



Vaccines For Children (VFC)

Provider Manual

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Introduction and Audience

The Vaccines for Children (VFC) Program is foundational to our nation’s vaccine infrastructure and critical to providing vaccine access to children who otherwise may not be able to pay for vaccines. The purpose of this packet is to support West Virginia provider participation in and compliance with the VFC Program to support increased vaccination access and coverage among children in West Virginia. This information should be made accessible to all staff handling vaccine.

To the extent possible, language included in this guide aligns with the most current Centers for Disease Control and Prevention (CDC) [VFC Operations Guide](#). Content has been adapted and supplemented to include West Virginia-specific requirements, processes and guidelines.¹

VFC Program Overview

What is the VFC Program?

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 (see [VFC Patient Eligibility](#)):

- American Indian or Alaska Native (AI/AN)
- Medicaid-eligible
- Uninsured
- Underinsured²

VFC Fast Facts	
?	VFC benefits an estimated 40 million children
?	Approximately 38,000 provider sites are enrolled in VFC
?	Approximately 72 million VFC vaccine doses were 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 programs (“awardees”) to implement and oversee the VFC Program. These programs provide vaccines to participating provider locations to meet the specific needs of eligible children in their jurisdictions.

¹ Disclaimer: The content contained in these materials is provided only for educational and informational purposes for the users in West Virginia. West Virginia attempts to ensure that content is accurate and obtained from reliable sources but does not represent it to be error-free. West Virginia does not warrant that any functions will be uninterrupted, that defects will be corrected, or that the website will be free from viruses or other harmful components. Any links to third party information on the website are provided as a courtesy and do not constitute an endorsement of those materials or the third party providing them.

² 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. ³ <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>

What are the benefits of participating in the VFC Program?³

The goal of the VFC Program is to ensure that a VFC Program-eligible child does not contract a vaccine preventable disease because of their parent or guardian's inability to pay for the vaccine. As a primary driver of health equity in public health, the VFC Program supports improved immunization coverage levels among eligible children by:

Protecting children's health:

- Automatically covers vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and approved by the CDC, which includes all vaccines for children ages 18 years and younger
- VFC Program-provided vaccines protect against 19 different diseases
- Prevents 472 million illnesses and 29.8 million hospitalizations in the United States (U.S.)³

Providing free vaccines:

- Provides publicly purchased vaccines for eligible children at no charge to VFC Program-enrolled public and private providers in all states and U.S. territories

- Eliminates or reduces vaccine cost as a barrier to vaccinating eligible children **Saving money:**

- Saves parents and enrolled providers out-of-pocket expenses for vaccine
- Provides cost savings to states via bulk purchases of vaccines through CDC's contracts at lower prices while eliminating state-to-state variations in price
- Saves nearly \$2.2 trillion (U.S.) due to the prevention of illnesses **Minimizing barriers to vaccination:**

- Eliminates cost as a barrier to vaccinating children
- Provides opportunities for vaccinations at over 37,000 U.S. healthcare providers and locations, extending the reach of the VFC Program
- Enrolled providers increase the potential number of children vaccinated in a jurisdiction and allow VFC Program-eligible children to stay in their medical homes for comprehensive health care
- Reduces racial, ethnic, and socioeconomic disparities in child vaccination rates, improving equity.
- Discourages the practice of referring children from the private sector to the public sector for vaccination

Improving private-public collaboration:

- Allows enrolled private providers to receive publicly purchased vaccine.
- Coordinates with public agencies—including state health departments, state Medicaid programs, and programs serving families and children—to recruit and retain a network of VFC Program providers.

³ <https://www.cdc.gov/vaccines/programs/vfc/about/index.html>

Vaccines covered by VFC

All vaccines covered in the VFC Program are recommended by the Advisory Committee on Immunization Practices (ACIP) to protect infants, children, and teenagers from 19 vaccine-preventable diseases.

Advisory Committee on Immunization Practices (ACIP)
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

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 providers must comply with immunization schedules⁴, dosages, and contraindications that are established by ACIP and included in the VFC Program unless:

1. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child.
2. The particular requirements contradict state law, including laws pertaining to school attendance and/or religious and other exemptions.

The following table lists the diseases and vaccines covered by the VFC Program. For the most recent individual VFC Program vaccine guidelines, please visit the [CDC VFC Program Information for Providers website](#).

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.

⁴ CDC immunization schedules for all ages are available at: <https://www.cdc.gov/vaccines/imz-schedules/child-easyread.html>

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, SPIKEV-AX®/Moderna COVID-19 Vaccine, and Novavax COVID-19 Vaccine	Mpox	Jynneos
Dengue †	Dengvaxia	Mumps	MMR, ** MMRV§
Diphtheria	DTaP,* Td,** Tdap,* Kinrix, ¶ Quadracel,¶ Pentacel,§§ Pediarix,¶¶ Vaxelis §§§	Pertussis	DTaP,* Tdap, Kinrix, ¶ Quadracel, ¶ Pentacel, §§ Vaxelis, §§§, Pediarix
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 syncytial virus (RSV)	Respiratory syncytial virus (RSV) monoclonal antibody: nirsevimab Respiratory syncytial 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 §§§

† 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)

Source: [CDC VFC Operations Guide](#)

VFC Program Funding and Oversight

Funding for the VFC Program is approved annually by the Office of Management and Budget (OMB) and funds are allocated to CDC through the Centers for Medicare and Medicaid Services (CMS). CDC awards VFC funding through a cooperative agreement to 61 state, local, and territorial immunization programs.

