

2019

# Provider Handbook



**PA. DEPARTMENT OF HEALTH  
DIVISION OF IMMUNIZATIONS**

Health and Welfare Building  
Room 1026  
625 Forster St.  
Harrisburg, PA 17120-0701

Phone: 717-787-5681  
Fax: 717-214-7223

Toll Free: **1-888-646-6864**  
EMAIL: [paimmunizations@pa.gov](mailto:paimmunizations@pa.gov)

# Welcome to the Pennsylvania Vaccines for Children Program

<p><b>How to Contact Us:</b>          Pennsylvania Department of Health (PADOH)          Division of Immunizations (DOI)          625 Forster St., Room 1026          Harrisburg, PA 17120          Toll Free: 1-888-646-6864          Phone: 717-787-5681          Fax: 717-214-7223          Fax: 717-441-3800 or 717-441-3777          Email: <a href="mailto:paimmunizations@pa.gov">paimmunizations@pa.gov</a>          Website: <a href="http://www.health.state.pa.us/vfc">http://www.health.state.pa.us/vfc</a></p> <p><b>Include your PIN number on all communications with DOI (every page)</b></p>	<p><b>Ordering questions:</b>          1-888-646-6864</p> <p><b>SIIS questions:</b>          1-877-774-4748</p> <p><b>School Immunization questions:</b>          717-787-5681</p> <p><b>Storage &amp; Handling/Staff Changes:</b>          Contact the district/county immunization nurse assigned to your region. Contacts are listed below.</p>
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## DISTRICT/COUNTY IMMUNIZATION NURSES

<b>Jennie Harpster-Basiago</b> Community Health Nurse Supervisor (CHNS)	<i>Eastern Region:</i> 717-787-5681
<b>Jennifer Bixler</b> Community Health Nurse Supervisor (CHNS)	<i>Western Region:</i> 717-787-5681
<b>Shawn Baer</b> Community Health Nurse	717-395-2885
<b>William Court</b> Community Health Nurse	717-439-5911
<b>Duane Daniels</b> Community Health Nurse	717-395-4185
<b>Connie Douglas</b> Community Health Nurse	717-395-3774
<b>Stephanie Gellatly</b> Community Health Nurse	717-395-1586
<b>Peggy Glass</b> Community Health Nurse	717-364-7022
<b>Rosemary Grill</b> Community Health Nurse	717-395-3574
<b>Janet Hessert</b> Community Health Nurse	717-307-5132
<b>Diana Kint</b> Community Health Nurse	717-395-6381
<b>Terry Metcalf</b> Community Health Nurse	717-319-9064
<b>Connie Moose</b> Community Health Nurse	717-307-5257
<b>Corrine Putt</b> Community Health Nurse	717-395-4506
<b>Christian Royek</b> Community Health Nurse	570-892-4091
<b>Joe Shamonsky</b> Community Health Nurse	717-319-7413
<b>Dana Shope</b> Community Health Nurse	717-395-6215
<b>Beth Anne Smith</b> Community Health Nurse	717-395-6450
<b>Ann Weaver</b> Community Health Nurse	717-319-4706

<b>ALLEGHENY COUNTY</b>	<b>412-578-7973</b>
<b>BUCKS COUNTY</b>	<b>215-345-3455</b>
<b>ERIE COUNTY</b>	<b>814-451-6788</b>
<b>MONTGOMERY COUNTY</b>	<b>610-278-5117</b>

**PHILADELPHIA IMMUNIZATION PROGRAM 215-685-6498**

# VFC Provider Handbook 2019 Revisions

Table of Contents: updated to reflect changes.

Welcome Letter; updated to reflect current phone numbers.

Please note that all through the handbook, the quality assurance tool has been updated from Assessment Feedback Incentives and Exchange program (**AFIX**) to Immunization Quality Improvement for Providers (**IQIP**) model. All instances where the acronym “AFIX” was utilized have been updated to “IQIP” as well. Effective July 1, 2019, the AFIX tool will be replaced with IQIP.

## Section 2

Page 2-1 Updated 3<sup>rd</sup> bullet under New Provider Enrollment “The VFC provider handbook is available online at the Pa. VFC website. Printing this handbook is strongly recommended, and all providers will be held accountable to the Pa. VFC handbook requirements.”

