



Department of
Public Health
CITY OF PHILADELPHIA
LIFE • LIBERTY • AND YOU™



Vaccines for Children (VFC) Program Manual 2016

<http://kids.phila.gov/>

Updated: January 2016

Philadelphia Immunization Program
Division of Disease Control
500 S. Broad St.
Philadelphia, PA 19146

Contents

Section 1: Getting Started as a VFC Provider	3
Background of the VFC Program.....	3
Benefits to Providers and Patients.....	3
Provider Responsibilities Overview	4
Enrolling as a VFC Provider	5
Section 2: Ordering Vaccines from VFC	6
Philadelphia VFC Vaccines	6
Ordering VFC Vaccines	6
Section 3: Provider Responsibilities for VFC	8
Patient Eligibility and Screening.....	8
VFC Fees and Finance.....	9
Compliance with the ACIP Recommended Schedule.....	9
Record Keeping	10
Vaccine Information Statements (VISs)	10
Adverse Event Reporting	11
Reporting to KIDS Plus Immunization Information System (IIS)	12
Reportable Diseases.....	12
Site Visits: Provider Quality Assurance	13
Pharmaceutical Representatives	14
Section 4: Vaccine Storage and Handling.....	15
Office Management and Staff Training.....	15
Receiving Vaccine Shipments.....	15
Separating VFC and Private Vaccine	16
Proper Vaccine Storage Techniques	17
Equipment: Refrigerators, Freezers, Alarms and Thermometers.....	17
Refrigerators & Freezers	17
Digital Data Logger Thermometers.....	18
Alarm Systems.....	18
Maintaining and Documenting Storage Temperatures	19

Out-of-range Storage Temperatures 19

Emergency Plans 19

Section 5: Vaccine Accountability20

Changes in a Practice 20

Nonviable VFC Vaccine 20

Transporting and “Borrowing” Vaccine 21

Grounds for Suspension from VFC..... 22

Fraud and Abuse 22

Section 1: Getting Started as a VFC Provider

Background of the VFC Program

The Vaccines for Children (VFC) Program is a vaccine supply program that allows enrolled health care providers to give free immunizations to eligible children. By removing financial barriers to immunization for both patients and providers, VFC:

- Facilitates timely and age-appropriate immunizations for children.
- Reduces referrals to public clinics for immunizations.
- Facilitates children's return to a medical home for comprehensive care.
- Offers substantial cost savings to enrolled providers.

The Philadelphia VFC Program provides federally purchased vaccine to both public and private immunization providers for children from birth through 18 years of age who are:

- Medicaid-enrolled
- Uninsured
- Underinsured (eligible through a Federally Qualified Health Center only)
- or American Indian/Alaskan Native

VFC was created by the Omnibus Budget Reconciliation Act of 1993 and implemented in 1994 as a new entitlement program to be a required part of each state's Medicaid plan. The Centers for Disease Control and Prevention (CDC) purchases vaccines at a discount from manufacturers and distributes them to its grantees, which include state health departments and certain local and territorial public health agencies, including the Philadelphia Department of Public Health (PDPH). The grantees are then able to offer the vaccines at no charge to private physicians' offices and public health clinics registered as VFC providers.

VFC-eligible children are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices (ACIP) through passage of VFC resolutions. In 2015, the Immunization Program shipped over 600,000 doses of vaccine to over 200 Philadelphia County medical providers and clinics, valued at over \$25 million.

Benefits to Providers and Patients

The VFC Program reduces barriers to immunization opportunities for Philadelphia's children, helping protect them from vaccine-preventable diseases and also helping them maintain a consistent source of medical care. Children who might not otherwise have access to vaccines can receive them free of charge from VFC providers (administration and/or visit fees may be charged). VFC providers enjoy cost savings on vaccines as well as access to a variety of resources that the Philadelphia Immunization Program offers.

Benefits to Providers:

- VFC vaccine provided at no cost
- Free program participation
- Immunization coverage assessments
- Reduce families' out-of-pocket expenses
- Ensure timely vaccinations
- Keep patients in medical home for comprehensive health care
- Easier to provide high-quality care to patients
- Updates and training for staff members

Benefits to Patients:

- Ensure timely immunizations
- Reduce missed opportunities for immunizations
- No out-of-pocket costs to families for vaccines
- Easier to stay within medical home for comprehensive health care

Provider Responsibilities Overview

Providers who are part of the Philadelphia VFC Program must comply with program requirements in order to continue receiving VFC vaccines. These requirements are covered in greater detail in Sections 2 through 5, but the core responsibilities include:

- Consistent VFC eligibility screening of patients
- Administering VFC vaccine to VFC-eligible patients only
- Never denying vaccinations to VFC-eligible patients
- Never charging patients for the cost of VFC vaccine
- Ordering vaccines appropriately
- Complying with the current ACIP Recommended Immunization Schedule
- Properly documenting vaccines administered
- Providing patients and/or parents with Vaccine Information Statements (VISs) for each vaccine administered
- Reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Reporting all immunizations administered to patients to KIDS Plus Immunization Information System (IIS)
- Ensuring office staff are trained in vaccine storage and handling and vaccine administration
- Carefully managing vaccine stock through inventorying, maintaining proper storage temperatures, and the use of approved storage equipment
- Communicating any vaccine storage issues to the VFC Program immediately
- Assuming full accountability for any vaccine supplied by the VFC Program, including financial reimbursement for vaccine wastage