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. State, city, or territorial immunization programs manage and implement the VFC Program in their jurisdiction.



West Virginia VFC Program Administration and Contact Information

The VFC Program in West Virginia is managed by the West Virginia Immunization Services Division (ISD), referred to as “ISD” throughout this packet:

West Virginia Division of Immunization Services (ISD)
Office of Epidemiology and Prevention Services (OEPS)
Bureau for Public Health (BPH)
West Virginia Department of Health (WVDH)

Contact Information:
Phone: 304-558-2188
1-800-642-3634 (VFC vaccine)

VFC and WVSIS

West Virginia requires VFC providers to be enrolled and comply with the West Virginia Statewide Immunization Information System (WVSIS) requirements. WV Law requires all immunizations administered to patients 18-years-old or under must be reported to the immunization registry within two weeks.⁵ Information and forms for WVSIS participation are available at: <https://www.wvimm.org/wvsis/>.

Vaccine Administration Fees

VFC vaccines must be provided at no cost. Neither patients, Medicaid agencies, nor third-party payers can be billed for the cost of VFC vaccine.

VFC providers can charge a vaccine administration fee. The administration fee is per vaccine and not per antigen within the vaccine (combination vaccines).

- For non-Medicaid, VFC eligible children (American Indian/Alaska Native, uninsured, underinsured), VFC providers cannot charge the eligible child’s parent/legal guardian a vaccine administration fee that exceeds the maximum regional charge determined by the Centers for Medicaid and Medicare Services (in West Virginia, \$19.85).
- For Medicaid VFC eligible children, VFC providers must accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

Responsibility to Provide Vaccine

VFC providers cannot deny administration of a federally purchased vaccine to an established VFC eligible patient because the child’s parent/guardian/individual on record is unable to pay the administration fee.

The only fee that must be waived is the administration fee. Other visit or office fees may be charged as applicable.

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 within

⁵ WV Legislative Rule 64CSR7: https://oepls.wv.gov/reporting/documents/laws/64_CSR_7.pdf



90 days of vaccine administration. 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.

VFC Program Patient Eligibility Requirements

VFC providers are required to screen patients, from birth through 18 years of age, 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. When screening patients, providers should select and document the VFC eligibility category requiring the least out-of-pocket expense to the parent.

Provider Responsibility to Screen for Patient Eligibility

VFC providers are required to screen patients and document VFC eligibility at each immunization visit.

Patient eligibility screening records should be maintained for at least three years.

Patient Eligibility Screening Record

VFC eligibility must be documented for each vaccine administered (dose level eligibility). The provider may document in their EHR/EMR and report to WVSIS, record directly in WVSIS, document on paper forms, or use the WV Patient Eligibility Screening Form. Patient eligibility screening records should be maintained on file for a minimum of three years after service.

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 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 or enrolled in the Medicaid program
Uninsured	Children not covered by any health insurance plan
Underinsured	<ul style="list-style-type: none"> 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

Source: [CDC VFC Operations Guide](#)

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.

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

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 DIS.

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.

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.

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.

Children whose health insurance covers the cost of vaccinations are not eligible to receive VFC Program vaccines. This also applies if an insurance carrier denies a claim to pay for the cost and administration of the vaccine because the plan's deductible had not been met.

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.

Appendix A of this manual provides a summary view of VFC-eligibility status and insurance situations.

Bordering State

Some children may receive health care in a bordering state instead of their state of residency. 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 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 detention facilities may have special VFC eligibility circumstances.

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 jurisdiction'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

VFC Program Enrollment for Providers

Which providers can participate in VFC?

Any healthcare provider (including pharmacists) authorized by their state law granting them the authority to administer vaccines by prescription, vaccine protocol, or prescribing authority can be a VFC Program provider. You don't have to be a Medicaid provider to participate.

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

- Be licensed in the jurisdiction (state) 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.
- Report all immunizations administered to the immunization registry.
- 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.

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.

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

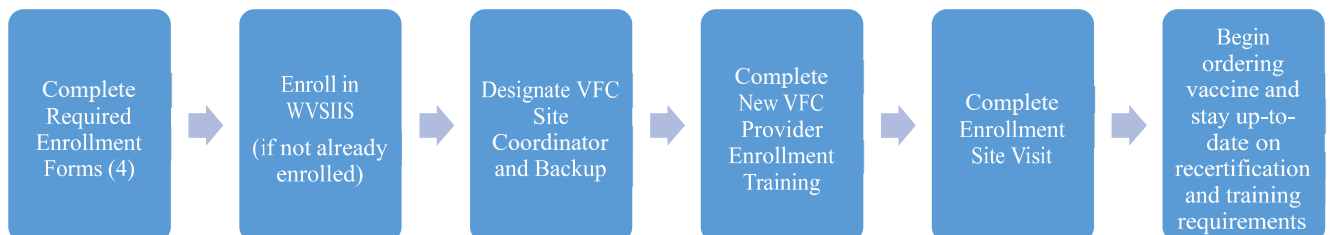
Specialty care provider locations can include, but are not limited to:

- Birthing facilities
- OB/GYNs
- Pharmacists*
- Specialty provider practices
- Urgent care centers
- School-based health centers
- School-located vaccination clinics*
- Providers serving adolescents in nontraditional environments (e.g., juvenile correctional facilities, family planning, and STC/HIV clinics)

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

How do I enroll in the VFC Program in West Virginia?

