

Philadelphia Vaccines for Children Program Manual

2009-10 Edition

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Philadelphia Immunization Program
Philadelphia Department of Public Health
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Philadelphia, PA 19146
<https://kids.phila.gov>

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Section

1

Getting Started as a VFC Provider

This section reviews the basics of the Philadelphia VFC Program, which will be covered in more detail in Sections 2 through 5. VFC Program Forms can be found in the “Forms” section of the Philadelphia Immunization Program Provider handbook, as well as on the KIDS Registry/Immunization program website: <https://kids.phila.gov>

Section highlights:

- ❖ VFC offers many benefits to parents and providers by removing vaccine cost as a barrier to timely immunization
- ❖ VFC is an entitlement program that is a required part of each state’s Medicaid plan
- ❖ Providers who are part of the VFC Program must comply with program requirements in order to continue to receive vaccines
- ❖ New providers may enroll in VFC after submitting appropriate paperwork and completing an orientation and storage & handling inspection
- ❖ VFC participation may be suspended or terminated at any time at the discretion of either the VFC Program or the enrolled 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, or American Indian/Alaskan Native. Underinsured children are eligible to receive VFC vaccine through a Federally Qualified Health Center (FQHC) only.

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) buys 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. Each year the Philadelphia VFC Program provides over \$22 million in free vaccine, enabling providers in the city to immunize over 280,000 children.

Benefits to Providers and Patients

Simply stated, 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 otherwise not 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 provides.

Benefits to Providers

- ◆ 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 to receive 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 with Vaccine Information Statements for each vaccine administered
- Reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS)
- Reporting all immunizations administered to patients <19 years old to the KIDS Registry
- 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

To enroll in the Philadelphia VFC Program, a provider must:

- Complete the Provider Enrollment Form, the Medical Practice Profile Form, and the Physician Profile/Group Signature Form
- Agree to an orientation and storage visit and comply with all storage and handling standards
- Agree to comply with the policies and procedures stated in the Provider Enrollment form and the VFC Manual.

The Provider Enrollment Form, Medical Practice Profile, and Physician Profile/Group Signature Form should be completed and mailed to the Philadelphia VFC Program, where they will be kept on file. These documents must contain an original signature. Signature stamps are not acceptable. Faxed copies may be used to initiate the enrollment process, but the signed originals must follow before your first vaccine order is processed.

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: to review VFC policies and procedures with you and your staff and to inspect the refrigerators and freezers to be used for vaccine storage. Prior to ordering any vaccines, the site visit must be completed, and 5 days of refrigerator and freezer temperatures must be recorded on a VFC temperature log and faxed or mailed to the VFC Program.

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 the KIDS Registry, 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.

Philadelphia VFC Contact Information

Please note: in the event of an emergency (power outage, etc.), if you cannot immediately get in touch with the person you are trying to reach, please try other VFC Program staff members until you reach someone on the phone. Staff members are frequently in the field away from their phones and may not be able to respond to voice mail messages immediately – keep trying until you get a live person!

Program	Name	Phone	Contact for...
Vaccines for Children (VFC)	Veronica Alvarez, Coordinator	215-685-6498	General VFC Issues
	Christine Wilson, Vaccine Inventory Specialist	215-685-6728	Submitting Vaccine Orders Vaccine Order Forms Vaccine Order Status
	Lisa Morgan, Provider Quality Assurance Specialist/ Vaccine Manager	215-685-6872	VFC Enrollments VFC Suspensions VFC Quality Assurance Visits Transferring Vaccine
VFC-AFIX Visits / Provider Education	Lisa Morgan, Coordinator	215-685-6872	Provider Education Programs VFC-AFIX visits
	Lorraine Matjkiw, RN, Mary Ann Silvestri, RN, Provider Quality Assurance Nurses	215-685-6466 215-685-6835	Provider Education Programs Medical Questions
	Srey Prak	215-685-6728	Copies of VIS Statements Educational Materials

