
- Following CDC-defined on-site actions and implementing future follow-up actions, including adding and adhering to awardee-defined actions for provider locations with the same or similar compliance issues during the past two site visits

Awardees are encouraged to conduct as many storage and handling site visits as needed; 5% of provider locations must receive unannounced storage and handling site visits during each budget period.

Provider Location Training

Awardee policies and procedures must address annual training of VFC provider location staff on all VFC requirements based on the Provider Agreement and current VFC Program Operations Guide.

Training components are outlined in Module 4 – Ensuring Provider Compliance.

Awardees should annually review storage and handling practices contained in CDC's *Vaccine Storage and Handling Toolkit* and the VFC Program Operations Guide to verify training information is correct.

Vaccine Management Policies and Procedures

Requirement: Awardee vaccine management and storage and handling policies and procedures must include standards necessary to prevent vaccine waste and ensure appropriate public vaccine stock from each funding category is available.

Areas to address include:

- Storage and handling
- Vaccine ordering
- Vaccine loss and returns
- Vaccine restitution
- Vaccine borrowing
- Vaccine transfer

If applicable, awardees 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

To assist providers with proper vaccine management, awardees are also required to develop a Vaccine Management Plan template for use by VFC provider locations. The template must address the components of the plan found in Module 3 – Vaccine Management.

Storage and Handling

Awardees must establish policies regarding DDL calibration testing timelines.

Temperature monitoring devices experience drift over time that affects accuracy. The frequency of calibration testing varies by manufacturer, make, and model, but calibration testing every two to three years is standard. Therefore, CDC recommends calibration testing be done every two to three years from the date the certificate was issued.

CDC also recognizes ice melting point testing may be performed to meet the standard for calibration testing, though significant oversight by the awardee is required to implement such testing. Awardees interested in using this method must contact their IOSB project officer to learn more about the process and oversight requirements.

If calibration testing indicates a DDL is no longer accurate within +/-.5°C (+/-1°F), it must be replaced; adjustment of such a DDL is not recommended.

Awardee-purchased devices must be tested every two to three years.

Vaccine Ordering

Awardees must implement policies and procedures that include timely review and approval of VFC provider location vaccine orders.

Before distributing vaccines, awardees must have policies and procedures for evaluating the appropriateness of orders. This includes a comparison of the ordering information and Provider Profile data to:

- Monitor for any issues with the provider location's inventory management that could cause:
    - Stockpiling or over-ordering, which can put vaccines at risk for waste or can indicate fraud or abuse
    - Under-ordering, which can result in vaccines not being available for eligible children

- Verify 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) the provider location serves.

See Module 3 – Vaccine Management for more information.

Stocking Non-Routine Vaccines

Non-routine vaccines include but are not limited to RSV maternal vaccine, pneumococcal polysaccharide (PPSV23) vaccine and meningococcal serogroup B (MenB) vaccine.

Stocking non-routine, VFC-covered vaccines at all times may not be a viable option for a provider facility. Therefore, awardee policies and procedures should address alternative options, including:

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

If limited amounts of non-routine vaccines are not routinely a part of the provider location's inventory, the procedure for making these vaccines available to patients must be covered in the provider location's Vaccine Management Plan.

Policies and procedures for provider location vaccine ordering and monitoring must include a requirement that provider locations submit vaccine inventory amounts with each order. This provides an opportunity for awardees to verify the provider location is not inadvertently stockpiling or building up excessive inventory, which could put VFC vaccine at risk.

Awardee Restitution

Awardees are required to develop and implement policies and procedures to ensure that approved provider vaccine orders contain appropriate quantities for the provider site relative to the eligible patient population(s) represented in the Provider Profile. Failure to comply may result in VFC vaccines administered to ineligible children. If this occurs, awardees may be required to purchase replacement VFC vaccine doses. Similar to provider restitution, **dose for dose replacement is required**. Awardee restitution also requires awardees to track and monitor replacement vaccine doses from bulk-order purchase through the shipment from the centralized distributor to providers to VFC-eligible patient administration. Additional details pertaining to awardee restitution are situational. These will be discussed directly with an awardee should the need arise.