West Virginia VFC Provider Enrollment Process Overview



Enrollment Forms

Four forms must be completed by each VFC provider to enroll:

1. Provider Agreement (Enrollment Form)
2. Provider Profile
3. VFC Storage Agreement
4. VFC Provider Address Form

These forms can be found in the [WVSIS Document Center](#). These forms are used to verify the provider's eligibility to participate and must be completed and submitted to ISD as part of recertification every two years.

Provider Agreement

This is a CDC-developed contract between the provider location and the WV ISD outlining VFC Program requirements the providers must comply with to receive publicly funded vaccines. This form must be completed as part of initial program enrollment, reenrollment, and as part of the VFC Program provider recertification process at least every 24 months.

When signing the Provider Agreement, the following apply:

- All VFC provider locations must complete and sign the 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.
- If the status of the individual signing the Provider Agreement changes, the provider must notify DIS.

Provider Profile

The Provider Profile Form requires providers to report the number of VFC eligible children, children enrolled in West Virginia Children’s Health Insurance Program (WV CHIP) and non-VFC-eligible children seen in the practice. Data from the Provider Profile Form is used by the ISD to evaluate vaccine orders and ensure the amount of VFC funded vaccine provided is appropriate for the number of VFC eligible children who receive care from that provider office.

Information supplied on the Provider Profile Form must be based on actual data representing populations served by the practice or facility during the most recent 12 months. Examples of appropriate data sources include:

- Doses administered data
- Benchmarking data
- Medicaid billing data
- Provider encounter data
- Immunization Information System (registry)
- Prior Ordering data
- Vaccine Replacement data

Maintaining Current Provider Profile

Provider locations must keep their Provider Profiles current to reflect any changes to their public and private patient categories and submit updates to DIS.

ISD uses the profile data to monitor vaccine orders to ensure provider locations are not inadvertently overordering, stockpiling, or building inventory, which can put vaccine at risk for waste or indicate fraud or abuse.

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.

VFC Storage Agreement

Providers who wish to receive VFC vaccine must agree to provide the appropriate storage units as well as adhere to the ISD handling requirements. Failure to comply may result in a suspension of vaccine provided. This form outlines the requirements and requires a provider signature upon enrollment into the program.

Provider Address Form

Any changes to a VFC provider address or contact information should be shared immediately by calling the ISD and completing this form.

West Virginia Immunization Information System (IIS) Enrollment

VFC providers in West Virginia are required to participate in the West Virginia Immunization Information

System (WVSIIS). The ISD has integrated some of its vaccine management functions into the WVSIIS Vaccine Ordering Management System (VOMS) module to support accountability. WV VFC providers are required to report all patients and vaccine administrations to WVSIIS along with the dose level VFC eligibility status for each dose administered. These records can either be manually

entered directly into WVSIS or electronically transmitted to WVSIS from the provider's electronic medical record (EMR) system. VFC providers not in compliance will not be able to continue participation in the VFC Program.

Steps to Initiate WVSIS Enrollment

- Providers with an existing WVSIS account should ensure their facility and user information is up to date and confirm required fields for the VFC Program can be transmitted to the IIS.
- Providers without an existing WVSIS account should work with the WVSIS Program to complete registration/enrollment paperwork, training, and onboarding steps.

For more information, [contact WVSIS](#).

Enrollment Site Visits

All providers enrolling in the VFC Program must have an initial VFC enrollment site visit prior to receiving VFC vaccines. Representatives from ISD conduct enrollment visits to ensure providers are educated on the VFC Program requirements. 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 (e.g., vaccine storage units and temperature monitoring equipment)
- Confirm providers know whom to contact if problems arise, especially with storage and handling issues
- Complete a Vaccine Management Plan

Training Requirements and Opportunities

The following training must be completed by all providers and VFC staff as part of VFC Program enrollment. These modules are also required for any new staff upon hire.

- CDC You Call the Shots: four modules (1, 10, 16, and 18) are required as part of initial enrollment
- Modules can be accessed through [CDC TRAIN](#)
- Instructions for obtaining continuing education (CE) credit are provided at the end of the modules.

Following new VFC Program enrollment, all VFC participating providers must participate in annual training on all VFC

requirements. The annual training requirement may be met by any of the following options:

- Re-completing You Call the Shots modules 10, 16, and 18.
- Attending a conference or webinar about VFC.
- Participating in virtual or in-person training led by VFC Quality Assurance staff, which may be combined with a compliance visit or scheduled separately.

You Call the Shots is an interactive, web-based immunization training course. It consists of a series of modules that discuss vaccine preventable diseases and explain the latest recommendations for vaccine use. Each module provides learning opportunities, self-test practice questions, reference and resource materials, and an extensive glossary.

Reenrollment

If a provider location leaves the VFC Program and later wants to reenroll, all steps for a newly enrolling provider location must be followed. This includes all education and documentation requirements, as well as an enrollment site visit.

VFC provider locations must reenroll and participate in [compliance visits](#) at a minimum of every two years to remain in the program. To prevent a lapse in enrollment, providers will need to complete the required [enrollment forms](#) as part of reenrollment.

Provider Recertification (Every 12 Months)

Each year, the ISD will collect updated Enrollment Packet forms and review provider locations to ensure they have met the VFC Program annual training requirements.

