

Handbook for Vaccine Supplied by the Division of Immunization

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Overview

The Virginia Department of Health (VDH), Division of Immunization (DOI) manages the Virginia Vaccines for Children (VVFC) program and the Virginia Vaccines for Adults (VVFA) program. Through utilization of private and public providers, DOI programs reduce barriers to immunizations for children and adults by supplying federally and state purchased vaccine for eligible clients.

The national Vaccines for Children (VFC) program was established to help raise childhood immunization rates in the United States and to keep children in their medical home. The entitlement program is associated with each State's Medicaid plan. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP).

ACIP also recommends vaccines for adults. In 2011, the DOI began to offer all ACIP-recommended vaccines for uninsured and underinsured adults through public providers. Barriers to adult immunization are reduced through utilization of providers located in underserved areas. DOI supplies federally and state purchased vaccine at no cost to adult health care providers.

The DOI manages distribution of VFC funded vaccine for the VFC entitlement program, and vaccine supplied through other funding sources such as state funds and Section 317 funds for non-VFC-eligible clients. DOI, through relationships with public providers, is able to serve populations in addition to VVFC eligible, such as children needing immunizations for school, and vaccines for adults who are underinsured or uninsured.

Program Benefits

- Increased vaccination rates
- Decreased morbidity and mortality from vaccine-preventable diseases
- Increased herd immunity for your local community
- Reduced referrals to public clinics, allowing these patients to remain in their medical homes and ensuring continuity of care
- Technical assistance to improve your vaccination rates, record keeping, vaccine handling, and vaccination opportunities

VVFC and VVFA Enrollment Process

To enroll, providers may call 1-800-568-1929 or 1-804-864-8055 or click on the link below to print the provider agreement form: <http://www.vdh.virginia.gov/immunization/>

Virginia Immunization Information System (VIIS)

All VVFC and VVFA-enrolled providers are required to share vaccines administered information into the Virginia Immunization Information System (VIIS) for both public and private stock, within 30 days of administration. To set up access to VIIS please review the enrollment website <http://www.vdh.virginia.gov/immunization/viis/enrollment/>

Practice Identification Number

A Practice Identification Number (PIN) will be assigned to you when you enroll. Knowing the PIN assigned to your facility helps us to quickly and accurately find your records and answer your questions. Please inform VVFC or VVFA if there is a change in any of the following at your medical facility: the primary vaccine or backup coordinator, mailing addresses, shipping addresses, practice hours, email addresses, or physicians. This helps ensure you receive your vaccine efficiently. PINs are assigned to a particular site and do not transfer with a physician or nurse when they leave the provider site.

Multiple Office Enrollments

Depending on your organization, you may be assigned more than one PIN. If there is more than one facility under the same medical group (sharing staff and/or patients) and each facility is storing and administering vaccine provided through DOI, a parent PIN is assigned. The parent PIN is assigned to the medical group's main location. A related PIN identifying all locations associated with the medical group will be assigned to each location. For example, a parent PIN might be P999. All other locations would be distinguished with the PIN and a letter following the number, such as: P999A, P999B, and P999C, etc. The provider population estimate section of each provider agreement should estimate the number of patients needing immunizations at each location.

Facility Types

The majority of providers enrolled in the VVFC program are private physician offices. Other enrolled facilities types include Federally Qualified Health Centers (FQHCs), Rural Health Clinics (RHCs), Community Health Centers (CHCs), Public Hospitals, and Local Health Departments (LHDs). Please contact the VVFC Program if you have questions about your classification.

Inactive Membership Status

Contact DOI if your facility is closing or no longer wants to participate in the VVFC or VVFA program. We will assist you in transferring unused, viable vaccines provided by DOI to a participating provider.

ELIGIBILITY

Eligibility Classifications
Funding/Provider Classifications
Out of State Eligible
Medicaid
Screening Documentation

Eligibility Classifications

A patient's eligibility for vaccine supplied through DOI depends on the facility type where the patient is being seen. A patient's eligibility may be either VFC eligible or State/317 eligible. Below are listed eligibility classifications:

VFC ELIGIBILITY:

Medicaid: A child through 18 years of age who is eligible for the Medicaid program.

