

DELAWARE VACCINES FOR CHILDREN PROGRAM

Policies and Guidelines

Effective March 2012

Provider Enrollment

Any qualifying practitioner authorized to administer pediatric vaccines under state law and interested in providing routine childhood vaccines through the Vaccine for Children (VFC) program is eligible to enroll with the Delaware VFC Program. The administrative requirements to enroll include:

1. Signing a Provider Enrollment Agreement to follow the Delaware VFC Program policy and guidelines,
2. Completing a Provider Profile form, and
3. Successfully completing an initial site visit.

Delaware's VFC providers receive free-federally funded vaccine to be administered to VFC eligible patients. Enrolled providers receive an \$8.00 administration fee for each vaccine administered to a VFC eligible patient, including uninsured VFC eligible patients.

Patient Eligibility

All providers must screen every child at each immunization visit for VFC eligibility. VFC eligibility does not have to be verified by the provider, but must be documented. The Delaware VFC Program has screening eligibility forms (*Patient Eligibility Screening Record*) available for use by enrolled VFC providers. Use of this form is not mandatory. Enrolled providers may choose to create their own form but the necessary information must be captured. Patient eligibility status information must be retained and able to be retrieved in the patient's record for three (3) years. All children 0-18 years of age who meet one of the following criteria are considered VFC eligible:

- a. Is enrolled in Medicaid,
- b. Has no health insurance,
- c. Is a Native American or Alaskan Native as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603), or
- d. Is underinsured. Underinsured children have private health insurance but the coverage does not include vaccines; the coverage includes only selected vaccines (the child is VFC eligible for non-covered vaccines); or, children whose insurance caps vaccine coverage at a certain amount (once the coverage amount is reached, these children are categorized as underinsured). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC).

Vaccine Ordering

Enrolled providers are responsible for the proper maintenance of their vaccine inventories and for ordering vaccine in the appropriate amounts. Vaccine orders will be placed by faxing a completed *VFC Vaccine Order Form* to the VFC program. Orders must include current inventory of VFC vaccine. Orders may take up to three (3) weeks to process. Providers are expected to maintain a five (5) week inventory and order vaccines in a manner that enables the provider to support that inventory. Vaccine inventory records, including packing slips must be maintained for three (3) years. Vaccine inventory records may be reviewed during VFC site visits to ensure proper safeguarding and accountability of federally-funded vaccines.



Short Dated Vaccine

Short dated vaccines must be reported to the VFC Program 60-90 days prior to expiration. The VFC Program will manage the transfer of vaccine to another provider so that it may be used prior to expiration. All VFC vaccine transfers will be coordinate through the VFC Program. If short-dated vaccine is identified, the provider will complete the *Short Dated Vaccine Report* form and submit to the VFC Program. In rare circumstances, the provider may be given instructions from the VFC Program to complete the transfer of the vaccine following the *Guidelines for Transporting Refrigerated Vaccine*.

Expired/Spoiled/Wasted Vaccine

Vaccines that are expired/spoiled/wasted must be returned for excise tax credit and waste accountability. All returned VFC vaccine is monitored and accounted for by the VFC Program using the CDC database. Vaccine cannot be returned to the CDC vaccine depot (McKesson) without notification to the VFC Program. The process for the return of vaccine is as follows:

1. Complete the *Vaccine Return Form*.
2. Fax the completed form to the VFC Program.
3. The VFC Program will supply a return shipping label to the provider.
4. Prepare the vaccine for return to McKesson by
 - a) Put spoiled or expired vaccine in a Ziploc bag or line the box for the return to prevent vaccine leakage. Include crumpled paper or bubble wrap to support the vaccine. You may rubberband or separate vaccine by type in the Ziploc bags.
 - b) Include a copy of the *Vaccine Return Form* originally submitted to the VFC Program.
 - c) Spoiled or expired vaccine must in the original vial or pre-filled syringe. Do not send multi-dose vials from which some doses have already been withdrawn. Multi-dose vials from which some doses have been withdrawn should be disposed of properly according to usual medical biosafety procedures. The following should NEVER be returned to McKesson:
 - Syringes you filled yourself but did not use,
 - Any used syringes with or without needles attached, and/or
 - Broken vials
 - d) Mail the package using the return shipping label received from the VFC Program.