Disenrollment/Termination

Either the ISD 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 circumstances⁶, this provider location is considered inactive and should be unenrolled and the Provider Agreement should be considered terminated.
- Compliance requirements have not been met and the provider location is unable or unwilling to take the corrective actions needed to address the issues of noncompliance.

If the Provider Agreement is terminated, the ISD will retrieve any unused VFC vaccines within 30 days. More information is available below on Compliance Site Visits.

Vaccine Management

To prevent costly vaccine waste, providers are responsible for maintaining vaccine quality from the time a shipment arrives until a dose is administered. Sound vaccine management practices related to ordering, inventory management, and storage and handling are critical to preventing and minimizing vaccine loss and waste and potentially putting VFC children at risk from compromised vaccine.

⁶ Example circumstances where a provider location may not be terminated for not ordering within 12 months include: the provider location is a specialty provider (only needs small quantities of vaccine) or the provider location is a store-only location (e.g., stores and distributes but does not administer vaccine).

Vaccine Coordinator Requirement

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. 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. Providers should contact the DIS, if needed, to provide training for new vaccine coordinators.

VFC providers are required to notify ISD whenever there is a change in vaccine coordinator staff as soon as the change becomes known in your office.

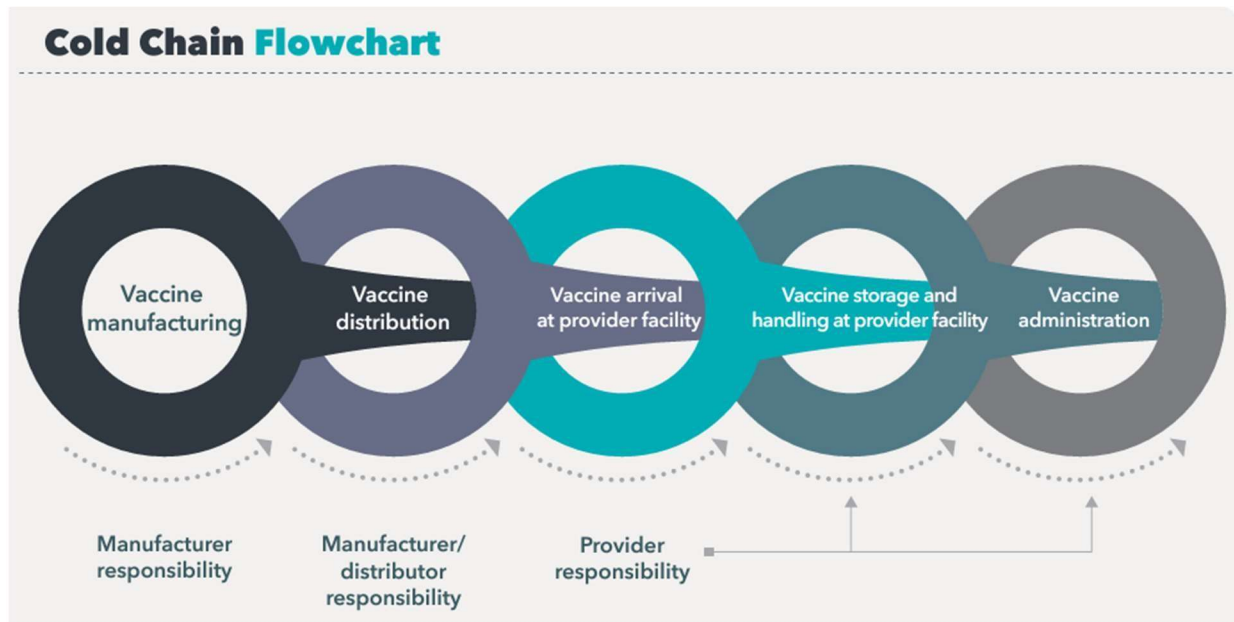
The vaccine coordinator is responsible for overseeing all vaccine management within the facility, including:

- Developing and maintaining the Vaccine Management Plan
- Monitoring all storage and handling and vaccine administration practices in the facility
- Ordering all ACIP recommended vaccines for the patient population served
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information
- Organizing vaccines within storage units
- Setting up temperature monitoring devices
- Checking and recording minimum/maximum temperatures twice daily per unit
- Ensuring staff are correctly checking and recording vaccine storage unit temperatures per temperature monitoring
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends.
- Rotating stock at least weekly
- Removing expired vaccine from storage units and notifying ISD (see management of expired, spoiled, wasted vaccine)
- Responding to temperature excursions (out-of-range temperatures)
- Maintaining and storing all documentation for a minimum of three years, such as inventory and temperature logs
- Participating in and ensuring and documenting all staff are properly trained, including:
 - New VFC enrollment training
 - Completion of annual training on VFC requirements
 - Training of new staff upon hire
 - Maintaining documentation and training certificates
- Monitoring operation of vaccine storage equipment and systems
- Overseeing proper vaccine transport and overseeing temperature excursions (TE)
- Ensuring appropriate handling of vaccines during a disaster or power outage
- Notifying the ISD in circumstances where vaccine may expire or be lost due to temperature excursions or any other reason

Storage & 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 that cannot be restored. Each time vaccines are exposed to improper conditions, potency is reduced even further. With loss of potency, vaccines become ineffective and are unable to provide immunity for the vaccinated individual.

Resource Highlight
 CDC's [Vaccine Storage and Handling Toolkit](#) provides comprehensive guidance on storage and handling requirements and best practices. Providers should reference this guide for details beyond what is included below.