Enrolling as a VFC Provider

Before you submit the VFC Enrollment forms, please ensure that your office meets these qualifications. You must:

1. Serve VFC-eligible children
2. Have appropriate refrigeration and freezer units
3. Record vaccine storage temperatures twice a day
4. Submit at least 2 weeks of vaccine storage temperature records that are in-range before receiving VFC vaccine
5. Have access to the Internet to access KIDS Plus IIS
6. Register for KIDS Plus IIS
7. Enroll in the VFC Program through KIDS Plus IIS
8. Electronically report all administered vaccines to KIDS Plus IIS
9. Agree to an orientation and storage visit and comply with all storage and handling standards
10. Agree to comply with the policies and procedures stated in the Provider Enrollment form and the VFC Manual

Beginning in June 2016 all VFC enrollments will be done electronically through KIDS Plus IIS. You must log in and complete all the required fields for VFC enrollment.

*If a provider maintains multiple clinical sites, each site must be enrolled separately. Each site will order and receive vaccine separately. Transferring vaccines between sites is **not** permitted.*

Once your enrollment materials are received, a representative of the Philadelphia VFC Program will visit your site to complete an orientation and storage and handling inspection. This visit has two purposes:

1. To review VFC policies and procedures with you and your staff
2. To inspect the refrigerators and freezers to be used for vaccine storage

After the orientation has occurred and storage units are approved, a VFC PIN will be assigned to the site. The PIN is used when ordering vaccines, reporting immunizations to KIDS Plus IIS, and in general communication with the Immunization Program.

A provider may participate in the VFC Program without being a Medicaid-enrolled provider, as long as VFC-eligible children are seen in the practice. VFC providers still control which patients they accept; a private health care provider is not required to accept a child into his or her practice or clinic just because the child is eligible for VFC vaccines.

Participation in the VFC Program may be suspended or terminated at the discretion of either the VFC Program or the enrolled provider. Please see “Grounds for Suspension” in Section 5 for a list of program violations that may be cause for a provider’s suspension from VFC. If the agreement is terminated, any unused VFC vaccine must be returned.

All VFC providers are required to complete VFC enrollment forms annually, due each June.

Section 2: Ordering Vaccines from VFC

Philadelphia VFC Vaccines

The Philadelphia VFC Program offers the following types of vaccines:

- DTaP (pediatric)
- Hepatitis A
- Hepatitis B
- Hib
- HPV
- Influenza
- MMR
- Meningococcal Conjugate (MCV4)
- Meningococcal B (MenB)
- Pneumococcal Conjugate (PCV13)
- Pneumococcal Polysaccharide (PPSV23)
- Polio (IPV)
- Rotavirus
- Tdap/Td
- Varicella

The Philadelphia VFC Program also offers the following combination vaccines:

- DTaP–IPV
- DTaP–IPV–HepB
- DTaP–IPV–Hib

Occasionally, manufacturers can underestimate demand, causing a shortage of a specific product. VFC providers will be notified if there are any changes to the availability of any of these vaccines.

Ordering VFC Vaccines

Providers enrolled in the VFC Program are responsible for ordering appropriate amounts of vaccine and maintaining proper vaccine inventory. Vaccine need for a practice is based on the number of VFC-eligible children seen in a practice as reported on the Medical Practice Profile and validated by KIDS Plus IIS.

Which vaccines can I choose?

The Philadelphia VFC Program offers choices of brand and presentation (vials or syringes) for a variety of vaccines. All vaccine orders are dependent on vaccine availability at the time of the order. You can order any vaccines that you see listed in the KIDS Plus IIS order screen.

How do I know how much and how often to order?

Vaccine orders are based on many factors, including practice patient population, time of year, and storage capacity. The Philadelphia VFC Program does not require providers to order according to a particular schedule, but does expect orders to be appropriate, timely and accurate. The Philadelphia VFC Program can provide guidance to new providers unsure about quantities or ordering frequency. Some helpful guidelines for ordering include:

- Determine vaccine ordering amounts by carefully considering:
 1. Your VFC-eligible patient population.
 2. The amount of vaccine your practice can store at one time.
 3. The time of year (think about flu season and back-to-school immunizations).
- It is generally better to order more frequently, in smaller quantities; however, providers can only order VFC vaccine once a month.
- Plan accordingly to allow about 2 weeks from the time your order is properly submitted until vaccine is delivered.
- Always consider the amount of vaccine storage space in your office, remembering that pre-filled syringes use significantly more space than vial vaccines.
- Upon request, VFC can provide order histories and KIDS Plus IIS data to help you determine your ordering needs.
- Ultimately, you know your practice and patient population best, so please use your best judgment in placing your orders.
- Providers may not order VFC vaccine more than once per month (except flu).

National shortages of vaccine do occur. This may make it necessary for the VFC Program to reduce the amount of vaccine made available to providers and/or to adjust vaccine order amounts, brands, and packaging as necessary in order to ensure equitable distribution of vaccine. The VFC Program also reserves the right to adjust vaccine orders to more accurately reflect vaccine need as demonstrated through KIDS Plus IIS reporting.

How do I order VFC vaccine?