Providers will be held accountable for excessive loss of vaccine caused by spoilage, waste or expiration. The *Non-Compliance with VFC Provider Requirements Protocol* will be used to determine outcomes from mishandling or improper storage or VFC vaccine.

Vaccine Brand Choice

The Delaware VFC Program allows enrolled providers the discretion to choose which vaccine brands will be used in their office. The *Vaccine Ordering Form* is updated on a regular basis to allow for new presentations of vaccines, as well as the availability of vaccines through McKesson Distribution.

Enrolled VFC providers shall administer all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and shall comply with the immunization schedule, dosage, and contraindications that are established by the ACIP and included in the VFC Program unless:

- a. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate
- b. The particular requirements contradict state law pertaining to religious and other exemptions.



Resources

The Delaware VFC Program has related forms and educational resources available at no cost to providers. Available resources can be ordered by completing a *VFC Forms Request* and submitting to the VFC Program by fax or mail. Forms and related resources may also be obtained through the website:

<http://www.dhss.delaware.gov/dph/dpc/immunize.html>

Vaccine Administration

Parents or guardians must be provided a copy of the appropriate *Vaccine Information Statement* (VIS) prior to each vaccine administered. VIS's are available for download on the CDC's website:

<http://www.cdc.gov/vaccines/pubs/vis/>

A copy of the VIS will go out from the Delaware VFC Program to enrolled providers via blast fax or email anytime there is an update or a new VIS is added. VIS's are also available for printing through the DelVAX registry. The National Childhood Vaccine Injury Act requires that the following vaccine and administration information be recorded and maintained in the child's record. Enrolled providers may use the Vaccine Administration Record form created by the Delaware VFC Program or they may choose to create their own form. The following elements must be present in the recording document or Electronic Medical Record/Electronic Health Record (EMR/EHR). This information must be retained by the vaccine provider for three (3) years.

1. Type of vaccine (DTaP, MMR, etc.),
2. Name of the vaccine manufacturer,
3. Lot number,
4. Name, title, and business address of the healthcare professional administering the vaccine,
5. Date vaccine was given (month, day, year),
6. Specific site where vaccine was given, and
7. VIS version date and date the VIS was provided to the parent or guardian.

(Resource: <http://www.cdc.gov/vaccines/pubs/vis/vis-facts.htm>)

Vaccines must be administered in accordance with the *Recommended Childhood Immunization Schedule*, approved by the ACIP. The current *Recommended Childhood Immunization Schedule* must be prominently displayed.

Pre-drawing vaccine into syringes is not an acceptable practice. Providers should draw vaccine only at the time of administration to ensure that the cold chain is maintained and the vaccine is not inappropriately exposed to light.

Vaccine administration procedures must be posted in an easily observable location for staff administering VFC vaccines.

Delaware law prohibits the administration of immunizations containing mercury to a child under eight (8) years of age or to pregnant women.

<http://delcode.delaware.gov/title16/c005/sc01/index.shtml>



Reporting Administered Immunizations

Delaware has a mandatory reporting law for all immunizations administered in Delaware. The complete regulation may be found at the following website:

<http://regulations.delaware.gov/AdminCode/title16/4000/4200/4202.shtml#TopOfPage>

An enrolled VFC provider must submit completed *Immunization Reporting Forms* to the Immunization Program on a regular basis. A completed *Immunization Reporting Form* must indicate VFC eligibility in order for the proper processing of the VFC claim and the \$8.00 administration fee to the VFC provider.