The terms "Medicaid-eligible" and "Medicaid-enrolled" are equivalent and refer to children who qualify for the state Medicaid entitlement program.

Medicaid is an entitlement - not insurance. (FAMIS is insurance. Children with FAMIS are not VFC eligible)

Uninsured: A child through 18 years of age who has no health insurance coverage.

American Indian (AI) or Alaska Native (AN): A child through 18 years of age and AI/AN as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).

Underinsured (at Federally Qualified Health Centers (FQHCs) or Rural Health

Clinics (RHCs): A child through 18 years of age who has commercial (private) health insurance but the coverage does not include vaccines, or a child whose insurance covers only selected vaccines, or a child whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, the child is categorized as underinsured). Underinsured children are VFC eligible through a FQHC or RHC.

STATE/317 ELIGIBILITY:

Code Required Vaccines (immunizations required for K-12 school entry) at Local Health Departments (LHDs): Patients who are not eligible as Medicaid, Uninsured, AI/AN, Underinsured at FQHC/RHC (defined above), and are under the age of 19 may receive routine vaccines required for school entry at LHDs. For example, a child with insurance is eligible for DOI supplied vaccines required for school entry at a LHD but the child is not VFC eligible. Rather, the child is State/317 eligible as dictated by billing policies for health departments. The LHD may bill the insurance as directed by VDH billing policies for LHDs.

The vaccines required for school can be found here:

<http://www.vdh.virginia.gov/immunization/requirements/>

*Hepatitis A, Influenza, Meningococcal, and Rotavirus vaccines are ACIP recommended vaccines, but are not required for school entry. Insured patients should receive privately purchased Hepatitis A, Influenza, Meningococcal, Rotavirus vaccine.

Underinsured Children at a LHD/Public Hospital: A child through 18 years of age who has commercial (private) health insurance but the coverage does not include vaccines, or a child whose insurance covers only selected vaccines, or a child whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached) is categorized as underinsured and is eligible for State/\$317 funded vaccine at a LHD or Public Hospital.

Uninsured and Underinsured Adults at a LHD/FQHC/RHC/Public

Hospital/Safety-net Clinic: An adult 19 years of age or older who is uninsured or underinsured is eligible for State/\$317 funded vaccine at a LHD/FQHC/RHC/Public Hospital/Safety-net Clinic. Influenza, MMR, TD/TDaP, Meningococcal, Varicella, Zoster, HPV, Pneumococcal, Hep B, Hep A vaccines are available for patients 19 years of age and older who are uninsured, or underinsured. Underinsured is defined as: A person who has commercial (private) health insurance but the coverage does not include vaccines, or a person whose insurance covers only selected vaccines, or a person whose insurance caps vaccine coverage at a certain amount (once that coverage amount is reached, the person is categorized as underinsured).

Note: Adults covered by Medicare with Part D are not eligible for vaccine provided through DOI since Medicare covers immunizations for adults.

Medicaid/Medicaid MCO patients who are 19 or 20 are not eligible for vaccine provided through DOI, and should receive private stock.

Medicaid/Medicaid MCO patients ≥ 21 are eligible for recommended immunizations except those that are covered by Medicaid/Medicaid MCOs. For example, flu and pneumonia for high risk is covered by Medicaid so the client should receive private stock.

Funding/Provider Classifications

Vaccines are supplied by DOI at no cost to enrolled providers using three primary funding sources:

- VFC funds are used to purchase vaccine for VFC eligible children. VFC eligible children are Medicaid, Uninsured, AI/AN, and Underinsured at FQHC/RHC
- Section 317 funds are used to purchase vaccines for underinsured clients and uninsured adults in LHDs, FQHCs, RHCs, and Public Hospitals, school based clinics, and for outbreak control
- State funds are used to support code-required vaccine for non-VFC eligible patients in LHDs, and adult immunizations. (Refer to billing policies for local health departments)

Section 317 and State funds supporting public providers expand the eligibility criteria in public settings as seen by the shaded portion of the table below. Use the table below to determine if a patient is eligible for vaccine provided by DOI. You need to know:

- 1) Type of provider seeing the patient (left column)
- 2) Does the patient meet at least one of the eligibility criteria for that setting?

