



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

**Vaccines for Adults at Risk (VFAAR)**

# **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

<b>Section 1: Getting Started as a VFAAR Provider.....</b>	<b>3</b>
Background of the VFAAR Program .....	3
Benefits to Providers and Patients.....	3
Provider Responsibilities Overview .....	4
Enrolling as a VFAAR Provider.....	4
<b>Section 2: Ordering Vaccines from VFAAR.....</b>	<b>5</b>
Philadelphia VFAAR Vaccines.....	5
Ordering VFAAR Vaccines .....	6
<b>Section 3: Provider Responsibilities for VFAAR.....</b>	<b>7</b>
Patient Eligibility and Screening.....	7
VFAAR Fees and Finance.....	8
Compliance with the ACIP Recommended Schedule.....	8
Record Keeping .....	8
Vaccine Information Statements (VISs) .....	9
Adverse Event Reporting .....	10
Reporting to KIDS Plus Immunization Information System (IIS) .....	10
Reportable Diseases.....	11
Site Visits: Provider Quality Assurance .....	11
Pharmaceutical Representatives .....	12
<b>Section 4: Vaccine Storage and Handling.....</b>	<b>13</b>
Office Management and Staff Training.....	13
Receiving Vaccine Shipments.....	13
Separating VFAAR and Other Vaccine.....	14
Proper Vaccine Storage Techniques .....	15
Equipment: Refrigerators, Freezers, Alarms and Thermometers.....	15
Refrigerators & Freezers .....	15
Digital Data Logger Thermometers.....	16
Alarm Systems.....	16
Maintaining and Documenting Storage Temperatures .....	16

Out-of-range Storage Temperatures ..... 17

Emergency Plans ..... 17

**Section 5: Vaccine Accountability .....18**

Changes in a Practice ..... 18

Nonviable VFAAR Vaccine ..... 18

Transporting and “Borrowing” Vaccine ..... 19

Grounds for Suspension from VFAAR ..... 19

Fraud and Abuse ..... 20

# Section 1: Getting Started as a VFAAR Provider

## Background of the VFAAR Program

The Vaccines for Adults at Risk (VFAAR) Program is a vaccine supply program that allows enrolled health care providers to give free immunizations to eligible adults.

The creation of the Vaccines for Children entitlement program in 1993 allowed PDPH to reallocate federal discretionary 317 funding to immunize at-risk adults. The adult immunization program started in 1994, targeting at-risk adults in shelters with Hepatitis A & B, influenza, and Td vaccines. The program has since expanded to include more community partners and vaccines, but still has the goal of serving the mostly medically at-risk adults in Philadelphia.

As of March 2015, VFAAR had 39 facilities enrolled in the program. In 2012, the Philadelphia Immunization Program distributed 13,295 doses of vaccines to VFAAR sites.

VFAAR Program sites include HIV treatment centers, FQHCs, health clinics in methadone maintenance programs, medical clinics that work with in the city's adult shelter system, social service organizations, family planning, STD clinics and primary care clinics. Philadelphia's nine Ambulatory Health Service (AHS) Health Centers provide adult immunization to eligible patients with VFAAR Program vaccine.

## Benefits to Providers and Patients

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

### Benefits to Providers:

- VFAAR vaccine provided at no cost
- Free program participation
- Immunization coverage assessments
- Updates and training for staff members

### Benefits to Patients:

- Ensure timely immunizations
- Reduce missed opportunities for immunizations
- No out-of-pocket costs to patients for vaccines

## Provider Responsibilities Overview

Providers who are part of the Philadelphia VFAAR 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 VFAAR eligibility screening of patients
- Administering VFAAR vaccine to VFAAR-eligible patients only
- Never denying vaccinations to VFAAR-eligible patients
- Never charging patients for the cost of VFAAR vaccine
- Ordering vaccines appropriately
- Complying with the current ACIP Recommended Immunization Schedule
- Follow federal guidelines for documenting vaccines administered
- Providing patients 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 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 VFAAR Program immediately
- Assuming full accountability for any vaccine supplied by the VFAAR Program, including financial reimbursement for vaccine wastage

## Enrolling as a VFAAR Provider

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

1. Serve VFAAR-eligible adult patients (patients age 19 through 64 years, uninsured adults only)
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 logs that are in-range for review before finalizing program enrollment
5. Have access to the Internet to order vaccines online
6. Register for KIDS Plus IIS
7. Enroll in the VFAAR 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 VFAAR Manual

Beginning in June 2016 all VFAAR enrollments will be done electronically through KIDS Plus IIS. You must log in and complete all the required fields for VFAAR 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 VFAAR Program will visit your site to complete an orientation and storage and handling inspection. This visit has two purposes:

1. To review VFAAR 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 VFAAR 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 VFAAR Program as long as VFAAR-eligible adults are seen in the practice. VFAAR providers still control which patients they accept

**Participation in the VFAAR Program may be suspended or terminated at the discretion of either the VFAAR 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 VFAAR. If the agreement is terminated, any unused VFAAR vaccine must be returned.