VFC Vaccine Borrowing

VFC- enrolled providers are expected to maintain an adequate stock for both VFC and non-VFC eligible patients. The provider must assure that borrowing of VFC vaccine will not prevent a VFC eligible child from receiving a needed vaccination because a VFC vaccine was administered to a non-VFC eligible child. Borrowing of VFC vaccine is strongly discouraged, however, it is understood that on certain occasions borrowing may be necessary. Borrowing may only occur when there is lack of appropriate stock due to unexpected circumstances such as a delayed vaccine shipment, vaccine spoiled in transit to provider, or new staff that calculated ordering time incorrectly. VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory. Information must be documented on the *VFC Two-Directional Vaccine Borrowing Form* and maintained for a minimum of three (3) years. Replacement of borrowed VFC vaccine is dose-for-dose.

VACCINE MANAGEMENT

Vaccine Personnel

Providers must designate one staff member to be the primary vaccine coordinator and at least one back up vaccine coordinator, who is able to perform the same responsibilities as the primary coordinator in the event that the primary person is unavailable. These positions will be responsible for key requirements and will provide oversight for all vaccine management within the office. The designated vaccine coordinator and backup are responsible for the following vaccine management activities:

- Documenting the temperature, twice a day, on the temperature logs for each vaccine storage unit;
- Adjusting the temperature of the vaccine storage unit, if needed;
- The primary vaccine coordinator reviews temperature logs weekly when daily monitoring is being conducted by staff other than the primary vaccine coordinator to ensure proper temperature recording. The backup vaccine coordinator will monitor the temperature logs if the primary vaccine coordinator is unavailable;
- Following the office's vaccine storage and handling plan. A simple log sheet with the staff member's name and date of training should be kept as documentation.

Unless otherwise noted, the vaccine coordinator and/or backup will be the immunization contact(s) for the office.

VFC providers may call the VFC Program at any time to request additional education for new or continuing staff members.



Vaccine Security and Equipment Maintenance

Providers must post warning notices at both the electrical outlet and the circuit breaker of every storage unit to prevent power from being disconnected. Safeguard vaccine by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.

Vaccine Storage Practices

The vaccine storage practices listed below can be the responsibility of the vaccine coordinator or can be delegated to another staff member. If the practices are delegated, the vaccine coordinator must monitor the activity.

- Mark and/or separate VFC supplied vaccine from private purchase vaccine. Indicate VFC vaccine by placing a “VFC” sticker (provided by VFC Program) on the VFC vaccine in order to distinguish the vaccine from private stock.
- Rotate vaccine stock by placing vaccines with shorter expiration dates in front of those with longer expiration dates; check for short-dated vaccine.
- Notify the VFC Program within 60-90 days of any vaccines that will expire before they can be administered. Only with the approval and direct guidance of the VFC Program and only if the cold chain can be ensured, redistribute short-dated vaccine to providers who are able to administer it before the vaccine expires.
- Store vaccines requiring refrigeration in the middle of the refrigerator compartment away from the coils, walls, floor, and cold air vent.
- Store vaccines that require freezer storage in the middle of the freezer compartment, away from the walls, coils and peripheral areas.
- Space stored vaccine to allow for cold air circulation around the vaccine.
- Do not store vaccines in the door of the storage unit.
- Remove vegetable bins from the refrigerator; replace with cold water bottles.
- Stabilize refrigerator or freezer temperatures with proper placement and use of water bottles and frozen packs.
- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily visible.
- Store vaccine products that have similar packaging in different locations to avoid confusion and medication errors.

Storage and Handling Plans

Providers may develop their own written routine or procedures for storage and handling plans. The storage and handling plan should be simple and the processes outlined in the plan should be presented in a clear and concise manner.

- Routine vaccine storage and handling plans should include guidance on the following aspects of routine vaccine management:
 - Ordering vaccines
 - Controlling inventory
 - Storing vaccines and monitoring storage conditions
 - Minimizing vaccine wastage
 - Vaccine shipping, including receiving, packing and transporting



Emergency/ Contingency Plan

Providers may develop their own written emergency/ contingency plan or use the template developed by the VFC Program. The plan should include guidance on what to do in the event of refrigerator or freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions. The emergency plan should include the following:

- Person(s) responsible for preparing and transporting vaccine, including contact information.
- Receiving facility information- location and contact person that will receive vaccine. Including date of agreement with receiving facility.
- How receiving location will be notified of transport.
- How to pack vaccine for transport.
- Worksheet to document vaccine involved in power or equipment failure.