Vaccine Purchase Policy

Vaccine purchase policy, also known as "vaccine supply policy," determines which vaccines an awardee will purchase, which funding source(s) will be used, and which populations will be eligible to receive the vaccines.

Types of vaccine purchase policies include:

Universal

Through a combination of VFC, 317, and state funding, the immunization program supplies all ACIP-recommended pediatric vaccines to public and private VFC-enrolled provider locations to vaccinate all children in the awardee's jurisdiction.

Universal Select

Through a combination of VFC, 317, and state funding, the immunization program supplies all but a few ACIP-recommended pediatric vaccines to public and private VFC-enrolled provider locations to vaccinate all children in the awardee's jurisdiction.

VFC and Underinsured

Through a combination of VFC, 317, and state funds (if applicable), the immunization program supplies all ACIP-recommended pediatric vaccines to public and private VFC-enrolled provider locations to vaccinate only VFC and underinsured children.

VFC and Underinsured Select

Through a combination of VFC, 317, and state funds (if applicable), the immunization program 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 immunization program limits the supply of certain vaccines to only VFC-eligible children in both public and private settings.

VFC-Only Supply

Through the use of VFC funds, the immunization program supplies all routinely recommended pediatric vaccines to private VFC-enrolled provider locations to vaccinate only VFC-eligible children.

Private provider locations do not receive 317- or state-funded vaccine for underinsured children. However, the underinsured may be served via VFC, 317, and/or state/local funds in public clinics.

VFC-Only AND Universal Hepatitis B Birth Dose

Private provider locations do not receive 317- or state-funded vaccine for non-VFC-eligible children. Non-VFC-eligible children may be served using 317 and/or state funds in public clinics.

In some cases, VFC-only states may provide 317- or state-funded hepatitis B vaccine to public and/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, while 317 or state-purchased vaccine is used for 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

Awardees must monitor provider compliance with vaccine loss policies as outlined in Module 3 – Vaccine Management, including dose-for-dose replacement and timely return of wasted vaccine.

requirements outlined in Module 3 – Vaccine Management and Module 4 – Ensuring Provider Compliance
Vaccine loss policies should include using VTrckS to:

- Enter all spoiled and expired vaccine returns, as well as correct any discrepancies between returns entered and vaccines shipped to the centralized distributor.
- Collect, monitor, and report information to CDC on the total number of publicly purchased vaccine doses ordered by vaccine type.
- Collect, monitor, and report to CDC the number of publicly purchased (VFC, 317, and state) doses by vaccine type that expired, were spoiled, or were otherwise wasted due to improper vaccine storage and handling by VFC providers.

Additional information on the return process in VTrckS can be found in the Centralized Vaccine Distribution Guide on the ISD Awardees SharePoint Portal.

Vaccine loss policies 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 storage and handling incident category.
- Identifying the aggregate number of vaccines wasted for reasons other than storage and handling incidents, based on VTrckS category, such as broken vials or vaccines that were drawn into a syringe but not used.

Restitution Policy

Awardee restitution policies must state that providers are to replace vaccine on a dose-for-dose basis. This allows the restoration of doses to the VFC-entitled children for whom they are intended. Deviation from this method (e.g., purchasing equipment) may be considered if there are extenuating circumstances for an individual provider location. Awardees must submit written justification to VFC@cdc.gov and receive CDC approval prior to allowing restitution using any method other than dose-for-dose replacement. Financial payment as a form of restitution is not allowed under any circumstances.

Awardees with a restitution policy must monitor the use of replacement doses in a provider's facility to verify these doses are used only for eligible children and allocated proportionally to the original funding source (VFC, 317, or state). This can be done through:

- Development and use of a paper or electronic form to be used by provider locations—the form should track private replacement doses purchased through final administration to an eligible child (a sample VFC/317 Vaccine Restitution Report is located on the ISD Awardees SharePoint Portal).
- An alternative process proposed by the awardee—this requires CDC review and should be submitted to the IOSB project officer.

Additional restitution information may be found in Module 3 – Vaccine Management.