Page 2-2 Updated 8<sup>th</sup> bullet under Provider Requirements “with reason for refusal” and added link ([AAP-Refusal-to-Vaccinate](#));

Page 2-2 Added bullet under Provider Requirements “Not to send to collections for lack of payment of administration fee;

Page 2-5 Updated wording under Provider Annual Enrollment Update “Yearly CDC education modules 10 and 16 (You Call the Shots) must be successfully completed. Additional training may be required by the VFC program, and/or requested by the provider at any time.”

Page 2-6 updated subsection titled “Withdrawing from the VFC Program” to “Withdrawing, Relocating, Merging or Disenrolling from the VFC Program.”

Page 2-6 Added bullets under Withdrawing, Relocating, Merging or Disenrolling from the VFC Program “ Equipment that was previously grandfathered into the program will not be accepted as meeting the PA VFC requirements (example: household combo units) and “For sites disenrolling, vaccine will be picked up based on field staff availability.”

## Section 3

Page 3-2 Added wording “offer an alternative. In event of a shortage, provider will be required to carry brands made available through the Pa. VFC program.”

Page 3-2 Updated wording - the 10 vaccines are listed below “and are subject to change due to vaccine availability:”

Page 3-3 Added bullet under Vaccine Ordering “Credentials are issued per person, to the individual who has completed the required CDC modules, and not per site. New personnel will be required to contact Pa. VFC to acquire their individual credentials, upon successful completion of CDC modules.” and “Sharing of credentials may result in site suspension or disenrollment from the Pa. VFC program.”

Page 3-3 Added bullet under Prior to Placing Your Order “Confirm your site is not under suspension, or that there are no outstanding issues related to an incident report, training or reenrollment.”

Page 3-4 updated bullets under Placing a Vaccine Order “based on projected patient schedule” and “conforming to package size.”

Page 3-5 Added bullet under Shipment of Order “Flu delivery is subject to change due to timing of CDC allocations.”

Page 3-6 Added sub-section “Expiration Dates: VFC Vaccine compared to Private Vaccine.”

## **Section 4**

Page 4-1 Added bullet under Properly Functioning Equipment “units required (medical/pharmaceutical grade strongly recommended for all new enrollees, and for purchases/replacements)” and “new enrollment, reactivation and/or replacement unit purchases.”

Page 4-5: Updated bullet under Certified Digital Data Loggers “at least every 30 minutes, if not more often.”

Page 4-9: Added wording on Optional Training “CDC offers additional online training opportunities for providers on immunizations, storage and handling, and vaccine administration at the following link: <https://tceols.cdc.gov/> and “Per provider request, a DOI nurse will perform an on-site educational visit. All education should be documented on the Education Roster (Section 6-F).”

Page 4-10: Updated wording under Clearly Written Procedures “An alternate site with access available 24/7 is required.”

Page 4-16: Added section and graphic “Defrosting manual-defrost freezer units.”

Page 4-18: Added bullet under temperature log requirements “Once temperatures have been documented, follow instructions provided by manufacturer of temperature monitoring device to clear the temperature data on the display.”

Page 4-23: Updated text under Vaccine Adverse Event Reporting System and included links "<https://vaers.hhs.gov/>" and "[www.hrsa.gov/vaccinecompensation/index.html](http://www.hrsa.gov/vaccinecompensation/index.html)"

## **Section 5**

Pages 5-4 to 5-7: Added sections, "Sending or Transferring Vaccine" and "Sending/Transferring an Electronic Shipment of Vaccine."

## **Section 6**

Added bullets under PA VFC Education Roster "When roster is updated, remember to fax copy of educational certificates to the PA DOI at 717-214-7223, no later than April 1 of each calendar year" and "Please include your PIN on all correspondence with the VFC program."

Added additional column under Vaccine Emergency Handling Procedures and Disaster Recovery Plan "Alternate Site Check- Initial & Date."

Added two new Vaccine Return and Accountability forms "Wasted/Destroyed" and "Spoiled/Expired Returnable."

Updated wording on Interim/Final Status Report of Corrective Action Following Cold Chain Failure to "Interim/Final Status Report Following Cold Chain Failure."

Deleted wording on Interim/Final Status Report "Date cold chain failure resolved" and "To be completed by Division of Immunizations."

Added new document "Recording Vaccine Temperatures."

Deleted "Recording Freezer Temperatures" and "Recording Refrigerator Temperatures."

Added four new temperature logs: Fahrenheit Refrigerator Temperature Log, Fahrenheit Freezer Temperature Log, Celsius Refrigerator Temperature Log, Celsius Freezer Temperature Log.

Added wording under Transporting Refrigerated Vaccines "Equipment designed specifically for transporting vaccine may have varying instructions; please contact manufacturer for guidance on these occasions."