Provider Classification	Eligibility Classification					Adults ≥ 19 years of age
	Children <19 years of age					
(PIN Prefix)	Medicaid NOT FAMIS	Uninsured	AI/AN	Underinsured*	Insured child/Code Required	Uninsured & Under-insured*
Private Physician (Ps)	VVFC Eligible	VVFC Eligible	VVFC Eligible			
Local Health Department (FIPS Code)	VVFC Eligible	VVFC Eligible	VVFC Eligible	(State/317) Eligible	(State) Eligible	(State/317) Eligible
FQHC/RCH (Fs)	VVFC Eligible	VVFC Eligible	VVFC Eligible	VVFC Eligible		(State/317) Eligible
Public Hospital (As)	VVFC Eligible	VVFC Eligible	VVFC Eligible	(State/317) Eligible		(State/317) Eligible
VVFA sites (Oth PIN Prefixes)						(State/317) Eligible

*2012 CDC policy change to use Section 317 funds and the federal contract for uninsured and underinsured children and adults. Note: Eligibility for federally purchased vaccine changes during CDC-declared outbreak response.

Out of State Eligible

Patients should be vaccinated with vaccine supplied by the state in which the provider/facility is located. Facilities should include border state children served by their practice in their population estimates on the provider agreement. For children covered under Medicaid, bill the administration fee to the state providing the child’s Medicaid coverage.

Medicaid

- Department of Medical Assistance (DMAS) will reimburse \$11 for all shots administered to VFC eligible clients. DMAS will also reimburse for the appropriate office visit fee on the same date as the vaccination reimbursement.

Reimbursement is paid per vaccine CPT code billed. For example, 90715 Tdap will reimburse at \$11 when the “shot” code is billed. Billing requirements may vary for MCOs.

- For Adult (non-VFC-eligible) patients DMAS will reimburse for cost of vaccines (CPT codes) and an appropriate office visit fee if the vaccine is determined to be medically necessary, or is covered by Medicaid Expansion. Use privately purchased vaccine when requesting reimbursement. Note: It is fraudulent to request reimbursement for vaccine provided free of charge.
- DMAS will not reimburse for an administration fee using CPT 90460-90461.

Screening Documentation

DOI provides federally and state purchased vaccine at no charge to providers for administration to eligible patients. To ensure DOI supplied vaccine is administered to eligible patients, each patient should be screened at each patient visit. Screening forms at <http://www.vdh.virginia.gov/immunization/> may be used or you may create a similar form. The VVFC office must approve all alternative screening methods.

AGREEMENT

Terms

Updating Your Agreement

Terms

The signed provider agreement form describes eligibility criteria discussed earlier, and program requirements. The agreement states but is not limited to the following:

- VFC providers may not store federally purchased vaccine in dormitory style refrigerators at any time
- Providers will replace vaccine lost due to mismanagement through dose-for-dose replacement

The provider agreement form with complete contract language found at the following link: <http://www.vdh.virginia.gov/immunization/>

Updating Your Agreement

Enrolled providers shall register annually to update contact information and population estimates.

You will be notified when it is time to update your agreement. In order to maintain current enrollment status, your practice will have approximately 30 days to return the agreement form to the Division of Immunization.

Although the VVFC and/or VVFA Program Provider Agreement is updated annually, please notify the DOI vaccine management office of new contacts, changes in mailing addresses, shipping addresses, practice hours, email addresses, and physicians as they occur. This helps ensure our data is current and that you receive your vaccine products in a timely and efficient manner.

ORDER CENTER

Vaccine Availability
When to Order Vaccines
Direct Ship Vaccine
Missing or Incorrect Shipments
Vaccine Holds

Vaccine Availability

All ACIP recommended vaccines may be ordered through the Virginia Department of Health, Division of Immunization. The Centers for Disease Control and Prevention (CDC) negotiates the pediatric and adult vaccine contracts with the vaccine manufacturers. When a particular brand of vaccine is not available, it may be due to constraints or limitations imposed by CDC or a vaccine manufacturer. If this occurs, the DOI will provide guidance on available options. The DOI Order Center may adjust orders based on population estimates, or vaccine usage patterns. Order adjustments are rare and occur when there are vaccine supply issues or excessive wastage patterns.