Vaccine Borrowing

Awardees can establish policies and procedures to approve vaccine borrowing under certain conditions. The circumstances and conditions for borrowing must be defined. Awardees may use the CDC vaccine borrowing report template or develop their own. The report should, at a minimum, contain the following information:

- Vaccine type borrowed
- Stock type used (VFC or private)
- Patient name
- Patient date of birth
- Date the borrowed dose was administered
- Reason appropriate stock type was not used
- Date the vaccine was replaced

Awardees must monitor and verify vaccine borrowing replacement using invoices or other appropriate means. Awardees 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 be transferred between provider locations only with approval from the awardee. Awardee policies and procedures must address the process for coordinating and documenting transfers. Transfer information must be entered into VTrckS by the awardee. During transport, vaccines must be handled in adherence to requirements in Module 3 – Vaccine Management.

See Module 3 - Vaccine Management for more information.

Vaccine Ordering Replacement Model

Implementing a vaccine ordering replacement model policy requires prior CDC approval. Awardee proposals must meet the criteria outlined in Module 3 – Vaccine Management.

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

VFC providers conducting VFC providers conducting temporary, mobile, off-site, or satellite clinics and community vaccinators must adhere to all general VFC program requirements. It is particularly important that they appropriately screen patients and document VFC eligibility. These alternative provider locations must also meet enhanced storage and handling requirements, which results in additional oversight responsibilities for the awardee, including:

- Adhering to current CDC Depot policy as described in the Immunization Program Operations Manual (IPOM) found on the ISD Awardee SharePoint site.
- Requesting, reviewing, and approving temporary, mobile, off-site, satellite and community vaccination procedures, including vaccine transport and vaccine temperature monitoring
- Maintaining a current list of clinic dates and locations, as well as vaccine amounts by fund type being transported for each clinic

Awardees must also work with community vaccinators to validate that the Provider Profile correctly reflects VFC vaccine need and takes into account 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 temporary, mobile, off-site, satellite and community vaccination clinic requirements and recommendations.

VFC Management Systems and Resources

CDC provides a variety of systems, tools, and resources for VFC data collection and evaluation. Links to these can be found in the VFC Resources section and throughout this guide, in the IPOM, and on the ISD Awardees SharePoint Portal.

CDC recommends using the following tools to help collect data and assess program performance:

- PEAR
- VFC provider satisfaction surveys
- CDC evaluation resources

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

Examples of Data Analysis Questions

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

PEAR Data

The VFC coordinator and other awardee staff may use the PEAR dashboards and reports to monitor provider location and program-level issues and trends.

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

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

Awardees should also review planned and required follow-up actions in PEAR that are overdue or not implemented. This information can indicate a lack of follow-up by staff, lack of structure for implementation of follow-up actions at the awardee level, and/or underreporting of follow-up actions by staff.

Helpful PEAR Reports/Dashboards for Program Monitoring

- Program Overview Dashboard
- Top 10 Non-Compliance Issues Report
- Storage and Handling/Certificate of Calibration
- VFC and Vaccine Accountability Metrics (VVAM) Interim Progress Report
- Follow up Action Details Report
- Question Summary Report
- Consult the document "Quick Tips: PEAR Reports for Awardees" for additional information on all PEAR reports available for awardee use.

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

Provider Satisfaction Surveys

VFC providers can be excellent sources for assessing what aspects of the VFC program are working or not working as planned. One way to collect provider opinions and feedback is through a provider satisfaction survey on VFC operational components and educational needs. These surveys can help determine what awardee quality improvement projects should be undertaken.

Before conducting any survey, awardees need to determine:
- Purpose of the survey
- Which provider locations to include
- What questions to ask
- How the survey will be conducted
- How results will be analyzed

A sample provider satisfaction survey can be found on the ISD Awardees SharePoint Portal.

Beginning July 1, 2024, awardees will be required to conduct an annual VFC provider satisfaction survey using a CDC-developed survey.

Evaluation Resources

Various CDC resources on program evaluation are available to awardees. The CDC Program Performance and Evaluation Office has a website on program evaluation.