All providers must order VFC vaccine through KIDS Plus IIS. If you do not have an account you must first complete the KIDS Plus IIS enrollment and confidentiality form. Then you must complete a short training on the software. Once that is done you will be able to order VFC vaccine. For more information, visit the Vaccine Online Ordering and KIDS Plus IIS pages on the Philadelphia Immunization Program website: <http://kids.phila.gov/>

Existing providers who do not have Internet access can order via paper order forms, which can be faxed to the VFC Program. Newly enrolled providers are required to order online and must have Internet access to do so.

Section 3: Provider Responsibilities for VFC

Patient Eligibility and Screening

Providers are responsible for ensuring that VFC vaccine is administered only to eligible children and are required to maintain a Patient Eligibility Screening Record on all VFC-eligible children.

Eligible for VFC

Children are eligible for VFC vaccines in private provider offices and clinics if they are less than 19 years of age and are at least one of the following:

- Medicaid-enrolled (including Medicaid managed care plans)
- Uninsured (no health insurance)
- Underinsured (eligible through a Federally Qualified Health Center only)
- American Indian or Alaskan Native

Underinsured Children

Children who have private insurance that does not cover immunizations are not eligible to receive VFC vaccines from private providers but may be referred to public VFC sites such as Federally Qualified Health Centers (FQHCs) or Philadelphia Ambulatory Health Services (AHS). A list of FQHCs and AHS Centers in Philadelphia is available on the Immunization Program website on <http://kids.phila.gov/>.

Alternatively, underinsured children may receive privately purchased vaccines in private provider offices as self-pay patients. If a child under 19 years of age is covered by Medicaid and has private insurance, he or she is VFC-eligible, but private insurance cannot be billed for the vaccine. Income is not a criterion for VFC eligibility.

Not Eligible for VFC

- CHIP (Pa's Children's Health Insurance Plan)
- Privately-insured patients
- Anyone 19 years of age and older

Screening for VFC eligibility

VFC recommends the use of the VFC screening form found on <http://kids.phila.gov/> although providers may incorporate the information into their own practice forms.

- Screening of the child must occur at every immunization visit.
- Providers must maintain a record (paper or electronic) of the screening for at least three years after the last administered VFC vaccine. After three years have passed, these records may be archived.
- The record must be readily available, whether electronic or paper, in the provider's office.
- Medicaid providers are not required to keep separate records of VFC eligibility screening for their beneficiaries. Maintaining of Medicaid-specific documentation in a patient's chart, whether electronic or paper, is considered adequate documentation of VFC eligibility. A copy of the Medicaid card can be used.

VFC Fees and Finance

Even though VFC vaccine is supplied free of charge to enrolled providers, it does not come without cost to the Philadelphia VFC Program. VFC vaccine is purchased from manufacturers under contract using federal taxpayer dollars, which is why the VFC Program must strictly enforce its policy of holding providers financially responsible for vaccine wasted through negligence.

Other VFC Financial Responsibilities

- Do **not** charge for VFC vaccine.
- Do **not** impose a vaccine administration fee higher than the fee cap established by the Center for Medicaid and Medicare Services (CMS) and the Commonwealth of Pennsylvania, which is currently \$23.14 per vaccine.
- Do **not** deny immunization services to any VFC eligible child even if the parent or guardian is unable to pay the administration fee (applies to non-Medicaid eligible).

Compliance with the ACIP Recommended Schedule

VFC providers must comply with current immunization schedules, dosages, and contraindications as established by the Advisory Committee on Immunization Practices (ACIP). The U.S. Recommended Childhood & Adolescent Immunization Schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines for children through age 18 years. In addition:

- The VFC program makes every effort to inform providers of changes to the schedule and vaccine recommendations, but it is ultimately the providers' responsibility to ensure their practice is following current guidance. The latest immunization schedules can be found on KIDS Plus IIS and on the Philadelphia Immunization Program website: <http://kids.phila.gov/>
- All recommended vaccines for a provider's patient population must be kept in supply and made available to eligible patients.
- Doses not given at the recommended age should be given at any future visit when indicated and feasible.

- Licensed combination vaccines (such as Pediarix®, Pentacel®, etc.) may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated.
- Providers should consult the manufacturers' package inserts for detailed recommendations.
- Additional vaccines may be licensed and recommended during the year.

Record Keeping

The National Childhood Vaccine Injury Compensation Act (NCVIA) of 1986 established a “no-fault” system to compensate children and their families following adverse events associated with childhood immunization. NCVIA also established documentation standards for immunization providers, mandated the use of Vaccine Information Statements (VISs), and mandated the reporting of certain adverse events following vaccination to the Vaccine Adverse Events Reporting System (VAERS).

Documentation of Immunizations

Federal law requires that, for all vaccines covered by the NCVIA, regardless of the funding source (public or private), providers must record the following information for each dose of vaccine administered:

- The type of vaccine
- The manufacturer and lot number
- The date administered
- The signature of the person administering the vaccine
- Administration site
- The publication date of the Vaccine Information Statement (VIS)

Signed parental consent is not required.