Other helpful Philadelphia Immunization Program contact information

Program	Name	Phone	Contact for...
KIDS Registry	Bhavani Sathya KIDS Registry Coordinator	215-685-6468	General KIDS information
	Longina Viscontò, KIDS Asst. Coordinator	215-685-6830	KIDS Reporting and User Access/Login Help
	Rafael Echevarria, KIDS Programmer/Analyst	215-685-6777	KIDS Technical Questions
	Brian Jorgage, KIDS Data Analyst	215-685-6455	KIDS Electronic Reporting
	Jenny Harvey, Data Quality Analyst	215-685-6808	KIDS Trainings
	KIDS Help Line	215-685-6784 215-685-6799 (FAX)	Immunization Records
Vaccines for Adults at Risk (VFAAR)	Kate Cushman, Coordinator	215-685-6424	Adult vaccine program
Community Influenza Program	Kate Cushman, Coordinator	215-685-6424	Community adult influenza program
Varicella Active Surveillance Program (VASP)	Niya Spells, Coordinator	215-685-6838	General VASP Questions
Community Outreach	Alexandra Ossa, Coordinator	215-685-6833	Community outreach program questions/referrals
	Tanya Jones, KIDS Provider Outreach	215-685-6494	Provider Chart Review
Perinatal Hepatitis B Program	Bruce Barlow, RN Coordinator	215-685-6853	Perinatal Hepatitis B program
Philadelphia Immunization Program Administration	James Lutz, Immunization Program Manager	215-685-6603	Immunization Program Questions
	Veronica Alvarez, Asst. Immunization Program Manager	215-685-6498	General VFC Issues
	Lauren Hutchens, Communications Coordinator	215-685-6854	Immunization program publications and alerts

Ordering Vaccines from VFC

Section highlights:

- ❖ Properly submit vaccine orders to ensure timely delivery
- ❖ Order before inventory drops below a 4-6 week supply
- ❖ Do not over-order (more than 3 months beyond need)
- ❖ Choice of vaccine brands and presentations is subject to availability
- ❖ Separate VFC sites under one provider must order separately; no transferring vaccine between sites

How Does VFC Work?

Each year, the CDC provides the Philadelphia VFC Program with a certain amount of funding to be used to purchase vaccine for its enrolled providers. VFC Providers order vaccine directly from the Philadelphia VFC Program, which reviews all orders before submitting them to the CDC. The vaccines are then shipped directly to providers from a third-party distributor (McKesson Specialty Ltd.); the Philadelphia Immunization Program does not maintain a supply of vaccine at its headquarters. Providers are responsible for ordering appropriately, according to vaccine need and in a timely fashion, to ensure the practice maintains its vaccine supply.

How Vaccines Become Available through VFC

The Advisory Committee on Immunization Practices (ACIP) has the advisory role to determine what licensed vaccines should be recommended for administration to children, adolescents, and adults in the U.S., and the operational role to approve which vaccines will be available through the VFC Program.

The ACIP meets three times a year, and during these meetings newly licensed vaccines may be discussed and recommended for use. Once a vaccine is recommended by ACIP, a vote is taken about whether to include the new vaccine in the VFC Program through consideration of a VFC resolution. VFC resolutions are specific to each vaccine and include populations eligible to receive the vaccine, the vaccination schedule, and precautions or contraindications to the vaccine. Once the VFC resolution is approved, CDC must negotiate a contract with the manufacturer to make the vaccine available under the VFC Program.

CDC and immunization programs receiving VFC funds are required to offer ACIP-recommended vaccines for which VFC resolutions have been approved and for which federal contracts have been established to purchase these vaccines.

The Philadelphia VFC Program does not distribute newly licensed vaccines without an approved VFC resolution, Vaccine Information Statement(s), and sufficient funds to cover all submitted orders.

Philadelphia VFC Supplied Vaccines

As of March 26, 2010

Combination products are available; the chart below just lists the antigens that are covered by available vaccine products. Consult the current order form for available products.