Source: CDC Vaccine Storage and Handling Toolkit

CDC's [Vaccine Storage and Handling Toolkit](#) provides guidance on safe and effective vaccine management practices for all health care providers. 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.

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 ISD contact information in case of a shipment issue
- Twice 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

Refrigerator and Freezer Units

Provider sites are required to have appropriate equipment that can store vaccine, maintain proper conditions, and provide adequate monitoring. 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 must be used to store frozen vaccines if using a refrigerator compartment of a household combination unit.
- The use of dormitory or bar-style refrigerator/freezers is always prohibited for VFC Program provider locations.

Providers should follow the manufacturer’s storage specifications for each vaccine, found in the manufacturer’s package insert. Vaccine products with similar packaging should be stored in different locations in the storage unit to avoid confusion and administration errors.

Providers must also protect the power source for all storage equipment, by following steps such as:

- Place “Do Not Disconnect” warning labels at the electrical outlet and circuit breaker.

Storage Unit Best Practices

- ❑ Store vaccines in their original packaging with lids closed until ready for administration.
- ❑ Separate the VFC vaccines from other public and private supply.
- ❑ Place short-dated vaccines (closest to expiration) in the front to be used first.
- ❑ Place vaccines and diluents in the center of the unit, 2-3 inches away from walls, ceiling, floor, door.
- ❑ Do not store vaccines in the doors, vegetable bins, or floor of the unit, or under/near cooling vents. (remove drawers/bins if possible)
- ❑ Never store food or beverages in a unit with vaccines.
- ❑ Place water bottles marked “Do Not Drink” throughout units-against walls, in the back, on the floor, and in the doors to help stabilize temperatures.
- ❑ Limit access to the vaccine supply to authorized personnel only.
- ❑ Install locks on refrigerators, and if possible, the electrical plug.

- Label fuses and circuit breakers to alert people not to turn off power. Labels should include immediate steps to take if the power is interrupted.
- Plug in only one storage unit per electrical outlet.
- Use a safety lock or outlet cover to prevent the unit from being unplugged.
- Avoid using built-in circuit switches that may have reset buttons, outlets that may be activated by a wall switch, multioutlet power strips
- In larger clinics, provide a source of back-up power (generator) and a security system to alert appropriate staff in the event of a power outage.
- If applicable, test back-up generators quarterly and maintain back-up generators at least annually.

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.

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

- A temperature probe or sensor (a buffered probe is required for immunization program-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.

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

VFC Storage and Handling Temperature Requirements

To ensure viability of VFC vaccines, provider sites must have:

- Storage units that maintain correct temperatures at all times
- Refrigerator temperatures between 2°C and 8°C (36°F and 46°F)
- Freezer temperature between -50°C and -15°C (-58°F and +5°F)
- Record and assess refrigerator and freezer temperatures twice each day (beginning and end of each clinic day)

- 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, 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 twice-a-day assessment and reporting requirement. This alternative approach must be approved by ISD 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.

Storage Unit Maintenance

Regular maintenance is necessary to ensure vaccine refrigerators and freezers work properly. If the unit remains too warm or too cold after the thermostat is adjusted, or the unit is making noises that are not normal, have the unit serviced or replaced.

What to do if Vaccine is Compromised During Shipment If providers believe a vaccine shipment was compromised, they must immediately contact DIS.

The provider should also contact:

- For a centralized distributor shipment: Contact centralized distribution immediately at 1-877TEMP123 (1-877-836-7123). This must be done the same day vaccines arrive.
- For a direct shipment from manufacturer: Contact ISD for VFC vaccine or the manufacturer for private vaccine.

Refrigerator	Freezer
<ul style="list-style-type: none"> ☐ Clean the storage units once/month. ☐ Check door seals and door hinges for gaps. ☐ Clean coils (if unit needs to be unplugged or moved, relocate vaccines to the backup data logger to the backup unit prior to doing so). ☐ Clean interior of each unit to discourage bacterial/fungal growth. Do so quickly to minimize risk of temperature excursion. 	<ul style="list-style-type: none"> ☐ If frozen vaccines are stored in a manual defrost freezer, it will be defrosted regularly and as needed to avoid frost build up in the unit. ☐ Remove excessive ice buildup. ☐ During manual defrost, the vaccines must be moved to the backup storage unit until the unit has been completely defrosted and returned to acceptable temperature range. ☐ Clean interior of each unit to discourage bacterial/fungal growth. Do so quickly to minimize risk of temperature excursion.

If your provider site relocates any storage unit in your facility or to a new location, or if your office is closed for any length of time, your facility VFC Coordinator or Backup Coordinator should notify ISD.

Receiving and Documenting Vaccines

Providers must ensure that vaccines are delivered during office hours. A trained staff member must be available to receive vaccine at least one day a week other than Monday, and for at least four consecutive hours during the day.

When receiving vaccine shipments, providers must:

- IMMEDIATELY unpack vaccine packages and store vaccines and diluents at the recommended temperatures upon receipt
- Check the shipping temperature monitor reading
- Inspect the vaccine and packaging- examine the shipping container and vaccine vials for signs of physical damage
- Document vaccine shipments
- Compare the contents of the container to the packing list to be sure they match; all vaccine packing slips must be kept for three years
- Check enclosed refrigerator and freezer temperature indicators
- Check shipment date: interval between shipment date and arrival at your office should be no more than 48 hours

If the provider believes a vaccine shipment is compromised, temperature monitors are out-of-range, or a warm indicator is activated, they should contact the ISD VFC staff immediately and label any compromised vaccine as DO NOT USE.