This information may be maintained in the patient’s electronic or paper chart, or in a central immunization log but must be available for review by federal representatives. The Philadelphia VFC Program strongly recommends the use of a Vaccine Administration Record in the patient’s chart. This form consolidates all of the required information on a single sheet, and allows rapid assessment of a child’s immunization status. The form can be found on: <http://kids.phila.gov/>

Vaccine Information Statements (VISs)

As required under the National Childhood Vaccine Injury Act (42 U.S.C. §300aa-26), all health care providers in the United States who administer vaccines to any child or adult shall, prior to administration of each dose of the vaccine, provide a copy to keep of the relevant current edition Vaccine Information Statements (VISs) that have been produced by the Centers for Disease Control and Prevention (CDC) to that individual or their parent/legal guardian.

Some of the legal requirements for providers regarding the use of VISs are as follows:

- Before vaccinating a child with a dose of any routine childhood immunization, a health care provider is required by federal law to provide a copy of the most current Vaccine Information Statement (VIS) available for that vaccine to the child's parent/legal guardian or the patient.
- The parent/guardian must be given time to read the VIS prior to administration of the vaccine.
- The parent/guardian must be offered a copy of the VIS to take home after the immunization is given.
- Patients with mobile devices that can display a PDF file (e.g., iPhone), now have the option to download VISs onto these devices to take home, rather than taking paper copies. Patients can go to: <http://www.cdc.gov/vaccines/pubs/vis/vis-downloads.htm> on their mobile device and download the appropriate VIS.
- You must record the date the VIS was given in the patient's record (date of administration).
- You must also record the publication date of the VIS (appears at the bottom of the VIS).
- You must offer the parent/guardian a copy of the VIS every time a dose in a vaccine series is given, even if the child has received previous doses of the same vaccine.
- The law applies to all doses of vaccine covered by the National Childhood Vaccine Injury Compensation Program and administered by a provider, whether VFC vaccine or privately purchased.

If there is no VIS for a non-routine combination vaccine (e.g. Pediarix[®], Pentacel[®], Twinrix[®]), provide the VISs for all vaccine components. CDC's "multi-vaccine" VIS may be used as a substitute for any or all of the VISs for routine vaccines given from birth through six months: DTaP, IPV, Hib, PCV, Hepatitis B, and Rotavirus.

VISs may be ordered through the CDC's Immunization Hotline at 1-800-232-2522, or downloaded from the CDC's website: <http://www.cdc.gov/vaccines/pubs/vis/default.htm>. On this site you may also sign up to be notified by email when a VIS is updated.

VISs are available in a variety of foreign language translations; these may be downloaded from the Immunization Action Coalition website: www.immunize.org. If you do not have Internet access, you may request a single copy of any foreign language VIS from the Philadelphia VFC Program.

Adverse Event Reporting

The Vaccine Adverse Event Reporting System (VAERS), jointly managed by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), provides monitoring of vaccine safety after a vaccine has been licensed for use. Reviews of adverse event reports submitted to VAERS can identify potential problems not observed during pre-licensure trials, because certain rare adverse events become apparent only when a vaccine is used in a larger population.

Under federal law, the following events must be reported:

- Any event listed on the Reportable Events Table that occurs within the specified time period.

- Any event listed in the manufacturer's package insert as a contraindication to subsequent doses of the vaccine.

Links to the Reportable Events Table and the VAERS Reporting Form are on: <http://kids.phila.gov/>

Providers may submit completed VAERS forms by mail or fax at (877) 721-0366. Providers may also enter reports online at <https://vaers.hhs.gov/>

In addition to the reports required by law, VAERS accepts reports from any interested party of real or suspected adverse events occurring after the administration of any vaccine. For further information, or for additional VAERS reporting forms, please contact the VAERS Program at 1-800-822-7967.

Reporting to KIDS Plus Immunization Information System (IIS)

The Philadelphia Health Code authorizes PDPH to establish immunization requirements, including reporting immunization data to KIDS Plus IIS.

All immunizations (including seasonal flu vaccine) given to **all** patients must be reported to KIDS Plus IIS, Philadelphia's citywide immunization database. This includes all vaccine doses, whether VFC vaccine or privately purchased. Providers are required to report all vaccine doses administered to all patients (children, adolescents, and adults).

The accuracy of data in KIDS Plus IIS depends upon timely (monthly) and complete reporting by providers in Philadelphia. Providers have the option to submit immunization data in a variety of formats but are encouraged to submit electronically. More information can be found at <http://kids.phila.gov/>. Newly enrolled VFC providers are required to report electronically to KIDS Plus IIS.

Reportable Diseases

Reporting of suspected or confirmed communicable diseases is mandated under Pennsylvania state law and Philadelphia city code. Physicians have the primary responsibility for reporting. Laboratories, school nurses, day care centers, nursing homes, hospitals, state institutions, or other facilities providing health services are also required to report the listed diseases and conditions. PDPH conducts surveillance for 65 reportable conditions of public health importance. PDPH staff members investigate cases to obtain information on risk factors for disease exposure and to identify and implement disease control measures.

The list of reportable diseases and conditions can be found on the Health Information Portal at <http://hip.phila.gov/>. Reports may be made by phone to the PDPH Division of Disease Control at 215-685-6748. Completed reporting forms can be faxed to 215-545-8362.

Site Visits: Provider Quality Assurance

The Philadelphia VFC Program conducts regular site visits of enrolled provider sites to ensure compliance with the VFC Program requirements. Providers should expect a site visit at least once per year, although these may occur more frequently. Depending on the type of visit, some preparation may be required of the provider/staff prior to the visit.