VACCINE	VFC COVERED CHILDREN	All or High Risk?
DT ¹	6 weeks through 6 years	See Footnote
DTaP	6 weeks through 6 years	All
Hepatitis A ²	12-23 months; 2-18 years	See Footnote
Hepatitis B	Birth through 18 years	All
Hib ³	6 weeks through 59 months	See Footnote
HPV ⁴	9 through 18 years	All
MMR ⁵	1 year through 18 years	All
Meningococcal Conjugate (MCV4) ⁶	10-18 years; 2-10 years	All; high-risk
Pneumococcal Conjugate (PCV13)	6 weeks through 59 months; 60-71 mo.	All; high-risk
Polio	6 weeks through 18 years	All
Tdap	11 years through 18 years	All
Td ⁷	7 years through 18 years	See Footnote
Varicella ⁵	1 year through 18 years	See Footnote #4
Pneumococcal Polysaccharide 23 (PPV23) ⁸	2 years through 18 years	See Footnote
Rotavirus	6 weeks to 32 weeks	All

- 1 DT vaccine will be supplied for use in children with valid contraindications to pertussis antigen, as described by the ACIP. Please refer to the "Other" section of your VFC order form for DT requests.
- 2 Hepatitis A vaccine is available for routine vaccination of all children 12-23 months of age, and for catch-up vaccination of all children 2-18 years of age who are unvaccinated for hepatitis A.
- 3 Hib vaccine is available for unimmunized high-risk children ages 5 through 18 years, with either functional or anatomical asplenia (SSD, post-splenectomy); immunodeficiency; HIV infection; or immunosuppression due to HIV infection or chemotherapy.
Update: As of 12/2009, the Hib booster dose previously deferred should be reinstated on time for 12-15 month-olds who have completed the primary series; children 16-59 months of age whose booster was previously deferred should be recalled.
- 4 Gardasil® is available for routine vaccination at 11 through 12 years of age, and catch-up vaccination for 13-18 years of age, and 9-11 years of age if protection is desired. It is best to start the vaccine before the onset of sexual activity and exposure to HPV. Catch-up vaccination is recommended for individuals 13 - 18 years of age who haven't been vaccinated or not completed the full series. Cervarix (HPV2) vaccine should be available from VFC beginning April 1, 2010.
Update: As of 12/2009, HPV4 may be given as a 3-dose series to **males 9-18 years** to reduce their likelihood of acquiring genital warts.
- 5 **Update:** 6/01/07 - MMRV is no longer available via the VFC program due to a supply shortage. MMR and Varicella are available as separate antigens.
- 6 **Update:** 10/19/07 - The FDA expanded the indication for MCV4 to include children 2-10 years of age at high risk.
- 7 Td vaccine will be supplied for use in children with valid contraindications to pertussis antigen, as described by the ACIP, and for catch up for those children 7-18 years with no history of a tetanus diphtheria containing vaccine. Please refer to the "Other" section of your VFC order form for Td requests.
- 8 Pneumococcal Polysaccharide (23-valent) is available for children and adolescents aged 2-18 years who have functional or anatomical asplenia, immunocompromising illness or medications, chronic illness, who are Alaska Native or American Indian, or who have received a bone marrow transplant.

Ordering 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 the KIDS Registry.

Which vaccines can I choose?

The Philadelphia VFC Program is proud to offer 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. If a vaccine is not available or in short supply due to manufacturing shortages, an order may be decreased in amount or replaced with a different brand or presentation to accommodate vaccine supply issues.

The VFC Program also supports the use of available combination vaccines (Pentacel[®], Pediarix[®], etc.). Available combination vaccines are listed on the VFC Vaccine Order Form.

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 VFC Program does not require providers to order according to a particular schedule, but does expect orders to be **appropriate, timely, and accurate**. The 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:
 - Your VFC-eligible patient population
 - The amount of vaccine your practice can store at one time
 - The time of year (think about flu season, back-to-school immunizations)
- It is generally better to order more frequently, in smaller quantities
- Order **before** supply drops to one month's worth.
- Plan accordingly to allow 2-3 weeks (sometimes more) 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 registry 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.

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 Registry reporting.

How do I put together an order?

Following these simple policies of the Philadelphia VFC Program will help ensure your vaccine orders are processed more quickly and accurately. Orders that are not properly submitted are subject to review and may result in delays.