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, recording the min/max reading at least twice daily. 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:

- Record temperatures twice daily
- 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

Temperature Logs

The West Virginia ISD requires monthly submission of temperature logs that must include the provider's name AND pin number on all temperature log sheets. Temperature logs should be sent to ISD between the first and fifth day of each month via email or fax. (DHHROEPSVFClogs@wv.gov or fax: 304-957-7591)

Options for documenting temperature readings include:

- 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.
 - Printable temperature logs are available on the [immunize.org website](http://immunize.org).
- Option 2: Use a continuous temperature monitoring and recording system that allows providers to electronically document temperature readings.

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.

Temperature Excursions (TE)

Temperature excursions (TE) are inappropriate storage conditions for any vaccine and require immediate action. Any temperature reading outside the recommended ranges in the manufacturers' package inserts is considered a temperature excursion.

Temperature Excursions

If a temperature excursion is suspected, immediately contact the Division of Immunization Services for assistance.

- Providers should follow their vaccine management plan SOPs, including adjusting temperature to the appropriate range and notifying ISD and the manufacturer 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 DIS.

More details on what to do in the event of a temperature excursion are available in the CDC Storage and Handling Toolkit. Details related to management of expired, spoiled, and wasted vaccines are available below under [Management of Expired, Spoiled, and Wasted Vaccines](#).

Vaccine Handling and Preparation

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

- Vaccines should be prepared immediately prior to administration.

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

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

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

Refer to CDC’s [vaccine administration website](#) and the Pink Book for detailed information and guidance on vaccine administration, including specifics for individual vaccines.

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. Homes/non-healthcare facilities are not acceptable alternative storage locations unless specially approved by Immunization Services.

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.

Further details on steps to follow in an emergency are included in the ISD Vaccine Management Plan template, and written procedures should be posted on all vaccine storage units. 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](#).

Vaccine Management Plan

VFC provider locations must develop, maintain, and implement a Vaccine Management Plan (see WV ISD Vaccine Management Plan template) with detailed and up-to-date SOPs for routine and emergency vaccine management. Plans must be reviewed and approved by DIS.

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 disasters.
- Standing orders for all vaccines in a provider's facility

At a minimum, Vaccine Management Plans must be updated annually and verified as current with the vaccine coordinator's signature and date of review. Plans must be updated when vaccine management practices change or when there is a change in staff that has responsibilities specified in the plan.

Vaccine Management Training

Vaccine management training first occurs during provider enrollment and includes a review of the key components of a Vaccine Management Plan. After enrollment, provider locations are required to receive training annually.

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

Vaccine loss due to expiration is commonly a result 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 based on the actual population served.

Provider locations should:

- Keep a 2-month supply of vaccine on hand.
- 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.

The Vaccine Coordinator or Backup Coordinator will be responsible for ordering vaccines and maintaining appropriate vaccine stock.

Once the ISD notifies the WVSIS program that the provider is compliant with all requirements and approved to begin ordering vaccine, provider ordering privileges and access to VOMS are activated.

To place an order:

- Temperatures logs, including the provider pin number on each page, must be sent to ISD prior to ordering.
- Provider reconciles inventory in VOMS and confirms current doses on hand.
- Provider places vaccine order in VOMS for requested order quantity
- ISD will review and approve VOMS orders and upload order and inventory files into VTrckS⁷ to be transmitted to McKesson for shipment.
- Provider will receive a prompt from VOMS to receive vaccine order once shipped and document receipt.
- Providers are required to report administered doses to WVSIS. These doses decrement from WVSIS inventory to be reconciled prior to placing next order.

Ordering Requirements

- ② Providers must be compliant with all new provider enrollment and re-enrollment, and/or recertification requirements to continue ordering.
- ② Maintain updated Provider Profile
- ② Provider locations must submit their total vaccine inventory amounts (i.e., number of doses physically on hand) with each vaccine order.
- ② Monthly temperature logs must be sent prior to ordering.

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.

Vaccine Inventory Management

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, 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

⁷ The Vaccine Tracking System (VTrckS) is an information technology system that is integrated into the West Virginia State Immunization Registry System (WVSIS) for tracking vaccine ordering and distribution.

<https://www.cdc.gov/vaccines/programs/vtrcks/index.html>

Privately purchased vaccine inventory includes any vaccine purchased by the provider to vaccinate patients who are not eligible to receive vaccinations under VFC or other state vaccine program(s).

VFC vaccine inventory must be reconciled in WVSIS prior to placing subsequent vaccine orders. WVSIS/VOMS manages publicly supplied vaccine inventory. All vaccines administered, public or private, must be recorded in the WVSIS.

Vaccine Transfer

Proper vaccine inventory management plays a major role in preventing the need to transfer vaccines. However, even with proper inventory management, providers may experience a situation where they have 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. If short dated vaccines are discovered that are not able to be used prior to the expiration data and you would like to transfer them to another provider, please contact ISD to coordinate. This should be a rare practice if provider locations are appropriately managing inventory.

Vaccine transfers can only occur:

- With prior approval and under direct guidance of the DIS.
- 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/transport containers and packaging.
- When temperature monitoring documentation validates the vaccine has not been exposed to a temperature excursion—this documentation must be transported with the vaccine.