The Philadelphia VFC Program conducts the following types of quality assurance visits:

1. VFC/AFIX visits
2. Storage and handling visits
3. Chart review visits
4. Follow-up visits, as needed

VFC/AFIX Visits

The VFC-AFIX Program combines a VFC site visit with AFIX visits. AFIX, which stands for **A**ssessment, **F**eedback, **I**ncentives and **eX**change of information, is a quality assurance program developed by CDC. The goal of the program is to assess immunization practices, assist providers in the diagnosis and resolution of barriers to immunization, recognize providers with high immunization coverage levels, and facilitate the sharing of “Best Practices.”

During a VFC-AFIX visit, a Quality Assurance Nurse will assess compliance with VFC policies and immunization procedures. A VFC-AFIX site visit has four components:

1. **Evaluation of vaccine storage and handling.** The Quality Assurance Nurse will inspect the refrigerator(s) and freezer(s) used for vaccine storage, review temperature logs, and conduct an inventory of vaccines on hand.
2. **Assessment of immunization coverage and adherence to the immunization schedule.** Providers with 10 or more active patients 24-35 months of age and/or 10 or more active patients 13-18 years of age will receive immunization coverage rate assessments using data from KIDS Plus IIS.
3. **Assessment of appropriate documentation.** A sample of charts will be reviewed to assess eligibility screening, use of current VISs, and adherence to documentation standards required by the NCVIA.
4. **Visit feedback.** The Quality Assurance Nurse will meet with appropriate staff to discuss key findings from the VFC-AFIX visit. It is recommended that the head physician, office manager, head nurse, or medical assistant be present during the feedback session. However, it is required that at least the head physician be available for this session. During the feedback session, the nurse and practice staff will discuss necessary quality improvement activities and opportunities for continued immunization education.

Storage and Handling Visits

The VFC-AFIX Program occasionally will perform storage and handling visits at sites. These visits may be scheduled in advance or they may be unannounced visits. During the visit a VFC staff person will look through the storage units housing VFC vaccine to ensure that vaccine is being properly stored. They will check to make sure that vaccine is not stored too closely to the walls of the unit, that vaccine is properly rotated, that no expired vaccines are being stored in the unit, and that the unit is not over-packed. The staff person will review temperature logs and will also look at the vaccine information statements (VIS) to ensure they are up-to-date. At the end of this visit your site will receive a short synopsis of what was found.

Chart Review Visits

The Philadelphia Immunization Program also conducts Provider-based Outreach (PBO) chart reviews in VFC provider offices, as needed, to ensure provider data in KIDS Plus IIS are accurate and current. By maintaining the integrity of the data in KIDS Plus IIS, PDPH can ensure that provider coverage level assessments are accurate and that only those children truly not-up-to-date are referred to the Immunization Program's community outreach program. The chart reviews can also help PDPH identify problems with data being sent by providers; in some situations problems have resulted in not only data missing from KIDS Plus IIS, but billing revenue not collected by providers due to data entry errors or miscoding in their billing system.

Follow-up Visits, as Needed

Follow-up visits usually occur as a result of issues found during VFC-AFIX quality assurance visits. Follow-up visits may include components of storage and handling visits as well as components of the quality assurance visit. Depending on the issues identified previously, charts may need to be reviewed and your site will be alerted in advance if this is necessary. Follow-up visits may also occur at the request of the site as a way to educate staff on VFC policies, procedures, or visit findings.

Pharmaceutical Representatives

Providers should know that VFC operates independently of industry influences and prides itself on being a “choice program.” This enables providers to choose the vaccines that best suit the needs of their practices from a variety of manufacturers.

While the pharmaceutical industry is an important partner in achieving our immunization goals, the pharmaceutical representatives who visit your office represent a pharmaceutical company and are **not** an extension of the Philadelphia VFC Program. While it is expected that these individuals will provide you and your staff with education on their products, the VFC Program will never ask nor encourage these representatives to assess provider vaccine inventory or order vaccine for your VFC patients. As a VFC provider it is your responsibility to ensure that only authorized VFC staff conduct inventory, audits, and offer recommendations on vaccine ordering.

Section 4: Vaccine Storage and Handling

Office Management and Staff Training

Designate one person in your practice to serve as your “Vaccine Coordinator.” This contact is responsible for ordering vaccines and ensuring that vaccines are stored and handled in a safe manner. A “Back-up Vaccine Coordinator” should also be designated and fully trained on these issues. Both contacts should be named on the “Medical Practice Profile” form.

ALL staff who may work with VFC vaccines must be trained on your office’s protocols for proper vaccine storage and handling. All individuals who will handle and administer vaccines must understand the specific storage requirements and stability limitations of each product.

The Philadelphia VFC Program offers a number of resources to assist with staff training. Review of vaccine storage and handling is part of the annual quality assurance site visit protocol, and on-site in-services are available upon request to the VFC Program. In addition, Provider Quality Assurance Nurses and the VFC Program staff are available to answer questions by phone. Other resources are also available on <http://kids.phila.gov/>.