- The Philadelphia VFC Program **does not** accept vaccine orders over the telephone. Orders should be submitted by fax to (215) 685-6510, or sent by mail to: VFC Program c/o Christine Wilson, 500 South Broad Street, Philadelphia, PA, 19146.
- Once your order is received, a VFC Vaccine Inventory Specialist reviews the order. An order with incomplete or missing documentation will not be processed. Such orders will be faxed back to the provider with a request for complete documentation.
- Properly completed orders are entered into a tracking database that can identify orders that exceed projected vaccine need based on Medical Practice Profile data and KIDS Registry data. Orders for inappropriate vaccine amounts or with temperature logs showing inappropriate temperatures will be referred to VFC Program management for review.
- If a provider has multiple clinical sites, each site should be individually enrolled in the VFC Program, and a separate vaccine order (with all appropriate documentation) must be submitted for each enrolled site. **Vaccine may not be transported between sites!**
- Providers with business hours outside of regular business and shipping hours are expected to pick up their vaccine shipments from PDPH.
- If the delivery instructions or operating days/hours change for any reason prior to receipt of an order, please notify VFC immediately at (215) 685-6728.

Top 5 Tips For Smooth VFC Orders!

1. Include the *signature* of the person authorized to order vaccine on the order form.
2. Include the most current temperature logs for your practice with *every* order (logs must include refrigerator and freezer temps from at least the last 5 business days).
3. Fill out order forms *completely!* In addition to a signature, always include your:
 - Correct VFC PIN
 - Practice Name
 - Telephone Number
 - Hours of Operation
4. Use the *most current order form*. The most current version of the order form can be obtained at <https://kids.phila.gov>, or by calling (215) 685-6728. The form is also distributed to providers whenever it is updated.
5. Indicate your current vaccine inventory on the order **form**.

Section

3

Basic Provider Responsibilities Under VFC

Section highlights:

- ❖ Screen patients for VFC eligibility at every visit
- ❖ VFC vaccine may be given to VFC-eligible patients only
- ❖ You may not charge for VFC vaccines
- ❖ You may charge an administration fee per vaccine under the state cap (\$15.76) to non-Medicaid-eligible children, but cannot deny vaccine to patients who can't pay this fee
- ❖ Give VISs for every vaccine, every time!
- ❖ Document all federally required information following vaccine administration
- ❖ Report:
 - Adverse events following vaccination to VAERS
 - All vaccines administered to patients 0-18 years to the KIDS Registry
 - Suspected and confirmed reportable diseases to PDPH
- ❖ Expect announced and unannounced site visits for VFC-AFIX, storage inspections, and chart review

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.

Which patients are 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)
- American Indian or Alaskan Native

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 District Health Centers. FQHCs **must** see VFC-eligible patients for vaccines, even if they are not capitated to them as a patient. A list of FQHCs and District Health Centers in Philadelphia is included in the Immunization Provider Handbook.

Alternatively, these 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.

Children who are insured through the Pennsylvania State Children's Health Insurance Program (SCHIP) are not eligible for VFC vaccine. These children are considered to be privately insured and should be given vaccine from your private stock. They should never be referred to an FQHC for vaccines.

Children who have health insurance that covers only a percent of the cost of one or more vaccines (i.e., the insurance covers 80% of the cost of MCV4) are not eligible to receive VFC vaccine because they are considered to be insured for the purposes of the VFC program.

How do we screen for VFC eligibility?

VFC recommends the use of the VFC screening form found in the *Forms* section of the Immunization Provider Handbook and on <https://kids.phila.gov>, although providers may incorporate the information into their own practice forms.

- Screening of the child must occur at every visit but needs to be documented at the initial screening only, unless any changes to eligibility have occurred.
- Providers must maintain a record (paper or electronic) of the screening for at least three (3) years after the last administered VFC vaccine. After three (3) 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 financial responsibilities under VFC:

- 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, currently \$15.76 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 eligibles).

Compliance with the ACIP Recommended Schedule

VFC providers must comply with current immunization schedules, dosages, and contraindications as established by the 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.
- 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, VISs, and Adverse Event Reporting

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, and mandated the reporting of certain adverse events following vaccination.

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 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. A sample copy of the form appears in the *Forms* section of the Immunization Provider Handbook and on <https://kids.phila.gov>.