When to Order Vaccines

CDC recommends smaller, more frequent orders rather than large orders to minimize the amount of vaccine loss if an incident occurs during shipment or in the vaccine storage unit. It is important to conduct a thorough vaccine inventory and order accordingly. Do not wait until you are almost out of vaccine before ordering. Re-order when you have about **four weeks** of inventory on hand. Do not order vaccine if your facility is going to be closed for a holiday or an extended vacation.

Direct Ship Vaccines (Varicella & MMRV)

The special shipping and storage conditions associated with direct-ship vaccines, Varicella and MMRV, require shipment directly from the manufacturer (Merck). They will arrive separately from the rest of your order. Your facility should have procedures in place for immediate receipt and storage of these vaccines due to their temperature sensitivity.

Missing or Incorrect Shipments

If your vaccine does not arrive, call the DOI Order Center so we can track your order.

If you receive an incomplete or inaccurate order, please contact the DOI Order Center immediately. Check the packing slip against your order to see if it is correct. You may be asked to check your stock by lot number to make sure you did not overlook receipt of the order. It is recommended that you keep your packing slips.

Vaccine Holds

If your facility has been identified as having inadequate vaccine storage, excessive vaccine wastage, or other program violations, a temporary hold on vaccine ordering may be activated. The vaccine ordering hold will be lifted once the problem has been corrected.

INVENTORY

Storage and Handling
Temperatures
Accountability
Rotating Stock
Vaccine Returns
Vaccine Borrowing
Vaccine Loss Due to Negligence

Storage and Handling

It is important that all staff members recognize a vaccine delivery and know what to do upon its arrival. The shipment needs to be checked and stored in the refrigerator or freezer right away. Your facility should have procedures in place for immediate receipt and storage of vaccine due to its temperature sensitivity.

Separate refrigerator and freezer units are recommended for storing vaccine. CDC recommends the use of purpose-built or pharmaceutical/medical grade units when possible. Refrigerators or freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required vaccine storage temperatures year-round
- Be large enough to hold the year's largest inventory (considering flu & back-to-school seasons)
- Have a working certified data logger inside each storage compartment with a current and valid certificate of calibration testing
- Be dedicated to the storage of vaccines

Dormitory-style refrigerators are not adequate for storage of vaccines because they do not maintain appropriate temperatures. Dormitory style refrigerators are never acceptable for permanent storage of vaccines. Storage units must be free of any food or drink. For additional information on vaccine storage and handling requirements, please refer to CDC's Vaccine Storage and Handling Toolkit available online at:

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

Your Emergency Response Plan should be posted on or near your storage unit and must be updated on an annual basis. All staff should be familiar with your practice's written Emergency Response Plan for vaccine retrieval and storage in the event of a power outage or mechanical failure. All vaccine storage and handling plans must include the date, signature, and name of the preparer of the documents.

Temperatures

Continuous temperature monitoring is required for all VVFC and VVFA providers. Temperature monitoring devices must meet CDC's requirements listed here:

<http://www.vdh.virginia.gov/content/uploads/sites/11/2016/04/TemperatureMonitoringandCalibrationChecklist.pdf>

Keeping temperature logs of vaccine storage units to monitor viability of vaccines is required. Logging temperatures twice daily ensures appropriate temperatures are being maintained. Each temperature reading must be accompanied by (1) the time of the reading (min/max) and (2) the name (or initials) of the person who assessed and recorded the reading. Document each corrective action whenever temperatures are reported outside of the required range.

Retaining temperature logs (electronic and manual) for a minimum of three years is required.

VFC providers are required to have at least one back up thermometer with a current certificate of calibration on hand (not stored in unit alongside current thermometer).

Accountability

Vaccine accountability is monitored through use of the Virginia Immunization Information System (VIIS). Additional accountability reporting is required for local health departments (LHDs). LHDs are required to submit quarterly inventories to the Division of Immunization. District accountability reports are created using inventory and WebVision data. The quarterly reports are posted to the VDH internal website. Localities will be reminded of the due dates for inventory reports.