Receiving Vaccine Shipments

Staff accepting packages from vaccine shipping sources should know the importance of **immediate** vaccine storage and should know the name of their office’s Vaccine Coordinator. VFC vaccine is shipped according to the operating hours on file at the VFC Program as reported on the “Medical Practice Profile” form. If your office hours change, you must notify the VFC Program if you have a vaccine delivery/shipment pending.

All VFC vaccines are shipped to the provider from McKesson, with the exception of varicella vaccine, which is shipped directly from Merck & Co., Inc. All vaccine will be shipped via commercial carrier, either FedEx or UPS.

Generally, it takes McKesson 10-14 business days from the date the order was submitted by PDPH to actually ship provider orders (having an incomplete order will delay your vaccine shipment). Please allow 15 business days for delivery of varicella from Merck. Providers should expect vaccine deliveries Monday through Friday.

When vaccine is received from McKesson/Merck:

1. The packing slip will refer to the vaccine as “VFC Doses.”
2. Open the box immediately and inspect the contents. Contact the VFC Program immediately at 215-685-6728 if contents appear damaged.

3. Ensure that the contents of the box are accurate by checking the packing slip and your original order. If you have questions about your shipment, contact the VFC Program immediately.
4. With varicella vaccine shipments, always check the box lid for diluent.
5. Vaccine shipments are packed with one of several types of temperature monitors: a 3M MonitorMark Time Temperature Indicator™, a TransTracker C FREEZEmarker® Indicator and a ColdMark™ Freeze Indicator. Guides for reading the indicators are included in vaccine shipments – ensure that the indicators show that the temperatures have been maintained at a safe temperature; if not, call the VFC program immediately. Note that ice packs can be melted but the temperature can still be fine – always refer to the temperature indicator(s) to determine if proper temperatures have been maintained.
6. Once inspected, label and store the vaccine immediately (see next section).
7. If there is any question about the viability of vaccine, mark the vaccine as “Do Not Use,” store in appropriate refrigerator/freezer units and call VFC. Do not discard vaccine prior to calling the VFC Program.

McKesson ships vaccines in recyclable insulated cartons able to maintain proper temperatures for up to 72 hours. We encourage you to recycle these shipping cartons. Polystyrene (Styrofoam) is not accepted for curb-side pick-up in Philadelphia, but can be dropped off at the Northeast Sanitation Convenience Center located at State Road and Ashburner Street.

Merck will provide return labels and instructions in with the packing slip for the return of their Styrofoam coolers.

To return vaccine, please see the “Expired, Spoiled and Wasted Policy.”

Separating VFC and Private Vaccine

Private vaccine and VFC vaccine **cannot** be interchanged. The VFC Program will verify vaccine accountability during quality assurance visits. VFC vaccine should be clearly labeled as VFC vaccine to distinguish it from privately purchased vaccine.

VFC vaccine can be labeled as it is unpacked and placed into the storage unit. “VFC” stickers are available at no charge upon request from the VFC Program and may be affixed to cartons as the vaccine is unpacked. The order form for VFC stickers and other materials is available online at <http://kids.phila.gov/>

If you cannot check and label your VFC shipment immediately, place the entire contents into a plastic bag and place the bag into proper storage. Do not unpack the vaccine between patients; it is very easy for the unpacking process to be interrupted and for vaccine to be left out and forgotten.

The VFC Program requires storing vaccines in their original cartons. The practice of emptying cartons and storing loose vials in trays or bins can lead to several problems:

- Loose vials cannot be distinguished from private stock unless each vial is individually labeled as VFC vaccine.
- It is difficult to ensure that shortest-dated vaccine is used first when vials from multiple lots are stored in the same bin.
- It takes longer to count loose vials than cartons of vaccine during inventory.
- Identifying expired vaccine is more difficult, leading to increased wastage or potential administration of expired vaccine.
- The manufacturer's box acts as a thermal layer.
- In addition, some vaccines need to be protected from light, so storing all vaccines in their original box is a good all-around strategy.

Proper Vaccine Storage Techniques

- Store vaccines so air in the unit can freely circulate around the unit and vaccines (not packed tight).
- Do not store in drawers or on doors.
- Do not allow vaccines to touch the walls or floors of the unit, and keep them away from the cold vent from the freezer.
- Keep vaccines in original manufacturer's packaging.
- Store vaccines of the same type in rows to avoid confusion.
- Keep the vaccines that will expire the earliest at the front of the unit and put later-dated vaccines in the back to reduce wastage.
- Food and beverages need to be stored separately from vaccine.

Equipment: Refrigerators, Freezers, Alarms and Thermometers

Refrigerators & Freezers

Acceptable Storage Units:

1. The refrigerator unit in a household combination refrigerator-freezer (the freezer is not allowed)
2. Stand-alone refrigerator
3. Stand-alone freezer
4. Pharmaceutical storage units

Unacceptable Storage Units:

1. The freezer unit in a household combination refrigerator-freezer
2. Dorm-style refrigerators

The refrigerator(s) or freezer(s) used for vaccine storage must:

- Be able to maintain required vaccine storage temperatures year-round.

- Be large enough to hold inventory (including seasonal flu vaccine) in the inner-compartment and allow air space to flow between vaccines.
- Have a working thermometer (temperature-buffered probe required, such as a glycol-encased probe) stored in each freezer and refrigerator compartment.