Vaccine Information Statements (VISs)

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, Palm Pre, some BlackBerries), now have the option to download VISs onto these devices to take home, rather than taking paper copies. Patients can go to 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 chart (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.

A full set of VISs is supplied in your Immunization Provider Handbook. In addition, 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.

By federal law (42 USC 300aa-25), 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.

Copies of the *Reportable Events Table* and the *VAERS Reporting Form* are included in the Immunization Provider Handbook and <https://kids.phila.gov>

Providers may submit reports by mail or fax directly to VAERS; always make sure to fax a copy of any report forms submitted directly to VAERS to the Immunization Program at (215) 685-6806 as well. Alternatively, providers may fax reports to the Immunization Program, which will submit the report to VAERS. Providers with Internet access may also enter reports directly into the on-line VAERS reporting system, at <http://www.vaers.org>

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.

Other Reporting Requirements: KIDS Registry; Reportable Diseases

The Philadelphia Health Code, as approved by City Council, authorizes PDPH to establish immunization requirements, including reporting immunization data to the KIDS Registry, as well as requirements for reporting of suspected or confirmed cases of communicable diseases.

KIDS Registry

All immunizations given in Philadelphia to children 0 through 18 years of age must be reported to the KIDS Registry, Philadelphia's citywide immunization database. This includes all vaccine doses, whether VFC vaccine or privately purchased.

The accuracy of data in KIDS 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 <https://kids.phila.gov> as well as in the KIDS Registry section of the Immunization Provider Handbook.

Reportable Diseases

PDPH conducts surveillance for 65 notifiable conditions of public health importance. PDPH staff investigate cases to obtain information on risk factors for disease exposure and to identify and implement disease control measures.

Physicians have the primary responsibility for reporting, but other health care professionals and sites providing health services are also required to report the listed diseases and conditions. The list of reportable diseases and conditions, which include many vaccine-preventable diseases, can be found on <https://kids.phila.gov> as well as in the Immunization Provider Handbook. Reports may be made by telephone to the PDPH Division of Disease Control at (215) 685-6748.

Some providers in West and Southwest Philadelphia also participate in the Varicella Active Surveillance Project (VASP), which monitors post-vaccine epidemiology of varicella disease (including Zoster) through a collaborative agreement with the CDC. For more information about VASP, visit <https://kids.phila.gov/vasp> .

Site Visits: Provider Quality Assurance

The Philadelphia VFC Program conducts regular site visits of enrolled provider sites to ensure compliance with VFC Program requirements. Providers should expect a site visit at least once per year, but 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 VFC Program conducts three types of quality assurance visits:

- VFC-AFIX visits
- Vaccine storage inspections
- Chart review visits

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 will receive coverage rate assessments using data from the KIDS Registry.
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. During the feedback session, the nurse and practice staff will discuss necessary quality improvement activities and opportunities for continued immunization education.

Vaccine Storage Inspections

All enrolled providers will receive at least one vaccine storage inspection each year, either as part of a VFC-AFIX visit or as a separate visit. During a vaccine storage inspection, a trained VFC Program representative will inspect the refrigerator(s) and freezer(s) used for vaccine storage, check current temperatures, review temperature logs, and conduct a vaccine inventory.

Site visits are part of VFC Program participation

The VFC Program reserves the right to conduct unscheduled vaccine storage inspections in response to incidents of vaccine loss, or to information received during the ordering process, such as temperature logs showing inappropriate temperatures, wasted or expired vaccine, unusual ordering patterns, or unusual inventory reports. Providers with a history of problems pertaining to vaccine storage may be subject to unscheduled storage visits until storage and handling practices improve.

Providers should keep temperature logs on file for at least three years and must make temperature logs available for review during site visits.

Chart Review Visits

PDPH also conducts chart reviews in VFC provider offices as needed to ensure provider data in the KIDS Registry are accurate and current. By maintaining the integrity of the data in the KIDS Registry, 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 the registry, but billing revenue not collected by providers due to data entry errors or miscoding in their billing system.

A Note on 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.