Varicella, Proquad and Zostavax
Special Considerations for Transport

- Transport of varicella-containing vaccines is not recommended.
- If absolutely necessary, they should only be transported in a portable freezer that maintains the temperature between -58F and +5F (-50C and -15C)

Shipping vaccines is strictly prohibited. For specific instructions and guidance related to packaging and transporting vaccine, see CDC’s [Vaccine Storage and Handling Toolkit](#).

Management of Expired, Spoiled, and

Wasted Vaccines Providers should notify ISD of any VFC vaccine cold chain failure/wastage incidents immediately upon discovery of the incident to determine if the vaccine is non-viable.

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

- Remove the vaccines from any storage unit that stores viable vaccines.
- Label vaccines “Do Not Use.”
- Contact the manufacturer directly with questions about storage temperature excursion for specific vaccines.
- Report and record the incident, including the reason and number of doses lost (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.
 - All returnable vaccine must be returned in its original packaging, vial, or manufacturer prefilled syringe.
 - Returning expired or wasted vaccines to the distributor must be reported using a Vaccine Return Form.
- Non-returnable and returnable vaccine needs to be reconciled in WVSIS/VOMS and disposed of properly.

To help avoid vaccine loss:

- Short-dated vaccines (vaccines closest to expiration) should be placed in front of longer dated vaccines and used first.
- If short-dated vaccines are discovered that are not able to be used prior to the expiration date and you would like to transfer them to another provider, please contact the ISD and see [vaccine transfer](#) information below for guidance.

Types of Vaccine Loss

- Expired or spoiled vaccine: Nonviable vaccine in its original container (vial or syringe) that is expired or spoiled due to temperature excursions, transport conditions, or emergency situations such as a power failure.
- Wasted vaccine: Nonviable vaccine that 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.

McKesson Restrictions

The following should NEVER be returned to McKesson:

- Used syringes, with or without needles
- Broken vials
- Wasted products such as a syringe that was drawn up but not used
- Any multidose vial from which some doses have been withdrawn
- Diluent (expired or not expired)
- Private-purchased vaccine

Temporary, Mobile, Off-Site, or Satellite Clinics

Some providers may conduct temporary, mobile, off-site, or satellite clinics. These opportunities can improve access and vaccination coverage for VFC-eligible children. However, these situations require additional program oversight and vaccine accountability. These alternative provider locations are required to adhere to all general program requirements, including screening and

documenting VFC eligibility, as well as maintaining 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 to a location within the jurisdiction when direct delivery is not possible.
- 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 and complete a Provider Profile.
- All doses administered during off-site events must be recorded in WVSIS in real time or within two weeks following the event to ensure accurate inventory levels are maintained.

See CDC’s [Vaccine Storage and Handling Toolkit](#) and CDC’s [vaccine administration website](#) for details and best practices for vaccine handling during a temporary, mobile, off-site, or satellite clinic.

VFC Program Compliance

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.

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.

Site Visits

Multiple types of VFC site visits focus on 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)

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.

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 WVSIS.

Compliance Site Visit

The purpose of the compliance site visit is for ISD to evaluate whether providers are complying with and understanding VFC requirements outlined in the Provider Agreement, including patient screening and eligibility documentation and proper vaccine storage and handling.

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 first site visit occur at the three- to six-month time frame. Regardless, the initial compliance site visit must be completed within 12 months of enrollment. After that, each VFC provider will receive a compliance site visit at a minimum of every two years.

What happens during a VFC Compliance Site Visit?

The ISD will contact the VFC provider to schedule a VFC Compliance Site Visit. The visit involves assessment of provider knowledge regarding program requirements and vaccine storage and handling techniques utilized in the practice. It also provides an opportunity for providers to ask questions while allowing ISD staff to offer resources to support providers' efforts in vaccinating children.

The following VFC Program areas will be reviewed during the site visit:

- Provider location details
- Patient eligibility and billing
- Documentation
- Storage & Handling
- Inventory
- Training of staff

See Appendix B for more details related to what is assessed in these areas.

Storage and Handling Site Visit

VFC providers may receive an unannounced storage and handling visit during the calendar year. Unannounced storage and handling site visits are separate from VFC compliance site visits and serve as "spot checks" for proper vaccine storage and handling practices. 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](#).

Unannounced visits are most typical when a provider's routine compliance visit identified extensive follow up action, or if the provider was compliant, but it has been at least one year since the provider's last visit. The ISD is required to perform unannounced storage and handling visits with at least 5% of VFC provider sites in the state annually.

Maintaining Records

Providers must maintain all records related to the VFC Program for a minimum of three years and make these records available upon request. VFC records include, but are not limited to:

- VFC screening and eligibility documentation
- Billing records
- Medical records that verify vaccine administration
- Vaccine ordering records

Vaccine purchase and other accountability records (e.g., packing lists, borrowing forms, wastage reports)

- Storage unit temperature documentation

Immunization Record Retention

VFC providers must maintain immunization records that include:

- Name of vaccine administered
- Date vaccine was administered
- Date VIS was given
- Publication date of VIS
- Name of vaccine manufacturer
- Vaccine lot number
- Name and title of person who administered the vaccine
- Address of the clinic where the vaccine was administered

All administered vaccines must be reported to the WVSIS.

VFC Site Visit Follow-Up and Corrective Actions

Overall, VFC Compliance Site Visit results confirm that VFC providers understand and implement the program in their practices successfully. However, on occasion, some issues and educational needs are identified and require additional follow up and communication by ISD staff to ensure the provider's success with the program. Some issues can be corrected during the visit, while other issues may warrant further follow up and communication from DIS. The ISD will work with provider staff to develop a corrective action plan, including follow up steps and a timeframe to address any noncompliant practices identified. This Provider Follow-Up Plan 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 a checklist for providers 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 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.