The refrigerator model must be large enough to properly store a 5 week vaccine supply at the busiest time of year, making sure to consider the larger volume of vaccine stored during flu season, and also leaving room for water bottles in the refrigerator.

Important Storage Unit Basics

- Keep water bottles in the refrigerator door, and ice packs in the freezer.
- Put “Do Not Disconnect” stickers at the outlet and on the storage unit.
- Vaccine storage units must **not** be used to store food/beverages.

Digital Data Logger Thermometers

The VFC Program requires the use of a certified, calibrated, continuously-monitoring digital data logger with a biosafe glycol-encased probe. The glycol-encased probes must be placed in the same area where the vaccine is stored (in the middle of the storage unit). The Philadelphia Immunization Program will distribute at least two thermometers to each provider site.

All VFC sites should have one back-up certified, calibrated digital thermometer with a biosafe glycol-encased probe. These thermometers have already been provided by the VFC Program in 2015.

Digital data loggers must have a certificate of calibration from an accredited laboratory. More information can be found on the Storage and Handling page on: <http://kids.phila.gov/>

Never use dial and mercury-filled thermometers for vaccine temperature monitoring. Only use certified calibrated digital thermometers.

Use of digital data loggers are not a substitute for visually inspecting and documenting temperatures twice daily.

Alarm Systems

Providers who store over \$15,000 worth of VFC vaccines in their storage units are **strongly advised** to invest in an alarm system that monitors the unit 24 hours a day and notifies the provider of any fluctuation in temperature outside of the recommended range. Providers storing vaccines worth \$15,000 or more who choose not to install alarm systems for storage units must understand the risks of foregoing such protection and agree to be held financially responsible for reimbursement of vaccines wasted as a result of an event causing out-of-range temperatures (power outage, doors left open, refrigeration unit malfunction, etc).

Maintaining and Documenting Storage Temperatures

The only way to assure that your vaccine supply is being maintained at the proper temperatures is to regularly monitor freezer and refrigerator temperatures. All vaccines have specific storage temperature requirements, and vaccine stored at temperatures outside of the recommended ranges can be damaged and/or rendered ineffective.

Providers must check vaccine storage temperatures twice daily (during business days), and report the storage unit temperature on VFC Program's temperature logs (available in °F and °C). VFC logs are supplied on the Storage and Handling page on: <http://kids.phila.gov>

Starting June 2016 all storage unit temperatures will be reported through KIDS Plus IIS. This will replace the paper forms.

Temperature logs should be maintained for every unit (refrigerator or freezer) used to store vaccine and must be submitted with every vaccine order.

Out-of-range Storage Temperatures

Following are instructions for use of the paper Temperature Log Form required by VFC:

If the recorded temperature is outside of these ranges, you must **immediately** respond to protect your vaccine:

1. Store vaccine under proper conditions as quickly as possible, and label it "Do Not Use."
2. Contact the VFC Program immediately for further instruction about the viability of the affected vaccine. Be prepared to describe the types of vaccine (brands) affected, the storage temperature, and the length of time that the vaccine was stored at inappropriate temperatures.
3. Do not assume vaccine is spoiled without explicit instruction from the Philadelphia VFC Program.
4. Record all actions taken.

If vaccine is spoiled due to storage at improper temperatures, you must report vaccine as nonviable through KIDS Plus IIS. More information can be found in the "Nonviable VFC Vaccine" section on pages 20-21 of this document and on the Storage and Handling webpage: <http://kids.phila.gov>

Emergency Plans

Refrigerators and freezers can malfunction. Provider facilities can experience power outages. These events can disrupt vaccine storage, subjecting vaccines to improper storage temperatures and potentially leading to vaccine loss. It is critical that you and your staff develop a written plan to safeguard your vaccine as carefully as possible. All staff members who handle VFC vaccines should be aware of this plan, which should be posted on or near the refrigerator. Critical elements of any emergency plan include:

- Philadelphia VFC Program contact information
- Person(s) responsible for preparing / transporting vaccine and their contact information
- How this person will be notified that vaccine needs to be moved
- Location that will receive vaccine
- How receiving location will be notified of transport
- How to pack vaccine for transport
- Worksheet to document vaccine involved in power or equipment failure

The Immunization Program has a worksheet for developing an emergency vaccine and retrieval storage plan.

In any vaccine emergency, the first step should be to contact the Philadelphia VFC Program at 215-685-6424 as soon as possible. At a minimum the emergency plan must be reviewed and updated annually (or as necessary) or when there is a change in staff who have responsibilities specified in the emergency plan.

In any type of power outage:

- Try not to open freezers and refrigerators until power is restored.
- Monitor temperatures and duration of power outage.
- Do not discard vaccine.
- Do not administer any of the affected vaccines until you have discussed the situation with the VFC Program.

Section 5: Vaccine Accountability

Changes in a Practice

Staff changes are a common occurrence in VFC Provider offices. Any changes to the VFC contact, physicians, address, phone number, office hours or patient eligibility numbers must be reported to the VFC Program immediately. In all cases a new Medical Practice Profile will need to be completed. If the practice is moving to another location, the VFC Program will help coordinate transporting vaccine and will conduct a storage inspection upon moving the refrigeration and freezer units. Temperatures must be monitored in the new location for a minimum of two weeks prior to moving vaccine.