Specific resources include:
- CDC Evaluation Framework
- CDC Evaluation Self-Study Guide
- Evaluation Resources

Awardees that need assistance or detailed information should contact their IOSB project officer. The project officer can identify specific individuals available to assist in developing, implementing, or interpreting evaluation measures for the VFC program.

Addendum: Special Considerations for COVID-19 Vaccine

This addendum to the 2023-2024 VFC Operations Guide provides supplemental information and guidance related to the addition of COVID-19 vaccine to the VFC formulary.

Inventory

- VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for COVID-19 vaccine. During this time awardees will not require VFC providers to meet the private inventory minimum requirements for COVID-19 vaccine if they do not intend to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than March 31, 2024.
    - This includes VFC providers who serve only Medicaid-eligible patients and no privately insured children; they are not required to privately purchase COVID-19 vaccine.
- If VFC providers utilize this flexibility to not maintain private stock during this season, providers should share information with their privately insured patients about other ways to access COVID-19 vaccine in their areas, including through local pharmacies and health departments.
- In locations where providers report that demand for COVID-19 vaccine is low, awardees should allow providers to order the minimum packaging size of VFC COVID-19 vaccines, as feasible.
    - In these cases, site visit reviewers may observe that COVID-19 inventory is a much lower quantity than other ACIP-recommended vaccines.
    - Based on information that CDC has received from all three COVID-19 vaccine manufacturers, presentations for most of the new fall vaccines will be more typical (i.e., unit dose presentations rather than multidose vials), which will significantly reduce vaccine minimum order quantities.
- At the discretion of the awardee, certain specialty VFC providers, temporary/off-site vaccination clinics, and pharmacies may offer a limited formulary of vaccines, such as COVID-19 and influenza vaccines only.

Eligibility Criteria

- A child's eligibility criteria for VFC COVID-19 vaccine are the same as for other VFC vaccines.
    - After COVID-19 vaccine becomes available for commercial ordering, there may be a window of time before a child's particular insurance has coverage for it in place. During this period, the child meets the definition of "underinsured" for COVID-19 vaccine and is eligible for VFC COVID-19 vaccine in an FQHC/RHC or other provider with delegated authority to vaccinate underinsured children.

Borrowing

- For VFC providers who maintain private stock of COVID-19 vaccine and vaccinate privately insured children, bidirectional borrowing of COVID-19 vaccine will be allowed for the 2023-2024 respiratory virus season as described below.
- CDC's borrowing guidance does not supersede jurisdictional policy related to borrowing. VFC providers should refer to awardee or jurisdictional policy to determine if borrowing is allowed in their jurisdiction.
- Borrowing is only applicable if the provider is purchasing private stock and is approved only for in-

stances when:

- There is a lack of vaccine stock because of delayed or spoiled shipments.
- As part of the initial set up of private purchasing contracts and ordering systems, there has been a delay for the provider in being able to procure private stock of COVID-19 vaccine.
- Vaccine will expire soon and will be lost if not used. Provider locations with a small privately insured patient population can use this option to administer short-dated, privately purchased vaccine to a VFC-eligible child and replace it with a longer-dated, VFC dose.
- New staff calculated ordering intervals incorrectly, leading to a lack of sufficient private or public vaccine stock.

- Borrowed COVID-19 vaccine must be repaid (dose for dose) within one month and administered to the appropriate population.
  - If VFC vaccine is borrowed for a privately insured patient and then repaid to VFC inventory, the repaid dose must be administered to the appropriate category of VFC-eligible child. Note: Given the variability of COVID-19 vaccine types per age group, the same vaccine type borrowed must be repaid.

Vaccine Borrowing Documentation

- A Vaccine Borrowing Report must be completed when either:
  - Privately purchased vaccine is administered to a VFC-eligible child, or
  - VFC vaccine is administered to a privately insured child.
- Awardees may report the information using CDC's template or by developing their own as long as it contains all the components of the CDC template. The template can be found on the ISD Awardees SharePoint portal. See Module 6 - Program Operations for additional information.