Added wording under Pre-Purchase Worksheet for Digital Data Logger "Ability to clear current min/max temperatures from the screen?"

Updated all links under Vaccine Manufacturer/Distributor Contact List.

Updated all links and information under Resources and Websites.

Updated all links under Acronyms.

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# INTRODUCTION

From 1989 to 1991, a measles epidemic in the United States resulted in tens of thousands of cases of measles and hundreds of deaths. Upon investigation, the Centers for Disease Control and Prevention (CDC) found that more than half of the children who had measles had not been immunized, even though many of them had seen a health care provider.

In partial response to that epidemic, Congress passed the Omnibus Budget Reconciliation Act (OBRA) on Aug. 10, 1993, creating the Vaccines for Children (VFC) Program. The purpose of this program is to improve immunization levels across the United States by providing vaccines, at no cost, to enrolled public and private providers. VFC became operational Oct. 1, 1994. Known as section 1928 of the Social Security Act, the VFC program is an entitlement program (a right granted by law) for eligible children birth through age 18.

Funding for the VFC program is approved by the Office of Management and Budget (OMB) and allocated through the Centers for Medicare & Medicaid Services (CMS) to the CDC. The program is regulated by the CDC National Center for Immunization and Respiratory Diseases (NCIRD). The VFC program is now operational in all 50 states, the District of Columbia, and five territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico and the Virgin Islands).

Pennsylvania began its VFC program in October 1994 under the administration of the Pennsylvania Department of Health (DOH), Division of Immunizations (DOI). CDC makes VFC vaccines available to the state through a federal grant for distribution to public health clinics and private providers enrolled in the VFC Program at no cost to the provider.

# SECTION 1 – VFC ELIGIBILITY

## Patient Eligibility Screening

Before administering a VFC vaccine to a child, the provider must question the child's parent or guardian to determine whether he or she is eligible for VFC vaccine, and document findings (Section 6-C).

**Children (birth through 18 years) are eligible for VFC vaccines if they meet at least one of the following criteria:**

- Are enrolled in Medicaid, i.e., children who have health insurance covered by a state Medicaid program;
- Are uninsured, i.e., have no health insurance;
- Are American Indian or Alaska Native; or
- Are underinsured. This includes a child who has health insurance but whose coverage does not include vaccines, or a child whose insurance covers only selected vaccines (VFC eligible for non-covered vaccines only).

**Note:** Underinsured children are eligible to receive VFC vaccine only through a federally qualified health center (FQHC), rural health clinic (RHC) or a state health center (SHC) under an approved deputization agreement. \*

\*This is the formal extension of VFC authority through a memorandum of agreement to provide VFC vaccine to eligible, underinsured children from a participating FQHC or RHC to another VFC-enrolled provider. Under this arrangement, the deputizing FQHC or RHC retains its full scope of authority as a VFC provider while extending the authority to deputized VFC providers to immunize underinsured children with VFC vaccine.

Children with health insurance that covers vaccines, and who fail to meet one of the previously mentioned criteria are **not eligible** through the VFC program, even when the insurance requires a deductible. There are no income restrictions imposed by the VFC program, as long as the child meets all other enrollment criteria.

## Insured Children

Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines, even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible (high

deductible plan) had not been met. Children with the Pennsylvania’s Children’s Health Insurance Program (CHIP) are not eligible for VFC vaccine.  
 Covered benefits and VFC eligibility table follows:

VFC eligibility scenario: Child is insured and ...	Insurance Status	VFC Eligible
Has not yet met plan’s deductible	Insured	No
Plan covers all ACIP recommended vaccines but excludes certain products/combination vaccines	Insured	No
Plan covers only a portion of the vaccine cost and does not have Medicaid as secondary insurance	Insured	No
Plan covers only a portion of the vaccine cost and has Medicaid as secondary insurance	Medicaid eligible	Yes
Has not yet met plan’s deductible and has Medicaid as secondary insurance	Medicaid eligible	Yes
Has exceeded plan’s annually allowed number of provider visits or insurance doesn’t cover vaccines	Underinsured– Only through FQHC/RHC or deputized SHC	Yes
Cannot access health insurance due to being incarcerated	Uninsured	Yes

### Charges and Fees for Immunization of the VFC-Eligible Clients

Provider’s bill according to Current Procedural Terminology codes that are based on each vaccine (type of immunization) administered. Reimbursement through Medicaid varies by state. Some state Medicaid agencies reimburse a vaccine with multiple antigens at a higher rate than a single antigen vaccine. Some states limit the amount of administration fees reimbursed per visit. Please check with the state Medicaid agency to determine how the VFC administration fees are reimbursed. State Medicaid agencies cannot eliminate reimbursement of an administration fee because of how the vaccine is administered (i.e., injection versus orally administered). All Medical Assistance (MA) providers with billing/coding questions should contact the MA provider inquiry number at **1-800-537-8862**.