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

## **Section 2: Ordering Vaccines from VFAAR**

### **Philadelphia VFAAR Vaccines**

The Philadelphia VFAAR Program offers the following types of vaccines:

- Hepatitis A
- Hepatitis B
- HPV
- Influenza
- MCV4
- MMR
- PPSV23
- Tdap/Td
- Varicella

The Philadelphia VFAAR Program also offers the following combination vaccines:

- Hep A – Hep B

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

## Ordering VFAAR Vaccines

Providers enrolled in the VFAAR 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 VFAAR-eligible adults seen in a practice as reported on the Medical Practice Profile and validated by KIDS Plus IIS.

### Which vaccines can I choose?

Not all VFAAR sites need access to all available types of VFAAR vaccines. A VFAAR site may not see an adult population that needs access to all types of ACIP routine adult vaccines, therefore, the VFAAR program will review information about your provider site to identify the at-risk patient group your specific provider office serves. After review, the VFAAR program will communicate with you the type of VFAAR-funded vaccines your specific provider site may order through the VFAAR Program. Each provider site is considered unique based on their patient population.

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.

### 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 VFAAR Program does not require providers to order according to a particular schedule, but does expect orders to be appropriate, timely and accurate. The Philadelphia VFAAR 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 VFAAR-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 VFAAR 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, and remembering that pre-filled syringes use significantly more space than vial vaccines.

- Upon request, VFAAR 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 VFAAR vaccine more than once per month (except flu).

National shortages of vaccine do occur. This may make it necessary for the VFAAR 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 VFAAR 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 VFAAR vaccine?**

All providers must order VFAAR 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 VFAAR 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 VFAAR Program. Newly enrolled providers are required to order online and must have Internet access to do so.

## **Section 3: Provider Responsibilities for VFAAR**

### **Patient Eligibility and Screening**

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

#### **Eligible for VFAAR Vaccine**

- Between the ages of 19 and 64 years
- Uninsured
- Site-specific requirements

#### **Not Eligible for VFAAR Vaccine**

- Medicaid and Medicare patients
- Privately-insured adults
- Anyone younger than 19 years or older than 64 years

## Screening for VFAAR eligibility

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

- Screening of the adult 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 VFAAR 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.

## VFAAR Fees and Finance

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

### Other VFAAR Financial Responsibilities:

- Do **not** charge for VFAAR 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 VFAAR eligible adult even if the patient is unable to pay the administration fee.

## Compliance with the ACIP Recommended Schedule

VFAAR providers must comply with current immunization schedules, dosages and contraindications as established by the Advisory Committee on Immunization Practices (ACIP).

The U.S. Recommended Adult Immunization Schedule indicates the recommended ages for routine administration of currently licensed vaccines for adults older than 18 years.

Additional vaccines may be licensed and recommended during the year.

The adult ACIP-recommended schedule can be found: [www.cdc.gov/vaccines/schedules/hcp/adult.html](http://www.cdc.gov/vaccines/schedules/hcp/adult.html) and there is a link on the Philadelphia Immunization Program website.

## Record Keeping

The National Childhood Vaccine Injury Compensation Act (NCVIA) of 1986 established a “no-fault” system to compensate people following adverse events associated with 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 patient 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 VFAAR staff. The Philadelphia VFAAR 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 an adult'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 patient, 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 patient and/or the legal guardian.
- The patient/guardian **must** be given time to read the VIS prior to administration of the vaccine.
- The patient/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 patient/guardian a copy of the VIS every time a dose in a vaccine series is given, even if the patient 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 VFAAR vaccine or privately purchased.

If there is no VIS for a non-routine combination vaccine (e.g. Twinrix®), provide the VISs for all vaccine components.

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](http://www.immunize.org). If you do not have Internet access, you may request a single copy of any foreign language VIS from the Philadelphia VFAAR 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 influenza vaccine) given to all patients must be reported to KIDS Plus IIS, Philadelphia's citywide immunization database. This includes all vaccine doses, whether VFAAR 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 VFAAR 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 VFAAR Program conducts regular site visits of enrolled provider sites to ensure compliance with VFAAR 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 VFAAR Program conducts three types of quality assurance visits:**

1. VFAAR visits
2. Storage and handling visits
3. Follow-up visits, as needed

### **VFAAR Visits**

A VFAAR visit will assess compliance with VFAAR policies and immunization procedures. A VFAAR site visit has these components:

1. **Evaluation of vaccine storage and handling:** VFAAR staff 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 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.
3. **Visit feedback.** VFAAR will meet with appropriate key staff to discuss key findings from the VFAAR 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 VFAAR staff person and practice staff will discuss necessary quality improvement activities and opportunities for continued immunization education.

### **Storage and Handling Visits**

The VFAAR Program will perform storage and handling visits at sites. These visits may be announced in advance or they may be unannounced visits. During the visit a VFAAR staff person will look through the storage units housing 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.