Vaccine Storage and Handling

Section highlights:

- ❖ Designate a VFC vaccine contact as well as a backup
- ❖ Check and record temperatures twice a day for every day the practice is open
- ❖ Store vaccines in the manufacturer's original cartons
- ❖ Label VFC vaccine and keep separate from private stock
- ❖ Providers are liable for vaccine losses due to improper storage and monitoring equipment
- ❖ Report short-dated VFC vaccine expiring within 60-90 days that will not be used before the expiration date
- ❖ Rotate stock and inventory vaccines monthly
- ❖ Have a written plan to safeguard vaccine in the event of an emergency
- ❖ If you experience a vaccine emergency or a problem with vaccine shipments, immediately contacting VFC should always be the first step!

Office Management and Staff Training

Designate one person in your practice to serve as your “VFC Vaccine Contact.” This contact is responsible for ordering vaccines and ensuring that vaccines are stored and handled in a safe manner. A “back-up” VFC Vaccine Contact 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 need to be trained on your office’s protocols for proper vaccine storage and handling. All individuals who will handle and administer vaccines need to know the specific storage requirements and stability limitations of each.

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 management team are available to answer questions by phone. Other resources are also available on <https://kids.phila.gov> and in the Immunization Provider Handbook.

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 VFC contact. VFC vaccine is shipped according to the operating hours on file at the VFC Program as reported on the Medical Practice Profile. **If your office hours change unexpectedly, 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. 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 (not having a complete order form will delay your vaccine shipment). Please allow 15 business days for delivery of Varicella from Merck. Providers should expect vaccine deliveries on Tuesdays, Wednesdays and Thursdays.
- Provider orders with unrestricted delivery information (able to accept vaccine shipments during normal business hours; 9am to 5pm) will be processed immediately. Orders with special handling instructions or limited delivery times will be carefully reviewed to ensure that vaccines are delivered within the specified windows of time.

In the event of a vaccine emergency or any problems with a vaccine shipment, immediately contacting the VFC Program should always be your first step!

When vaccine is received from McKesson:

- Open the box immediately and inspect the contents. Contact the VFC Program immediately if contents appear damaged.
- Make sure doses listed on the packing slip match the contents listed as well as doses requested in your vaccine order. **If you have questions about your shipment, contact the VFC Program immediately at (215) 685-6728.**

NOTE: *Neither the packing slip nor the box is labeled “VFC.” To identify a vaccine shipment as a VFC shipment, the invoice will state, “This vaccine was purchased with public funds. All VFC vaccines are shipped by McKesson.”*

- With varicella vaccine shipments, always check the box lid for diluent.
- Vaccine shipments are packed with one of two types of temperature monitors: a 3M MonitorMark Time Temperature Indicator™, or 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.
- Once inspected, label and store the vaccine immediately (see next section)
- 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. Please 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. *As of June 2009, McKesson no longer asks for providers to return cartons to them; we encourage you to recycle cartons through your local recycling program.*

Separating VFC and Private Vaccine

- Private vaccine and VFC vaccine should not be interchanged. The VFC Program will verify vaccine accountability during quality assurance visits.
- VFC vaccine should be 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.
- 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 **strongly recommends** 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 short-dated or expired vaccine is more difficult, leading to either wastage of short-dated vaccine or potential administration of expired vaccine.
- 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 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 cartons.
- 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 help identify short-dated vaccines.
- Food and beverages need to be stored separately from vaccine (units that store food are opened more frequently, by more people, which makes it harder to maintain temperatures, and easier for doors to be left ajar accidentally).

Equipment: Refrigerators, Freezers, Alarms, and Thermometers

Refrigerators and Freezers - what type of vaccine storage equipment is required?

- Two types of storage units are acceptable:
 - 1) A refrigerator with a freezer compartment that has a separate exterior door (we recommend separate temperature dials for each compartment)

OR

- 2) Stand-alone refrigerators and freezers.

Not acceptable: “Dorm style” units (refrigerators that have a freezer compartment that does not have a separate door).

- 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 the year's largest inventory in the inner compartment and allow air space to flow between vaccines;
- Have a working thermometer stored in each freezer and refrigerator compartments.