For non-Medicaid VFC-eligible children (i.e., American Indian/Alaska Native, uninsured and underinsured), the administration fee is based on vaccine dose, **not the number of antigens** contained in a vaccine dose. The administration fee charged to a non- Medicaid VFC-eligible child cannot exceed the maximum regional charge (i.e., **\$23.14 per vaccine**), except in

universal-purchase states (Pennsylvania is not a universal-purchase state), and then only if certain conditions are met. However, "The provider will not deny administration of a qualified pediatric vaccine to a vaccine-eligible child due to the inability of the child's parents to pay an administration fee." This requirement must be met by all VFC providers. Furthermore, the VFC legislation does not require providers to honor vaccine requests by VFC-eligible children who "walk-in" for immunizations only and are not established patients in their practice.

**No VFC-eligible client may be refused administration of a vaccine due to an accompanying adult's inability to pay an administration fee.**

## SECTION 2 – PROVIDER ENROLLMENT/ REQUIREMENTS/RESPONSIBILITIES

### New Provider Enrollment

Providers interested in enrolling in the Pennsylvania Vaccines for Children Program (Pa. VFC Program) should call 1-888-646-6864 to request a VFC enrollment packet. The steps to enroll are:

- Complete and submit the Pa. Vaccines for Children Program provider agreement form (Pa. VFC PPA) by fax to 717-214-7223.
- Upon receipt of the completed Pa. VFC PPA, a provider identification number (PIN) will be assigned to your facility.
- The [VFC provider handbook](#) is available online at the Pa. VFC website. Printing this handbook is strongly recommended, and all providers will be held accountable to the Pa. VFC handbook requirements. The VFC handbook should be reviewed by the physician(s), office manager, primary and backup VFC contacts prior to the enrollment/training site visit.
- Prepare your office and staff for a site visit to go over the administrative requirements of the program and to ensure proper storage and handling of vaccines when received.
- View the video, “Keys to Storing and Handling Your Vaccine Supply” and print credentials from the CDC website. This is required for all new enrollments and re-activations. The video is found at the following site:

<http://www2a.cdc.gov/vaccines/ed/shvideo/>

<http://www.youtube.com/watch?v=0atwOngjVQY>

- An immunization nurse from your district will contact you to schedule an enrollment/training site visit to review all aspects of the VFC program, to ensure that the vaccine storage units and dataloggers meet the requirements of the CDC, and to answer any questions staff may have. This visit takes approximately two hours.
- After completion of the enrollment/training visit, the immunization nurse will notify the department that your facility has been approved to order and receive VFC vaccines.
- VFC staff will notify the PA Statewide Immunization Information System (PA-SIIS) to provide the primary and back-up VFC coordinators with unique usernames and passwords referred to as “logon credentials.” This will allow staff to order vaccines online, update facility address and list vaccine shipping hours.

## Provider Requirements

Any physician, health care organization or medical practice licensed by the state of Pennsylvania to prescribe and administer vaccines may enroll as a provider in the VFC program. Requirements for provider enrollment are simple yet ensure accountability. Pa. VFC PPA (Section 6-B) details physician eligibility requirements for participation in the VFC program. By signing this agreement, the health care provider agrees that he/she has read, understands, and will comply with the following program requirements:

- Provide Pa. VFC program with accurate and valid email addresses for both VFC primary coordinator and backup coordinator;
- Notify Pa. VFC program of any changes in primary or backup coordinator email addresses;
- Update Pa. VFC program with patient population changes;
- Administer VFC program vaccines to VFC-eligible children;
- Retain all VFC documentation, including patient eligibility screening records, for a minimum of three years;
- Make immunization records available to the department, upon request and during CDC required site visits;
- Comply with the appropriate immunization schedule, dosage and contraindications established by the CDC's Advisory Committee on Immunization Practices (ACIP);
- Document and retain parent/guardian/individual refusal/rationale for not having client immunized ([AAP-Refusal-to-Vaccinate](#));
- Provide current vaccine information statements (VIS), maintain records in accordance with the National Childhood Vaccine Injury Act, and according to federal law, provide patients, or their parents or legal representatives, with the appropriate VIS whenever a vaccination is given (<http://www.cdc.gov/vaccines/hcp/vis/index.html>);
- Not to impose a charge for the cost of the vaccine to any eligible patient;
- Not to impose a charge for the administration of the vaccine in any amount higher than the maximum fee of **\$23.14**;
- Not to deny administration of a vaccine to a child due to the inability of the child's parent/guardian/individual of record to pay an administrative fee;
- Not to send to collections for lack of payment of administration fee;
- Comply with VFC program procedures and requirements; and
- Adhere to all federal and state requirements.