Rotating Stock

Organize your DOI supplied vaccine stock so doses with earlier expiration dates are used first. Upon receiving a shipment of vaccine, check expiration dates and store the earliest expiration dates in the front and the latest expiration dates in the back of the appropriate storage unit.

Vaccine Returns

Please report any expired, spoiled, wasted, or transferred vaccine supplied through DOI. To reduce wastage, contact the VVFC program to assist in transferring overstocked vaccine to a nearby provider. The return/transfer form is located here: <http://www.vdh.virginia.gov/immunization/>

Vaccine Borrowing

If your practice does not have DOI supplied vaccine in stock and an eligible child needs vaccinations, you may use vaccine from your private stock to immunize the child. Usage of your private stock vaccine should be documented on the borrowing form. Once vaccine is received from DOI, you may administer corresponding number of doses to privately insured patients and document each dose on the borrowing form. Instances of borrowing should be rare and unplanned.

Vaccine Loss Due to Negligence

The Division of Immunization will require providers to reimburse the program for vaccine that has been wasted due to negligence or failing to correctly store, handle, or transport vaccine. Negligence is defined as loss of vaccine on the part of the provider/clinic staff.

The following situations qualify in this category:

1. Vaccine stored improperly (i.e., refrigerating vaccine that should have been frozen, or freezing vaccine that should have been refrigerated)
2. Vaccine left out of refrigerator or freezer
3. Refrigerator or freezer unplugged or electrical service interrupted (circuit breaker)
4. Leaving the door of refrigerator or freezer ajar resulting in temperatures falling below the acceptable range
5. Prolonged storage of vaccines when temperatures are recorded out of range resulting in vaccine spoilage
6. Failure to properly read and record refrigerator and freezer temperatures, and/or failure to take immediate corrective actions when temperatures are out of appropriate range.
7. Pre-drawing or pre-mixing vaccine, then not administering in accordance with vaccine manufacturer/CDC recommendations
8. Transporting vaccine inappropriately, thus not maintaining the cold chain
9. Failure to notify the Order Center when provider office hours change or the practice moves, resulting in vaccine spoilage
10. Discarding vaccine prior to the manufacturer's stated expiration date
11. Expiration due to over-ordering. Providers should notify the VVFC program three months prior to expiration date of vaccine they cannot use to arrange for a vaccine transfer
12. Failure to rotate stock appropriately
13. Using dorm style refrigerators or using improper refrigeration unit to store the vaccine
14. Not using a certified thermometer and/or incorrect placement of the thermometer

Note: Temperatures recorded on temperature logs are considered official documents when making vaccine viability decisions. A thermometer's margin of error is not considered when temperatures are recorded at or below 36°F/2°C for refrigerators and at or above 5°F/-15°C for freezers.

Reimbursing the VVFC Program for wasted vaccine:

1. Instances of spoiled or expired vaccine supplied by DOI will be reviewed on a case-by-case basis. This review will help determine whether negligence was involved.
2. Excessive waste of vaccine may be determined to be abusive and will be evaluated in accordance to fraud and abuse policies.
3. If negligence is found and restitution is necessary, DOI will send the provider a letter informing them of the request for restitution.

SITE VISITS

Overview of Site Visits

Types of Site Visits

Requesting Help

Overview of Site Visits

Federal guidelines require on-site visits with VVFC enrolled providers. CDC has developed standardized web-based tools for collecting data which is submitted at the time of the visit. Therefore an internet connection is requested to complete these visits.

The VFC Compliance Visit evaluates the provider's compliance with program requirements using a CDC developed, web-based data collection tool called Provider Education Assessment and Reporting (PEAR).

The VFA Compliance Visit evaluates the provider's compliance with program requirements, as well.

Types and Purposes of VVSA Site Visits

Enrollment Visits (Member < 90 days): These visits are for newly enrolled providers in the VVFC/VVFA program. The Consultant visits the provider and educates all appropriate staff members on program implementation. These site visits last approximately one hour. The consultant discusses program requirements and reviews 3 to 5 charts primarily to determine if the practice is already documenting appropriately. The consultant's findings are shared with the provider at the conclusion of the visit.