Restitution

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

Site Visits

- Awardees are required to conduct all VFC site visits (i.e., compliance, enrollment, and unannounced storage and handling) in person unless local conditions indicate medium or high COVID-19 hospitalization rates.
  - If the provider location is in an area experiencing medium or high hospitalization rates, awardees may choose to conduct hybrid or virtual site visits. Please consult the CDC COVID Data Tracker for hospitalization rates in your jurisdiction. Awardees must review this tracker prior to scheduling the site visit to determine the most appropriate visit method (i.e., in-person, hybrid, or virtual), and continue to monitor the tracker and adjust the visit method as needed up until the date of the visit. Awardees will be required to acknowledge medium or high hospitalization rates in PEAR before a visit can be started.
- Awardees will be allowed to conduct virtual enrollment visits for specialty VFC providers, including drive thru clinics and birthing facilities due to their limited formulary of VFC vaccines.
- Virtual enrollment site visits must be approved via email by CDC VFC staff. Minimally, awardees must

review the following at the virtual enrollment visit:

- Provider Agreement
- Provider Profile
- Vaccine Management Plan
- Training documentation (if not done by program)
- Electronic storage and handling documentation
  - Pictures of storage units
  - Pictures of DDL probe placement
  - Certificates of calibration
  - Pictures of "Do Not Disconnect" Signage Placement

NOTE: All awardees will be required to resume conducting enrollment visits in-person if CDC designates.

Awardee Safety Guidance for VFC In Person Site Visits

Please refer to the following links below for more information on protecting yourself while conducting in-person VFC site visits during the COVID-19 pandemic.

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-covid-spreads.html
https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
https://covid.cdc.gov/covid-data-tracker/#datatracker-home

Addendum: Special Considerations for Nirsevimab

Nirsevimab is an FDA-licensed monoclonal antibody that provides passive immunity against RSV-associated infection. On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) voted to recommend nirsevimab as an immunization for all infants aged <8 months, as well as some children up to age 20 months (see ACIP recommendations), and a VFC resolution was passed to include nirsevimab in the VFC program. This addendum provides supplemental information and guidance related to the addition of the nirsevimab immunization to the VFC formulary.

Inventory

- VFC providers will be allowed a fexible, time-limited ramp-up period to meet the private inventory requirement for nirsevimab. During this time, awardees will not require VFC providers to meet the private inventory minimum requirements for nirsevimab if they do not intend to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than August 1, 2024.
    - This includes VFC providers who serve only Medicaid eligible patients and no privately insured children; they are not required to privately purchase nirsevimab.
- If VFC providers utilize this fexibility to not maintain private stock during this season, providers should explore if other in-network options exist for their nirsevimab-insured private patients to access nirsevimab (i.e., from another local in-network practice or system that does have private inventory of nirsevimab, or FQHC, RHC, or deputized VFC provider authorized to immunize underinsured children).
    - CDC recognizes that with current supply and demand issues, this may not be possible, but if supply changes, we encourage providers to assist their private patients in identifying access routes.
- In locations where providers report that demand for nirsevimab is low, awardees are to allow providers to order the minimum packaging of VFC nirsevimab that is feasible. In these cases, site visit reviewers will observe that nirsevimab inventory is a much lower quantity than other ACIP-recommended vaccines.
- At the discretion of the awardee, certain specialty VFC providers, including birthing facilities (e.g., birthing hospitals or centers), may offer a limited formulary of VFC vaccines, based on the populations served in their facility. VFC-enrolled birthing facilities offering nirsevimab must offer hepatitis B vaccine at birth as well (and vice versa).

Eligibility Criteria

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

Borrowing

- For those VFC providers who maintain private stock of nirsevimab and vaccinating privately insured children, bidirectional borrowing of nirsevimab will be allowed for the 2023-2024 respiratory virus season as described below.
- CDC's borrowing guidance does not supersede jurisdictional policy related to borrowing. VFC providers should refer to awardee or jurisdictional policy to determine if borrowing is allowed in their jurisdic-

tional.