## Provider Responsibilities

In addition to specific requirements needed to participate in the Pa. VFC program, specific responsibilities must be met as well. Those responsibilities consist of:

### Notifying DOH regarding (Section 5):

- Change in facility name
- Change in facility address
- Change in facility telephone or fax number
- Change in facility hours of operation
- Change in primary VFC contact
- Change in back-up VFC contact
- Change in medical director/primary physician
- Change in provider status from public to private, or private to public

#### **Staff training (Section 4):**

- Provide internal training on proper vaccine storage and handling guidelines;
- Provide internal training on vaccine administration protocols to each new employee at time of employment orientation and review annually; and
- Document these trainings and those who attended as required.

#### **Developing and maintaining written procedures (Section 6-E):**

- Emergency handling procedures
- Vaccine management plan
- Vaccine disaster recovery plan

#### **Twice-daily temperature documentation (Section 6-H):**

- Time when temperature was checked
- Initials of staff checking unit temperature
- Current, min, and max temperature
- Corrective action documentation on the temperature log (if needed)

#### **Vaccine storage and handling (Section 4):**

- CDC/DOH requirements/recommendations
- Equipment (refrigerators/freezers)
- Digital data loggers/continuous temperature monitoring systems
- Maintenance of cold chain.

## **Provider Annual Enrollment Update**

In order to remain enrolled in the VFC Program and continue to receive VFC vaccines, it is mandatory to complete, sign and submit the Pa. VFC PPA annually. This document must be updated annually, or whenever there is a significant change in patient

enrollment or when the physician who signed the Pa. VFC PPA leaves the practice. Provider sites must complete the annual enrollment update online via the Pennsylvania Statewide Immunization Information System (PA-SIIS) website [Section 5].

- Keep a copy of the original Pa. VFC PPA.
- Document and forward all updates to the DOH as changes occur regarding staff with vaccine administration privileges.
- Fax, email or mail to the DOH.

A separate form must be completed for each site receiving vaccine. Failure to submit the annual enrollment update as directed by the Pa. VFC Program will result in suspension of vaccine ordering privileges and may lead to disenrollment.

## **Pa. VFC compliance site visits**

At a minimum, a VFC compliance site visit will occur every other year at all Pa. VFC enrolled provider offices. Additional site visits will occur at the request of the provider for educational purposes or at the request of the DOH for programmatic issues, including unannounced site visits. The model used to achieve quality assurance in the Pa. VFC program is the Immunization Quality Improvement for Providers (IQIP) model. **IQIP** is a quality improvement strategy to raise immunization coverage rates and improve standards of practices at the provider level.

A **VFC compliance site visit** determines if Pa. VFC vaccines are being distributed, handled and administered according to the laws and policies that are part of the Pa. VFC program, which includes the following:

- Appropriate vaccine ordering procedures and accountability (Section 3);
- Appropriate vaccine storage and handling (Section 4);
- Proper documentation of children's Pa. VFC eligibility status;
- Sampling patient records to ensure appropriate Pa. VFC eligibility screening and documentation of VFC eligibility;
- Ensuring proper administration of Pa. VFC purchased vaccines only to Pa. VFC eligible children;
- Compliance with documentation and record-retention requirements;
- Proper use and documentation of the vaccine information statements (VIS), which must be offered to the parent/guardian prior to each immunization;
- Maintaining records of children who had an adverse reaction to a vaccine according to the National Childhood Vaccine Injury Act;
- Maintaining accurate inventory of vaccine lot numbers received and administered;
- Agreeing not to charge a vaccine administration fee that is higher than the maximum fee (**\$23.14**) established by the state;

- Agreeing not to charge for the cost of the vaccine; and
- Agreeing not to deny immunizations because of the parent's inability to pay a vaccine administration fee.

Yearly CDC education modules 10 and 16 (You Call the Shots) must be successfully completed. Additional training may be required by the VFC program, and/or requested by the provider at any time. (Section 4-8, 4-9).