VVFC/VVFA Compliance Visit: These are the most common type of visits that the consultants perform. A VVFC/VVFA site visit is a formal visit to enrolled providers for the purpose of evaluating the provider's compliance with VVFC/VVFA program requirements. These visits evaluate the following components of vaccine management:

1. Review of vaccine management plan for appropriate vaccine handling, storage and ordering procedures. This includes a physical inspection of vaccine storage units, temperature measuring devices, twice daily temperature recording, vaccine accountability, procedures for vaccine retrieval and storage in times of emergencies, and inventory management, including stock rotation to prevent outdating.
2. Proper documentation of eligibility status.
3. Compliance with documentation and record retention requirements. This includes distribution of current Vaccine Information Statements and maintaining records in accordance with the National Childhood Vaccine Injury Act.
4. Compliance with other program requirements. This includes not charging for the cost of the vaccine, not charging a vaccine administration fee that is higher than the maximum fee established by the state, and agreeing not to deny vaccinations because of inability to pay a vaccine administration fee.

5. Review of coordinator and back-up coordinator training documentation.

A Follow-up Plan is provided at the conclusion of the visit and if necessary a corrective actions are assigned. This visit lasts approximately two hours.

Immunization Quality Improvement for Providers (IQIP) site visit: The Centers for Disease Control and Prevention (CDC) IQIP program is a quality improvement program for healthcare providers enrolled the VVFC program. The goal of IQIP is to increase vaccination of children and adolescents with all Advisory Committee for Immunization Practices (ACIP)-recommended vaccines by reducing missed opportunities to vaccinate and improving immunization delivery practices at the provider level. IQIP focuses on provider immunization workflow and 3 core quality improvement strategies (giving a strong vaccine recommendation, leveraging IIS functionality to improve immunization practice, and scheduling next immunization visit before the patient leaves the office). Please allow 2 hours for these reviews.

Educational Visit: These visits are often requested to increase knowledge and understanding on vaccine handling and storage and the VVFC/VVFA program. These visits are tailored to fit the groups' individual needs/requests and vary in duration. **Storage Check Visit:** This is a visit where storage temperatures/conditions are checked. Due to the variation of conditions, these visits vary in duration.

Site Visit Follow-up: A VFC site visit follow-up is defined as any contact made with an enrolled provider. For example, follow-up may occur to remind a provider that documentation is needed.

Unannounced Storage and Handling Visit: The purpose of a storage and handling site visit is to assess a provider's compliance with and knowledge of VFC storage and handling requirements. Unannounced storage and handling visits are performed on 20% of enrolled and active providers and usually take less than an hour.

Requesting Help

DOI staff is available to help you. A provider can request assistance, educational materials, or guidance from the Division of Immunization. To make a request, contact your regional consultant or the Central Office at (800) 568-1929.

ADDITIONAL RESOURCES

Please visit the following web addresses for additional or supplemental information related to the Virginia Vaccines for Children program.

Transport Guidance:

<http://www.vdh.virginia.gov/content/uploads/sites/11/2016/01/VaccineInventoryManagementTransportPreparation.pdf>

VVFC Home Page: <http://www.vdh.virginia.gov/immunization/vvfc/>

VVFA Home Page: <http://www.vdh.virginia.gov/immunization/vvfa/>

CDC Home Page: <http://www.cdc.gov/vaccines/programs/vfc/index.html>

Recommended Childhood and Adolescent Immunization Schedules:

<http://www.cdc.gov/vaccines/schedules/index.html>

CDC Recommended Vaccine & Immunization Guidelines:

<http://www.cdc.gov/vaccines/recs/default.htm>

Vaccine Adverse Event Reporting: <http://vaers.hhs.gov/professionals/index>

Epidemiology and prevention of Vaccine Preventable Diseases (The Pink Book):

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

The ACIP-VFC Vaccine Resolutions:

<http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>

National Immunization Survey Data: <http://www.cdc.gov/nchs/nis.htm>

Information on FAMIS and FAMIS Plus:

https://www.coverva.org/main_programs.cfm

Vaccine Information Statements (VISs)

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