- Borrowing is only applicable if the provider is purchasing private stock and is approved only for instances when:
    - There is a lack of vaccine stock because of delayed or spoiled shipments.
    - As part of the initial set up of private purchasing contracts and ordering systems, there has been a delay for the provider in being able to procure private stock of nirsevimab.
    - Vaccine will expire soon and will be lost if not used. Provider locations with a small privately insured patient population can use this option to administer short-dated, privately purchased vaccine to a VFC eligible child and replace it with a longer-dated, VFC dose.
    - New staff calculated ordering intervals incorrectly, leading to a lack of sufficient private or public vaccine stock.
- Borrowed nirsevimab must be repaid (dose for dose) **within one month** or after every 5 doses borrowed (after use of 5 doses for small practices, at the discretion of the awardee) and administered to the appropriate population (i.e., if federally VFC purchased VFC vaccine is borrowed for a privately insured patient and then repaid to VFC inventory, the repaid dose must be administered to a federally vaccine-eligible VFC child).
- Awardees must receive proof of privately purchased doses that includes the number of doses, lot numbers, and documentation that authenticates doses returned or doses repaid were administered to the appropriate recipients.

Vaccine Borrowing Documentation

- A Vaccine Borrowing Report must be completed when either:
    - Privately purchased vaccine is administered to a VFC-eligible child, or
    - VFC vaccine is administered to a privately insured child.
- Awardees may report the information using CDC's template or by developing their own as long as it contains all the components of the CDC template. The template can be found on the ISD Awardees SharePoint portal. See Module 6 - Program Operations for additional information.

Replacement

- Awardees with replacement models must be extremely cautious in applying these models for nirsevimab, based on the cost of this product and the potential for fraud.

Virtual Enrollment

- Awardees will be allowed to conduct virtual enrollment visits for specialty VFC providers, including birthing facilities.
- Virtual enrollment site visits must be approved via email by CDC VFC staff. Minimally, awardees must review the following at the virtual enrollment visit:
    - Provider Agreement
    - Provider Profile
    - Vaccine Management Plan
    - Training documentation (if not done by program)
    - Electronic storage and handling documentation
        - » Pictures of storage units

» Pictures of DDL probe placement
» Certificates of calibration
» Pictures of “Do Not Disconnect” Signage Placement

NOTE: All awardees will be required to resume conducting enrollment visits in-person if CDC designates.

Glossary

Abuse (related to Fraud)

Provider/provider location practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program (also includes actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient), or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. Also includes program recipient practices that result in unnecessary cost to the Medicaid program.

Advisory Committee on Immunization Practices (ACIP)

Consists of 15 medical and public health experts selected by the Department of Health and Human Services secretary to provide advice and guidance to the secretary, assistant secretary for health, and CDC on the control of vaccine-preventable diseases. The committee develops recommendations for the routine administration of vaccines to children and adults in the civilian population, including guidance on age for vaccine administration, number of doses and dosing intervals, and precautions and contraindications. ***See VFC-ACIP resolutions***.

Affordable Care Act

The comprehensive health care reform law enacted in March 2010 (sometimes known as ACA, PPACA, or "Obamacare").

The law has three primary goals:

1. Make affordable health insurance available to more people. The law provides consumers with subsidies ("premium tax credits") that lower costs for households with incomes between 100% and 400% of the federal poverty level.
2. Expand the Medicaid program to cover all adults with income below 138% of the federal poverty level. (Not all states have expanded their Medicaid programs.)
3. Support innovative medical care delivery methods designed to lower the costs of health care generally.

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. These sites have only been approved for the following awardees: Alaska, American Samoa, Guam, and the 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 (usually public health department clinics), who 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 Department of Health and Human Services (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 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 collectively "share" the cost of their members' medical care.

Insurance

A plan that is:

- Regulated by a state's insurance commissioner and/or
- Subject to the Employee Retirement Income Security Act of 1974 (ERISA), a federal law that sets minimum standards for most voluntarily established pension and health plans in private industry to provide 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, and default on Health Education Assistance Loans. This list is maintained by the OIG of DHHS. 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

Awardees are required to recertify currently enrolled VFC provider locations a minimum of every 24 months. To recertify a VFC provider location, awardees must:

- Verify provider eligibility (licensure in the jurisdiction).
- Collect a signed Provider Agreement and ensure 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 and distinct concepts and are not interchangeable terms.