An **IQIP site visit** is needed to evaluate quality improvement activities, including the following:

- Assessing the provider's immunization coverage rates through an evaluation of patient immunization records for both Pa. VFC and non-Pa. VFC eligible patients;
- Providing feedback of performance data to clinicians and office staff to make them aware of their immunization practices; and
- Providing guidance to help staff diagnose service delivery problems, adopting interventions for improvement and producing information on the following:
  - Current Advisory Committee on Immunization Practices (ACIP) recommendations;
  - Valid contraindications to immunizations;
  - Record-keeping practices;
  - Patient flow sheets; and
  - Reminder/recall systems.

A **follow-up visit** is a contact/visit to the provider site to review progress after a recent site visit. Follow-up contacts/visits will continue until all issues are resolved.

An **annual provider training visit** is a visit to a Pa. VFC enrolled provider office to perform an educational information session. A Pa. VFC provider may request a Pa. VFC personnel training visit whenever the need arises. This is required for new staff at the practice site. All aspects of the VFC program are reviewed during an education visit. In addition, the Pa. VFC provider handbook is reviewed thoroughly with office staff during this visit.

Given the amount of funding and considerable resources that are invested in implementing and managing the Pa. VFC program, quality assurance site visits are important to evaluate whether the program is managed appropriately and is achieving the desired outcomes. Evaluation provides objective insight into a program and identifies opportunities to assess its impact, make improvements or build program capacity. For the Pa. VFC program, it is important to evaluate program processes and outcomes. The desired outcome of the Pa. VFC program is to ensure that viable vaccine is administered to eligible children.

**Unannounced storage and handling visits** are now a requirement from CDC. Unannounced visits are separate from the VFC compliance visits and will serve as a spot check for proper storage and handling practices.

## Withdrawing, Relocating, Merging or Disenrolling from the VFC Program

To ensure a smooth transition of services, the following steps must be taken in the event a facility chooses to discontinue participation in the Pa. VFC Program, is relocating, and/or merging with another facility.

- **Notify the Pa. VFC program 30 days in advance at (1-888-646-6864)** if the office plans to dis-enroll, relocate or merge with another facility.
- Submit a complete inventory of all Pa. VFC vaccines on-site to include brand, lot number, expiration date and number of doses.
- Submit three months of temperature logs.
- Refer VFC-eligible children to another VFC Provider. If necessary, contact the DOH for help finding another VFC provider.
- Equipment that was previously grandfathered into the program will not be accepted as meeting the PA VFC requirements (i.e. household combo units).
- For sites disenrolling, vaccine will be picked up based on field staff availability.

## Fraud Waste and Abuse

The Pa. VFC Program recognizes that majority of VFC providers stand by their legal and professional duties and provide critical health care services to VFC patients every day. The Pa. VFC Program is committed to safeguarding federally funded vaccines by targeting fraud perpetrators and saving taxpayer dollars while reducing the burden on legitimate providers.

The comprehensive program to prevent and detect fraud, waste and abuse consists of:

- Procedures for the identification of potential fraud, waste and abuse in the Pa. VFC Program;
- A process to conduct a timely, reasonable review of potential violations of federal and state criminal, civil and administrative laws, rules and regulations; and
- A process to refer potential violations of federal and state criminal, civil and administrative laws, and violations of federal and state rules and regulations to law enforcement for further investigation within a reasonable period.

The goal of the Pa. VFC Program's fraud, waste and abuse initiative is to:

- **Prevent** fraud, waste and abuse before it occurs;
- **Detect** fraud, waste and abuse that is taking place; and
- **Report** suspected fraud, waste and abuse\*

All Medical Assistance (MA) providers who suspect welfare fraud should call 1-800-932- 0582.

\* Provider may be withdrawn from the VFC program if fraud and abuse is confirmed; the immunization nurse will retrieve all VFC vaccines at the time of withdrawal.

## **SECTION 3 - VACCINE MANAGEMENT, ORDERING AND RETURNING**

Providers are responsible for the proper maintenance of their vaccine inventory and for ordering vaccine.

### **Management**

- Post a vaccine expiration list on the refrigerator and freezer.
- Check and rotate inventory on a weekly basis.
- Administer short-dated vaccines first.
- Inform immunization nurses their role in assisting and relocating vaccines expiring in 90 to 120 days to avoid waste.
- Deplete current, single antigen vaccine inventory before switching to a combination antigen vaccine.