Nonviable VFC Vaccine

VFC enrolled providers are responsible for ensuring that their staff takes all possible measures to prevent vaccine loss by following the procedures outlined in this manual.

VFC providers must document and report all incidents of vaccine loss. This includes losses due to:

- **Expired** – VFC product that exceeds the listed expiration date.
- **Spoiled** – VFC product that has been exposed to out-of-range temperatures, and is no longer viable.
- **Wasted** – VFC product that is in a broken vial/syringe, was drawn from a vial but never used, or product in an open vial that was never finished.

Expired, spoiled, and wasted vaccine is nonviable and must be reported to the Philadelphia VFC Program within 30 days after expiration, spoilage or wastage.

Expired and spoiled vaccine must be reported in KIDS Plus IIS. For wasted vaccine, adjust your on-hand inventory in KIDS Plus IIS.

The Philadelphia VFC Program requires reimbursement for instances of expired, spoiled and wasted VFC vaccine. This reimbursement will consist of dose-for-dose vaccine replacement at the private cost.

Vaccine doses that are wasted or expired have 5% wastage/expired vaccine allowance based on your site's total VFC vaccine orders from the previous fiscal year (July 1 – June 30). Once your site exceeds this 5% threshold, your site is required to reimburse the Immunization Program dose-for-dose through private purchase.

Transporting and “Borrowing” Vaccine

Can I transfer vaccine between sites?

No. Providers are **not** permitted to transfer vaccine between sites or practices. Vaccine inventory is carefully monitored by the VFC Program, and providers discovered to be transporting vaccine between sites will be suspended from the program. If your practice is moving, call the VFC Program to arrange coordination of vaccine transport.

What about “borrowing” vaccine for VFC patients?

There may be situations when VFC patients present to your office for vaccines but your practice does not have a particular vaccine or vaccines in your VFC stock. To avoid missing the opportunity to immunize these patients, providers may opt to use vaccine from their private stock. They may then be reimbursed later by the VFC Program. This is the procedure:

1. Call the VFC Program at 215-685-6424 to first ask permission to do this.
2. Keep a list of which VFC patients receive private vaccine doses, including patient name, date of birth, type of vaccine, vaccine lot number, and date of administration, and submit this information to VFC within 5 business days.
3. Once your VFC vaccine supply is replenished, you may replace the doses used from your private stock with an equal number of VFC vaccine doses. You must report to VFC the lot number and dose amounts of the replacement vaccine.
4. **You may never borrow VFC stock to immunize private patients.**

Borrowing private vaccine for VFC patients should be done only in limited circumstances. Providers should instead be vigilant about watching inventory and ensuring sufficient supplies of vaccine for **both** VFC and private patients are maintained.

Grounds for Suspension from VFC

Providers can be suspended from the VFC Program for a variety of program violations. The suspension is not a permanent termination of program privileges, so long as the violations are addressed in a timely manner. Upon suspension, no vaccine will be delivered to the provider until the suspension is lifted.

Grounds for VFC Program suspension include:

- Negligence in vaccine storage and handling
- Inability to account for vaccine supplied by VFC including flu vaccine
- Improper vaccine administration (not following ACIP recommendations, etc.)
- Transferring vaccine between sites
- Administering VFC vaccine to patients who are not VFC eligible including flu vaccine
- Refusal to cooperate with required VFC site visits
- Failure to report to KIDS Plus IIS in a timely fashion
- Failure to download and submit data logger information on a monthly basis

Fraud and Abuse

As the cost of childhood vaccines increases and the complexity of immunization programs grows, the VFC Program becomes more vulnerable to fraud and abuse. Therefore, the VFC Program actively works to prevent, identify, investigate, and resolve all cases and suspected cases of fraud and abuse within the VFC Program.

How are Fraud and Abuse Defined?

The following definitions, as defined in the Medicaid regulations at 42 CFR § 455.2, apply to VFC Program Operations.

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 law.”*

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. It also includes recipient practices that result in unnecessary cost to the Medicaid program.”*

What are examples of Fraud and Abuse?

Fraud or abuse can occur in many ways. The VFC Program differentiates between intentional fraud and abuse and unintentional abuse or error. Some examples of potential fraud/abuse:

- 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 charge (\$23.14) for administration of a VFC vaccine to a federally vaccine-eligible child
- Not providing VFC-eligible children VFC vaccine due to parents' inability to pay for the administration fee
- Not implementing provider enrollment requirements of the VFC Program
- Failing to screen patients for VFC eligibility
- Failing to maintain records and comply with other requirements of the VFC Program
- Failing to fully account for all VFC vaccine
- Failing to properly store and handle VFC vaccine
- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involves over-ordering of VFC doses
- Wastage of VFC vaccine

What are the consequences of Fraud and Abuse?

The VFC Program will attempt to work collaboratively with providers to address issues of program noncompliance. The program will consider previous compliance issues and potential extenuating circumstances in determining remedial action(s). The goal is to work with providers in as positive a manner as possible to correct noncompliant behaviors and restore VFC Program privileges. Intervention may include any or a combination of the following actions:

- Education visits
- Follow-up site visits
- Formal intervention that requires development of a corrective action plan, including suspension from the VFC Program
- Termination from the VFC Program
- Referral to external agency (e.g. Medicaid) for further fraud and abuse investigation