Provider Review

Awardees are required to review key information for currently enrolled provider locations at a minimum of every 12 months. To review a VFC provider location, awardees must:

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

Reenroll

Previously enrolled provider locations who left the VFC program and are returning must be reenrolled by awardees. Awardees are required to 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 and distinct concepts and are not interchangeable terms.

Ship (Shipping)

Shipping, as compared with transport, typically involves longer distances and more time to move vaccine between locations. Often refers to the process of moving vaccine using a large shipping service, requiring adherence to shipping standards that go beyond CDC guidance for vaccine transport. CDC recommends that awardees NOT ship vaccines because of the potential risks to the cold chain and, ultimately, the viability of the vaccine.

Specialty Provider

A provider that only serves (1) a defined population due to the practice specialty (e.g., OB/GYN, STD, family planning, etc.) or (2) a specific age group within the general population of children ages 0–18. Local health departments and pediatricians are not considered specialty providers. The Immunization Program has the authority to designate VFC providers as specialty providers. At the discretion of the Immunization Program, certain enrolled providers such as pharmacies or community vaccinators may offer a limited selection of vaccines.

Transport (Transporting)

Transport involves the movement of vaccine over a short time and distance between provider locations. Transport is typically done by awardee staff or providers using private vehicles or courier services, over the course of less than eight hours. CDC expects vaccines to be transported only rarely.

Vaccine Funding Source

One of three types of funding awardees use to purchase vaccines:

- VFC funds: Federal entitlement funds used to purchase vaccines for administration to VFC- eligible children
- Section 317 funds: Federal funds provided through an annual appropriation that support 64 state and local awardee immunization programs. Federal 317 funds also support the purchase of vaccines for certain eligible populations.
- 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 a VFC-enrolled provider location can charge a non-Medicaid VFC-eligible child for each vaccine administered (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. The Centers f or Medicare and Medicaid Services (CMS) set and adjust these maximum regional charges.

VFC-ACIP Resolutions

The Advisory Committee on Immunization Practices (ACIP) has unique legal authority from Congress to provide recommendations for the VFC program. When recommending a new vaccine or a change in vaccine use, ACIP votes on a resolution to include the vaccine change in the VFC program. VFC resolutions passed by ACIP form the basis for VFC program policies on vaccine availability and use.

Vaccines procured through the VFC program must be administered according to the guidelines outlined by ACIP in VFC resolutions. (VFC vaccines may also be administered in accordance with state school attendance laws.)

CDC establishes contracts for VFC vaccines only after a VFC resolution is in place.

VFC Program Eligibility Categories

- **VFC-eligible child**
  A child who is 18 years of age or younger and meets one or more of the following criteria:
  - American Indian (AI) or Alaska Native (AN)
  - Medicaid-eligible/enrolled
  - Uninsured
  - Underinsured (has health insurance, but the coverage does not include any ACIP-recommended vaccines or includes only selected ACIP-recommended vaccines)
- **Uninsured**
  A child who has no health insurance coverage.
- **Underinsured**
  A child who has health insurance, but whose coverage does not include any ACIP-recommended

vaccines or only includes selected ACIP-recommended vaccines. An underinsured child is VFC-eligible only for the vaccines that are not covered.

Underinsured children are eligible to receive VFC vaccine only through a federally qualified health center (FQHC), a rural health clinic (RHC), or under an approved deputization agreement.