### **Vaccines Available Through the Pa. VFC Program**

- Diphtheria, tetanus and acellular pertussis (DTaP)
- Haemophilus influenzae type b (Hib)
- Hepatitis a (Pediatric)
- Hepatitis b (Pediatric)
- Human papillomavirus (HPV)
- Influenza
- Measles, mumps and rubella (MMR)
- Meningococcal conjugate (MCV4)
- Meningococcal B
- Pneumococcal conjugate 13 (PCV13)
- Pneumococcal polysaccharide (PPSV23)
- Polio (IPV)
- Rotavirus
- Tetanus and diphtheria (Td)
- Tetanus, diphtheria and acellular pertussis (Tdap)
- Varicella
- Several combination vaccines

In addition, the following non-VFC vaccines are available by request for department-approved public providers, including state health centers, county and municipal health departments, federally qualified health centers, rural health clinics and other public providers as approved by the DOH:

- Hepatitis A (adult)
- Hepatitis B (adult)
- Human papillomavirus (HPV - adult)
- Measles, mumps and rubella (MMR - adult)
- Meningococcal conjugate (MCV4 - adult)
- Meningococcal B (adult)
- Pneumococcal conjugate 13 (PCV13 - adult)
- Pneumococcal polysaccharide (PPSV23 - adult)
- Tetanus and diphtheria (Td - adult)
- Tetanus, diphtheria and acellular pertussis (Tdap - adult)
- Varicella (adult)

Currently the DOH provides 10 vaccines for which there are more than one manufacturer's brand. DOH staff will contact the provider if the brand ordered is not available and offer an alternative. In event of a shortage, provider will be required to carry brands made available through the Pa. VFC program.

The 10 vaccines are listed below, and are subject to change due to vaccine availability:

- DTaP                      Diphtheria, tetanus and acellular pertussis
  - Sanofi Pasteur (Daptacel)
  - GlaxoSmithKline (Infanrix)
  
- Hep A                      Hepatitis A
  - Merck (Vaqta)
  - GlaxoSmithKline (Havrix)
  
- Hep B                      Hepatitis B
  - Merck (Recombivax)
  - GlaxoSmithKline (Engerix)
  
- Hib                         Haemophilus influenzae type b
  - Merck (PedvaxHIB)
  - GlaxoSmithKline (Hiberix)
  - Sanofi Pasteur (ActHIB)

- Influenza                      Flu (seasonal change based on availability)
  
- MCV4                            Meningococcal conjugate
  - Sanofi Pasteur (Menactra)
  - GlaxoSmithKline (Menveo)
  
- Meningococcal B            Meningococcal
  - GlaxoSmithKline (Bexsero)
  - Pfizer (Trumenba)
  
- Rotavirus                      Rotavirus
  - Merck (RotaTeq)
  - GlaxoSmithKline (Rotarix)
  
- Tdap                             Tetanus, diphtheria and acellular pertussis
  - Sanofi Pasteur (Adacel)
  - GlaxoSmithKline (Boostrix)
  
- Td                                Sanofi (Tenvirac)  
Grifols (Td vaccine)

## Vaccine Ordering

Vaccine orders are placed online using PA-SIIS (Section 5).

- Credentials are issued per person, to the individual who has completed the required CDC modules, and not per site. New personnel will be required to contact Pa. VFC to acquire their individual credentials, upon successful completion of CDC modules.
- Sharing of credentials may result in site suspension or disenrollment from the Pa. VFC program.

### Prior to placing a vaccine order

- Confirm your site is not under suspension, or that there are no outstanding issues related to an incident report, training or reenrollment.
- Confirm your practice information in PA-SIIS (i.e., shipping address, shipping hours -- please make sure that office hours are correct/up to date) [Section 5].
- Accept previous shipments into PA-SIIS.

- Reconcile inventory in PA-SIIS (Section 5).
- Failure to adhere to the above requirements may lead to order being delayed or not processed.

### **Placing a vaccine order**

- Order once a month: first through 15<sup>th</sup>.
- Order only one month's supply of vaccine, based on projected patient schedule.
- Order by number of doses, **conforming to package size**.
- Order according to type of facility (private providers are allowed to order only pediatric vaccines; public providers may order pediatric and adult.)
- Indicate in PA-SIIS "NOTES" field if needed by a specific date or any other special instructions.
- Contact the DOH toll free line 1-888-646-6864 or email questions to [paimmunizations@pa.gov](mailto:paimmunizations@pa.gov) if you have problems or need help ordering vaccine.
- Review the order in PA-SIIS prior to clicking "update" to submit for approval.