At a minimum, both the storage and handling plan and the emergency/ contingency plan must be reviewed and updated annually. For example, when there is a change in staff responsibilities specified in the emergency/ contingency plan.

VACCINE STORAGE EQUIPMENT

Storage Units

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. All VFC providers must have acceptable storage units (listed below) prior to receiving vaccine. Providers that do not have acceptable storage units will not be shipped vaccine.

Two types of acceptable storage units:

1. A refrigerator that has a separate freezer compartment with a separate exterior door and dual temperature controls, or
2. Stand-alone refrigerators and freezers.

Dormitory style refrigerators are not acceptable storage units.

Refrigerators and 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.
- Be dedicated to the storage of vaccines. No food or beverage should ever be placed in the unit.

Thermometers

Vaccine storage units must be equipped with certified calibrated temperature monitoring devices. Temperature monitoring devices must be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instructions used during calibration of the product are traceable to an ISO/IEC 17025 accreditation testing laboratory, or the National Institute of Standards and Technology.

Temperature monitoring devices should be placed in the center of the storage unit compartment, preferably on the middle shelf or hanging from the upper shelf.



Temperature Monitoring

Temperature monitoring should be the primary responsibility of the vaccine coordinator and backup. If other staff must monitor temperatures, they must be trained how to respond and document actions taken when temperatures are outside the appropriate range.

- Post a temperature log on the vaccine storage unit door or nearby in a readily accessible place.
- Record on the temperature log, refrigerator and freezer temperatures twice each day (beginning and end) ensuring that refrigerator temperatures are between 35°F and 46°F (2°C and 8°C). The freezer temperature should be 5°F or lower (-15°C or lower). Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used. The actual temperature is required on the temperature log. Temperature logs may be obtained through the VFC Program at no cost to the provider.
- Take immediate action to correct improper vaccine storage conditions, including inappropriate exposure to light and inappropriate exposure to storage and temperatures outside the recommended ranges. Document actions taken on the *VFC Incident Report for Temperatures Outside of Normal Range* form and submit the completed form to the VFC Program. Contact the VFC Program as soon as possible.
- Maintain an ongoing file of temperature logs and store completed logs for three years.

Temperature Incidents (Out of Range Temperatures)

Immediate corrective action must take place when vaccine storage temperatures are found to be outside of the acceptable temperature ranges. Providers must notify the VFC Program if a facility has had a temperature incident. After determining the scope of the temperature incident, the program will work with the provider and vaccine manufacturers to assist in determining if the vaccines are viable. Contact the VFC Program by calling 800-282-8672.

Unreported Temperature Incidents

Providers who fail to report a temperature incident where vaccines are stored outside of the normal temperature range are considered non-compliant with VFC requirements. The VFC Program will determine outcomes from non-compliance issues by utilizing the *Non-compliance with VFC Provider Requirements Protocol*.

Vaccine Shipments

Providers must:

- Immediately check vaccine cold chain monitors and document on the packing slip shipments that arrive with a monitor that was activated.
- Take proper action if the cold chain monitor was activated. Store the vaccine appropriately by labeling “Do Not Use” and place in storage unit until vaccine is confirmed as non-viable or viable.
- If the provider believes that a vaccine shipment is compromised, temperatures are out of range, or a cold chain monitor indicates the vaccine may be compromised, the provider must contact the VFC Program within two (2) hours of receipt of the vaccine shipment. If this is outside of the VFC Program’s regular business hours, the provider must contact McKesson Customer Service within two (2) hours of the vaccine shipment delivery time at 1-877-836-7123.
- Develop a policy, complete with protocols and procedures, for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. See guidelines: *Transporting Refrigerated Vaccines*, (<http://www.eziz.org/assets/docs/IMM-983.pdf>).