- **Fully insured (not eligible)**

  A child with insurance that covers the cost of vaccine, even if the insurance plan has a high deductible or copay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met. 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	✚ – ISD Awardees SharePoint Portal	
■ – Other website	◆ – PEAR	■ - CDC's Pink Book

Document/System	Location	Awardee Use	Provider Use
VFC PROGRAM OVERVIEW			
July 1, 2023 - June 30, 2024 VFC Operations Guide	✚	X	
VFC Statute 42 U.S.C. and CMS Policy Letters	✚	X	
Maximum Vaccine Administration Fees for Non-Medicaid Eligible Children	✚	X	
Center for Program Integrity (CPI) State Directory – (5/1/18)	✚	X	
What's New (for PEAR system updates	◆	X	
MODULE 1 – PATIENT ELIGIBILITY AND INSURANCE CRITERIA			
Indian Health Care Improvement Act https://www.ssa.gov/OP_Home/comp2/F094-437.html	■	X	
VFC FAQs†	✚	X	
MODULE 2 – RECRUITING AND ENROLLING PROVIDERS			
Awardee Provider Agreement Application	✚	X	X
Enrollment Forms Overview (1/15/2020)	✚	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 http://oig.hhs.gov/exclusions/exclusions list.asp	■	X	
You Call the Shots Online Training Courses https://www.cdc.gov/vaccines/ed/youcalltheshots/htm	●	X	X
MODULE 3 – VACCINE MANAGEMENT			
CDC *Vaccine Storage and Handling Toolkit* https://www.cdc.gov/vaccines/recs/storage/default.htm	■ ●	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 http://www.immunize.org/handouts/temperature-logs.asp	■	X	X
Vaccine Storage Troubleshooting Record http://www.immunize.org/catg.d/p3041.pdf	■	X	X
Checklist for Certificate of Calibration/Testing Reports	+	X	X
Sample Form – VFC/317 Vaccine Restitution Report (8/21/2014)	+	X	X
VFC Replacement Policy FAQ (11/04/2016)	+	X	
Purpose-Built Vaccine Storage Units†	+ ◆	X	
CDC Vaccine Tracking System: VTrckS https://www.cdc.gov/vaccines/programs/vtrcks/index.html	●	X	X
MODULE 4 – ENSURING PROVIDER COMPLIANCE			
PEAR User Manual	◆	X	
Previsit 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	

Provider Type Definitions

Note: Definitions are found in the Glossary section of the PEAR User Manual and the Provider Profile Form

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.

Community Vaccinator

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

Correctional Facility

Juvenile correctional facilities as well as adult 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 to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STD services (including HIV/AIDS), and other preconception health services (e.g., screening for obesity, smoking, and/or mental health). This provider type is used for family planning clinics where vaccination services are provided. *NOTE: Non-health department clinics that offer only 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 and 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, with the exception of 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 Federally Qualified Health Centers 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 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 the unit is not the primary site for vaccine administration.

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 offsite or mobile locations.

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

Private practice locations, including solo, group, or HMO practitioners, where vaccination services are provided. *NOTE: 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 a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (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: 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, and teen health centers. *NOTE: Includes any temporary, mobile, off-site, or satellite locations where the provider of record (i.e., public health clinic personnel) is administering vaccine.*

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

A deputized provider has been delegated by a Federally Qualified Health Center (FQHC) or a Rural Health Clinic (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: 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: If vaccination services are provided in a location that is co-located in a physical facility with a refugee health clinic but are not administered by refugee health staff, 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 onsite 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 onsite 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, or 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 12th grade. *NOTE: For non-permanent school-based clinics, use the "Community Vaccinator" designation. The School-Based Clinic (permanent clinic location) provider type 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). Awardees have the option to allow specialty providers to administer only vaccines recommended for the specific populations the providers serve.

STD/HIV Clinic (non-health department)

Clinics that provide timely STD/HIV diagnosis, testing with on-site treatment, and partner services. This provider type is used for STD/HIV clinics NOT located within a health department where on-site vaccination services are provided. *NOTE: this category should be used by non-HD clinics that exclusively offer STD/HIV screening and treatment services.*

Student Health Services

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

Teen Health Center (non-health department)

Teen health centers that are NOT public health department-sponsored and provide on-site vaccination services.

Urgent/Immediate Care Center

Locations that provide immediate medical outpatient care for the treatment of 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, and referrals to health care. This provider type is used for WIC clinics that also provide vaccination services. *NOTE: If vaccination services are provided in a location that is co-located in a physical facility with a WIC clinic but are not administered by WIC staff, 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 or Walgreens Take-Care Clinic).