Storage unit basics

- **Separate external doors for fridge/freezer**
- **Best to have separate temperature controls for freezer and fridge**
- **Keep water bottles in the door, and ice packs in the freezer**
- **Vaccine storage units should not be used to store food/beverages**
- **Put 'Do not disconnect' stickers at the outlet and on unit**

Alarm systems – who needs them?

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 chose 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).

Thermometers

Beginning in 2010, the Philadelphia VFC Program will start issuing certified calibrated thermometers to VFC providers for each refrigerator and freezer used for vaccine storage, as recommended by CDC. Providers may continue using their own thermometers only if they meet VFC Program standards. The certified thermometers are to be used for recording temperatures. Every two years, the VFC program will also coordinate the recalibration of these thermometers.

Since these thermometers are PDPH property, providers will be held responsible for loss or damages.

Maintaining and Documenting Storage 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. Do not assume that your refrigerator and freezer will maintain the proper temperatures without monitoring. As with all equipment, refrigerators and freezers are subject to mechanical failure and/or user error. The only way to assure that your vaccine supply is being maintained at the proper temperatures is to regularly monitor freezer and refrigerator temperatures.

Providers must use the VFC Program's temperature logs (available in F° and C°) unless their own logs are previously approved by VFC. VFC logs are supplied in the Forms section of the Immunization Provider Handbook as well as on <https://kids.phila.gov>. These forms are designed to help staff clearly and quickly identify out-of-range temperatures and respond appropriately. Temperature logs should be maintained for every unit (refrigerator or freezer) used to store vaccine and must be submitted with every vaccine order.

**Check and
record temps 2
times a day!**

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

1. Record temperatures at **the beginning and end of each day that the practice is open.**
2. Place an “**X**” in the box that corresponds to the temperature and the day of the month for which you are recording the temperature.
3. Enter your initials and the exact time you monitored the temperature.
4. The recommended temperature ranges for vaccine storage are indicated on the temperature log form. **If the recorded temperature is outside of these ranges, you must respond IMMEDIATELY to protect your vaccine:**
 - a. Store vaccine under proper conditions as quickly as possible, and label it “**Do Not Use.**”
 - b. 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.
 - c. Do not assume vaccine is spoiled without explicit instruction from the VFC Program.
 - d. Record all actions taken on the back of the Temperature Log Form.

If vaccine is spoiled due to storage at improper temperatures, a Vaccine Loss Incident Report must be filed.

Do:

- **Document temps at the beginning and end of each day**
- **Choose a back up person to take temps**
- **Keep temp logs on file for 3 years**

Do not:

- **Ignore out of range temps**
- **Falsely document temps**
- **Forget to send 2 weeks of temp logs with orders**

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 Provider Handbook contains 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) 685-6728 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

Section Highlights:

- ❖ Call VFC immediately in the event of out-of-range temperatures and power outages
- ❖ Notify VFC of any VFC vaccine will expire within 60 to 90 days that you will not be able to use
- ❖ VFC must be notified whenever a practice changes ownership, location, office hours, phone/fax numbers, or practicing physicians
- ❖ VFC providers who experience vaccine losses due to expiration or improper storage will be suspended from the program until the wasted vaccines are reimbursed through private purchase
- ❖ The VFC Program works to prevent, identify, investigate, and resolve all cases and suspected cases of fraud and abuse within the program

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 should 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.

Reporting Short-Dated Vaccine and Vaccine Losses

Providers participating in the Philadelphia VFC Program are expected to document and report all incidents of vaccine loss. This includes losses due to:

- *Spoilage* – vaccine damaged due to improper storage conditions
- *Expiration* – vaccine not administered prior to expiration date
- *Wastage* – vaccine that could not be administered once removed from storage (for example, the parent refused vaccine after the dose was drawn up, or Varivax could not be administered within 30 minutes of reconstitution)

When a vaccine loss occurs, call the VFC Program immediately. The VFC Program will follow up with providers on the corrective actions required; in some situations, providers may be suspended from the program until the compromised vaccine is replaced. After making a report, a written vaccine loss incident report must be submitted to the VFC Program. The report **must:**

- Be printed on the provider's office or clinic letterhead.
- Be signed by the physician, medical director, or office manager responsible for the practice.
- Describe the circumstances of the loss. For example, a refrigerator or freezer malfunction, expiration due to poor inventory practices, improper storage temperatures, etc.
- Describe the steps the provider will take (changes in procedure, staff training, etc. as appropriate) to ensure that the loss does not recur.
- Include an itemized list of all the vaccine(s) involved, including the type(s) of vaccine, number of doses, lot number(s) and expiration date(s).
- Recognize the consequences for the vaccine loss, including the potential requirement for reimbursement.
- List the names of any patients and their DOB who received the compromised vaccine.