Both the reviewer and the provider location must maintain copies of these signed documents for a minimum of three years.

Annual Training

Every 12 months, all VFC participating providers must undergo training on ALL VFC requirements in the Provider Agreement and the current [CDC 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.

Options for meeting this requirement include:

Options	Details
Compliance visit training	<ul style="list-style-type: none"> • The VFC coordinator, backup coordinator, provider(s), and anyone who handles or administers VFC doses must be present. If any key staff are unable to attend, VFC staff will need to confirm they completed the training before the provider location meets the annual requirement. • During the visit, all requirements of VFC must be reviewed in addition to completing the compliance site visit review.
Educational visit	<p>☐ An educational visit is a site visit from VFC staff for the specific purpose of covering the required material to meet the annual training requirement. All key staff must be present.</p>
In-person, formal training event (conference, seminar)	<ul style="list-style-type: none"> • Subject matter must include all VFC Program requirements, including storage and handling procedures. • Example: Pink Book Course
Online training (live or self-paced)	<ul style="list-style-type: none"> • Live online training may be a webinar or conference call in which the VFC requirements are covered. <ul style="list-style-type: none"> ○ Self-paced training is a set of modules to be read through that might include learning checks periodically. Certificates of completion are required and should be saved from one compliance visit to the next. • Example: CDC You Call the Shots Modules 1, 10, 16, 18

Training Documentation

Providers must maintain documentation of annual provider training completion and be able to show the required VFC content was covered as a part of the training.



Continuing Education (CE) Credit

To obtain Continuing Education credit, follow individual training or module instructions.

Vaccine Information Statements (VIS)

Federal law requires that VIS be provided before certain vaccinations are given. VIS are increasingly available for patients to access electronically. All available VIS, including versions in numerous different languages, are available on the Immunize.org and [CDC websites](#). VIS are updated periodically, and providers are responsible for ensuring VIS with the most current publication date are used and recorded for each administered vaccine dose.

Vaccine Adverse Event Reporting System (VAERS) and the National Childhood Vaccine

Injury Compensation Act (NCVIA)

The National Childhood Vaccine Injury Compensation Act (NCVIA) requires healthcare providers to report certain adverse events to the Vaccine Adverse Event Reporting System (VAERS). Adverse events are defined as health effects that occur after immunization that may or may not be related to the vaccine. VAERS data are monitored continually to detect unknown adverse events or increases in known side effects.

Information that should be included when reporting to VAERS

includes: ☑ Vaccine information (brand name, dosage)

- Patient demographic information (age, date of birth, gender)
- Date, time, location of vaccine administration
- Date and time of onset of the adverse event
- Symptoms and outcome of the adverse event(s)
- Medical tests and laboratory results (if applicable)
- Current illnesses or medications
- History of adverse events following vaccination
- Physician's contact information (if applicable)

VAERS reports can be submitted online at <http://vaers.hhs.gov> or using a writable PDF VAERS report form.

Fraud and Abuse

When providers enroll in the VFC Program, they agree to comply with all the requirements of the program as defined in the Provider Agreement. Not adhering to the requirements, intentionally or unintentionally, could result in fraud or abuse of the VFC Program. For VFC-related purposes, the definitions of fraud and abuse are as follows:

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.

Non-compliance with program requirements may occur due to an unintentional lack of understanding of the VFC Program requirements, or the behavior may be intentional. The West Virginia ISD has specific policies and guidelines to follow for handling potential fraud and abuse of the VFC Program. If fraud is suspected, please contact the ISD to report.

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

Appendix A: 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.
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Source: CDC VFC Operations Guide

Appendix B: VFC Program Areas Assessed During Compliance Site Visit

Program Area	What is assessed?
Provider Location Details	<ul style="list-style-type: none"> • 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	<p>Review procedures, practices, and records to confirm provider understanding and implementation of:</p> <ul style="list-style-type: none"> • 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 administration fee

Documentation	<p>Review procedures, practices, and records to confirm provider understanding and implementation of:</p> <ul style="list-style-type: none"> • Properly screening patients for VFC eligibility and documenting the results at each immunization encounter • 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: • 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
Storage & Handling per Unit	<p>Assess that each individual storage unit:</p> <ul style="list-style-type: none"> • Is an approved storage unit based on VFC requirements • Contains a DDL with continuous monitoring capability and a current and
	<p>valid Certificate of Calibration Testing</p> <ul style="list-style-type: none"> • Has vaccines and DDL placed correctly in the unit Review provider location documents related to: • Temperature monitoring • Responses to a temperature excursion within the unit
Storage & Handling Sitewide	<p>Review cost and quantity of vaccine ordered to understand impact of VFC Program on facility</p> <ul style="list-style-type: none"> • 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 ISD and based on CDC’s Vaccine Storage and Handling Toolkit <ul style="list-style-type: none"> o Sharing any vaccine returns or wastage data during the last 12 months

Inventory	<p>Review procedures, practices, and records to confirm provider understanding and implementation of:</p> <ul style="list-style-type: none">• Ordering vaccine in correct quantities to maintain appropriate vaccine inventories• Complying with the childhood immunization schedule as recommended by ACIP• Separation of vaccine stock between private and public vaccine
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