Fraud and Abuse

The VFC Program is required to report suspected VFC fraud and abuse to state and federal authorities. Suspected VFC fraud and abuse will be reported according to Delaware's Division of Public Health, *Policy Memorandum Number 58- Immunization Program Vaccine Fraud and Abuse Policy*. The following are general examples of fraud and abuse that require corrective actions to take place:

- Providing VFC vaccine to non-VFC-eligible children.
- Selling or otherwise misdirecting VFC vaccine.
- Billing a patient or third party for VFC vaccine.
- Charging the parent/guardian/patient for the administration of a VFC vaccine to a publicly-funded vaccine eligible child.
- Not providing VFC-eligible children VFC vaccines due to a parent/guardian's inability to pay.
- Not implementing provider enrollment requirements of the VFC Program.
- Failing to screen patients for VFC eligibility.
- Failing to maintain VFC records and comply with other requirements of the VFC Program.
- Failing to fully account for VFC vaccine.
- Failing to properly store and handle VFC supplied vaccine.
- Ordering VFC funded vaccine in quantities or patterns that do not match provider profile or otherwise involves over-ordering of VFC vaccine.
- Wastage of VFC vaccine.

All reported suspect cases of fraud and/or abuse will be investigated to determine the intent of the provider. If it is found that the intent was to commit fraud and/or abuse, a formal investigation referral will be made. In the event that the fraud and/or abuse was/is due to oversight in training, an education resolution referral will be made.

Quality Assurance

The VFC Program will conduct annual quality assurance site reviews at provider's offices. These site visits will review compliance with the VFC Program requirements including:

- VFC screening and eligibility
- Patient chart review
- Vaccine storage and handling
- Vaccine administration
- Vaccine accountability
- General immunization knowledge
- Assessment of immunization coverage levels

Site visits are scheduled in advance. A final report, including immunization rates, will be given to all offices following the visit.

National Vaccine Injury Act

A Vaccine Adverse Event Reporting System (VAERS) report form must be completed and forwarded to the VFC Program for the adverse events (following immunization), which are listed in the National Childhood Vaccine Injury Act (NCVIA) Injury Table at <http://www.hrsa.gov/vaccinecompensation/vaccinetable.html>. A report of a death following immunization must be immediately reported to Delaware's Immunization Program at 800-282-8672.



Technical Assistance

Immunization Program staff are available to answer questions or provide additional immunization information by calling 800-282-8672 or (302) 744-1060, Monday thru Friday between 8:00 A.M. and 4:30 P.M. Additional information can be found 24 hours a day, seven days a week at <http://www.dhss.delaware.gov/dhss/dph/dpc/immunize.html>.

Continuing Education

The VFC Program will provide on-site education for new and continuing staff members of VFC providers. To request additional education contact the VFC Program, 800-282-8672 or (302) 744-1060.

List of Excluded Individuals and Entities

VFC enrolled providers must ensure no staff member, hired or contracted with their practice, is listed on the *List of Excluded Individuals and Entities* administered and published by the Department of Health and Human Services (HHS), Office of Inspector General (OIG): <http://oig.hhs.gov/fraud/exclusions.asp>. Hiring of a person listed on the *List of Excluded Individuals and Entities* will result in termination from Delaware's VFC Program. Notification will be sent to the state Medicaid agency.

Reference

Vaccines for Children Operation Guide, <http://www.cdc.gov/vaccines/programs/vfc/operations-guide.htm>, Centers for Disease Control and Prevention

Vaccine Storage and Handling Toolkit, Centers for Disease Control and Prevention

Vaccine Storage and Handling Guide, Centers for Disease Control and Prevention, December 2011, <http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf>

Delaware Code, Title 16- Health and Safety Regulatory Provisions Concerning Public Health, Chapter 5. Contagious Diseases Generally, Subchapter I. General Guidelines, §510. Immunization Containing Mercury. <http://delcode.delaware.gov/title16/c005/sc01/index.shtml>

9DE Reg. 1188, 7.0 Control of Specific Contagious Diseases, <http://regulations.delaware.gov/AdminCode/title16/4000/4200/4202.shtml#TopOfPage>