### **Follow-up Visits, as Needed**

Follow-up visits usually occur as a result of issues found during VFAAR quality assurance visits. Follow-up visits may include components of storage and handling visits as well as components of the quality assurance topics, documentation, and education. 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 VFAAR policies, procedures, or visit findings.

## **Pharmaceutical Representatives**

Providers should know that VFAAR operates independently of industry influences. This enables providers to choose the vaccines that best suit the needs of their practices from a variety of manufacturers, depending on what is made available through the VFAAR federal contract.

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 VFAAR Program. While it is expected that these individuals will provide you and your staff with education on their products, the VFAAR Program will never ask nor encourage these representatives to assess provider vaccine inventory or order vaccine for your VFAAR patients. As a VFAAR provider it is your responsibility to ensure that only authorized VFAAR 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 VFAAR 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 VFAAR Program offers a number of resources to assist with staff training. Review of vaccine storage and handling is part of the site visit protocol, and on-site in-services are available upon request to the VFAAR Program. In addition, the VFAAR Program staff is available to answer questions. 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. VFAAR vaccine is shipped according to the operating hours on file at the VFAAR Program as reported on the “Medical Practice Profile” form. If your office hours change, you must notify the VFAAR Program if you have a vaccine delivery/shipment pending.

All VFAAR 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 “317 Doses” – which is the federal VFAAR funding stream.
2. Open the box immediately and inspect the contents. Contact the VFAAR Program immediately at 215-685-6837 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 VFAAR Program immediately.
4. With varicella vaccine shipments, always check the box lid for diluent.

5. Vaccine shipments are packed with 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 VFAAR 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 VFAAR. Do not discard vaccine prior to calling the VFAAR 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 VFAAR and Other Vaccine

Private vaccine and VFAAR vaccine should **not** be interchanged. The VFAAR Program will verify vaccine accountability during site visits. VFAAR vaccine should be clearly labeled as VFAAR vaccine to distinguish it from privately purchased vaccine.

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

If you cannot check and label your VFAAR 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 VFAAR 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 VFAAR 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. 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 in the storage unit.
- 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.
- Store food and beverages 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 VFAAR 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 VFAAR sites should have one back-up certified, calibrated digital thermometer with a biosafe glycol-encased probe. These thermometers have already been provided by the VFAAR 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 VFAAR 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 VFAAR Program’s temperature logs (available in °F and °C). VFAAR 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 VFAAR:

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 VFAAR 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 VFAAR 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 VFAAR 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 VFAAR vaccines should be aware of this plan, which should be posted on or near the refrigerator. Critical elements of any emergency plan include:

- Philadelphia VFAAR 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 VFAAR Program at 215-685-6837 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 VFAAR Program.

## **Section 5: Vaccine Accountability**

### **Changes in a Practice**

Staff changes are a common occurrence in VFAAR Provider offices. Any changes to the VFAAR contact, physicians, address, phone number, office hours or patient eligibility numbers should be reported to the VFAAR Program immediately. In all cases a new Medical Practice Profile will need to be completed. If the practice is moving to another location, the VFAAR 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 VFAAR Vaccine**

VFAAR 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.

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

- **Expired** – VFAAR product that exceeds the listed expiration date.
- **Spoiled** – VFAAR product that has been exposed to out-of-range temperatures, and is no longer viable.
- **Wasted** – VFAAR 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 VFAAR 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 VFAAR Program requires reimbursement for instances of expired, spoiled and wasted VFAAR 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 VFAAR 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 VFAAR Program, and providers discovered to be transporting vaccine between sites will be suspended from the program. If your practice is moving, call the VFAAR Program to arrange coordination of vaccine transport.

### **What about “borrowing” vaccine for VFAAR patients?**

There may be situations when VFAAR patients present to your office for vaccines but your practice does not have a particular vaccine or vaccines in your VFAAR 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 VFAAR Program. This is the procedure:

1. Call the VFAAR Program at 215-685-6837 to first ask permission to do this.
2. Keep a list of which VFAAR 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 VFAAR within 5 business days.
3. Once your VFAAR vaccine supply is replenished, you may replace the doses used from your private stock with an equal number of VFAAR vaccine doses. You must report to VFAAR the lot number and dose amounts of the replacement vaccine.
4. **You may never borrow VFAAR stock to immunize private patients.**

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

## **Grounds for Suspension from VFAAR**

Providers can be suspended from the VFAAR 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, a provider will be unable to place orders for VFAAR vaccine.

**Grounds for VFAAR Program suspension include:**

- Negligence in vaccine storage and handling
- Inability to account for vaccine supplied by VFAAR including flu vaccine
- Improper vaccine administration (not following ACIP recommendations, etc.)
- Transferring vaccine between sites
- Administering VFAAR vaccine to patients who are not VFAAR-eligible including flu vaccine
- Refusal to cooperate with required VFAAR 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**

The VFAAR Program becomes more vulnerable to fraud and abuse as the cost of vaccines increase and the complexity of the immunization program grows. Therefore, the VFAAR Program actively works to prevent, identify, investigate, and resolve all cases and suspected cases of fraud and abuse within the VFAAR Program.