Transporting and “Borrowing” Vaccine

Can I transfer vaccine between sites?

No. Providers are **not** permitted to transfer vaccine between sites or practices. Vaccine that will expire in 60-90 days that will not be used by your practice should be reported to VFC using a Short Dated Vaccine form, and the VFC Program will arrange to have that vaccine picked up and moved to another provider if it can be used. 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 215-685-6872 to first ask permission to do this.
2. Keep a list of which VFC patients receive private vaccine doses, including patient name, DOB, 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.

*****It is important to note that providers 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.

Vaccine Wastage and Reimbursement

Although VFC-enrolled providers receive vaccines free of charge through the VFC Program, these vaccines are purchased by the city of Philadelphia through a federal grant. This means that providers must be held accountable for these increasingly expensive resources that are ultimately provided to them through taxpayer dollars.

VFC providers experiencing vaccine losses due to negligent storage and handling are required to replace wasted or spoiled vaccine through private purchase. The Philadelphia VFC Program understands that some losses (*e.g.*, due to equipment failure and power outages) are unavoidable. However, vaccine losses have resulted from improper monitoring of storage temperatures, over-ordering, not closing a refrigerator door tightly, or failure to report and return short-dated vaccine, resulting in loss due to expiration.

The VFC Wastage policy is designed to ensure proper accountability of VFC vaccines. Under this policy, providers must:

- Report all vaccine losses promptly to the VFC Program.
- Submit a letter describing the incident on practice letterhead, signed by the head physician.
- Purchase, through the vaccine manufacturer(s), replacement doses of vaccine, as instructed by the VFC Program. The replacement doses should have at least a 1-year expiration date.
- Submit a copy of the receipt, showing the vaccines purchased, lot number(s), and number of doses purchased to the VFC Program. Proof of payment will be required.
- Use this privately purchased replacement vaccine to vaccinate **VFC-eligible patients only**. The VFC Program may ask to see records documenting administration of this vaccine to VFC-eligible children.

VFC providers will be suspended from the VFC Program until vaccines are reimbursed through private purchase. ***Late reporting of short-dated vaccine (less than 60 days until expiration) can be considered vaccine wastage!***

Providers who refuse to purchase replacement vaccine will be suspended from the program and will be unable to order VFC vaccine. The VFC Program also will inform the regional Medicaid MCOs that the provider is no longer actively enrolled in the VFC Program.

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

Procedures to minimize vaccine loss

- Provide adequate vaccine storage and monitor storage conditions
- Do not over-order or stockpile vaccine!
- Order no more than a 2-3 month supply. Larger providers can also order more frequently in smaller amounts to accommodate their storage capacity.
- Never assume vaccine is spoiled in the event of a storage problem. Contact the VFC Program immediately for instructions.
- Conduct vaccine inventory **monthly**.
- Check expiration dates at least monthly.
- Rotate vaccine stock regularly; move the earliest expiration dates to the front.
- Report vaccine that will expire within 2-3 months (60-90 days) that you will not be able to use
- Do you store more than \$15,000-worth of vaccines? You need an alarm!

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
- Improper vaccine administration (not following ACIP recommendations, etc.)
- Transferring vaccine between sites
- Administering VFC vaccine to patients who are not VFC eligible
- Refusal to cooperate with required VFC site visits

Please note that suspension from the VFC Program also means suspension from the Vaccines for Adults at Risk (VFAAR) Program, and vice versa.

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 (\$15.76) 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 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 and follow-up
- Site visits
- Formal intervention that requires development of a corrective action plan
- Termination from the VFC Program
- Referral to external agency (*e.g.* Medicaid) for further fraud and abuse investigation