### **Vaccines to order in multiples of 5 doses**

- Pentacel
- ActHIB
- Menveo
- Menactra
- Adacel (SYR)

### **Vaccines to order in any number of doses (eg. 1 dose, 3 doses, 17 doses, etc)**

- Td
- PPV23

**All other vaccines are ordered in multiples of 10 doses only.**

### **Shipment of order**

- Vaccines should arrive 5 to 10 business days after ordering. Shipments are delivered Tuesday through Friday by express carrier: Federal Express (Fed Ex) or United Parcel Service (UPS). Varicella and MMR-V, when available, are shipped directly from the manufacturer (Merck) and can take 30 days to arrive.
- Notify front office staff or supply personnel when a vaccine delivery is expected.
- Ask receiving staff to notify VFC contact(s) immediately when vaccine is delivered.

- Properly store shipment in refrigerator/freezer as indicated on the package if VFC contact(s) is/are not available.
- **NEVER** refuse a vaccine shipment from McKesson Specialty Distribution or Merck.
- Flu delivery is subject to change due to timing of CDC allocations.

## Vaccine Expiring within Ninety Days

If vaccines are within 90 days of expiration and cannot be used, they may be transferred to a participating VFC provider. Contact your immunization nurse to properly coordinate such transfers.

- Providers who are affiliated within hospital systems or have multiple sites should rehome vaccines within those sites to prevent waste from expiration.
- Solo practices are to contact their local DOI nurse for assistance in relocation of expiring vaccine.

## Returning Vaccines

- All vaccines, including flu, deemed “**spoiled/expired returnable**” should be returned within **six months following expiration date**. However, vaccines that have expired more than six months previously will still be accepted. When requesting a shipping label for the return of vaccines, please allow one to five business days to receive notification. Complete the vaccine return and accountability form for returning all vaccines (Section 6-F).

Vaccines may be returned when:

- Expiration date has passed and unopened.
- Failure to store or handle properly (e.g., vaccine left out overnight, not put away upon arrival)
- There is a mechanical failure (refrigerator/freezer failure) - must complete incident report);
- There is a power outage/natural disaster (must complete incident report);
- The refrigerator/freezer is too warm (must complete incident report);
- The refrigerator/freezer is too cold (must complete incident report);
- There is spoilage of vaccine in transit (must complete incident report).

**\* Please remember that all vaccines that are being returned must be unopened. Multi-dose vials of polio vaccine that are open should not be returned. All other multi-dose vials that are open should not be returned either. See section 6-F: vaccine return and accountability for more detail on returnable and non- returnable vaccines.**

## Expiration Dates: VFC Vaccine compared to Private Vaccine

- Pennsylvania VFC distributes the Polio vaccine - Single-antigen IPV (IPOL) in 10-dose vials (MDVs). MDVs can be used until the expiration date printed on the vial unless the vaccine is contaminated or compromised in some way or there is a Beyond Use Date noted in the package insert.
- In order to prevent waste and be accountable for federal vaccines funds, it is **required** that providers fully utilize open vials of the Polio vaccine unless contaminated, exposed to temperature excursions or expired.
- Providers who also carry private vaccine are expected to follow the PA VFC policy on VFC public-funded vaccines regardless of internal policies on privately purchased vaccine.

## SECTION 4 - VACCINE STORAGE AND HANDLING

Keeping vaccines at the recommended temperature is called **maintaining the cold chain**. The cold chain begins at the manufacturer, extends to the distributor and continues in the provider site until the vaccine is administered. Proper vaccine temperature must be maintained during transit and at every link in the chain to ensure its viability.

Vaccine cold chain failure occurs when there is a break in any link of the chain. Cold chain failure may occur due to a power failure, staff error, equipment failure, etc. Preventing vaccine cold chain failure requires: properly functioning equipment, appropriately trained staff, clearly written procedures and easily accessible emergency operating protocols.

### Properly Functioning Equipment

- Vaccine storage units
- Certified digital data loggers/continuous temperature monitoring systems

### Vaccine Storage Units - Pa. VFC requirements (Section 6-J)

DOH-supplied vaccine must be stored in one of the following:

- Standalone storage units required (medical/pharmaceutical grade strongly recommended for all new enrollees, and for purchases/replacements); or
- Medical/pharmaceutical grade combination units.

All new providers enrolling in the VFC program are required to use standalone refrigerators and standalone freezers for vaccine storage. Household combination units are **not** permitted for new enrollment, reactivation and/or replacement unit purchases.

### CDC recommendations

CDC highly recommends medical grade units. All storage units must be approved by the VFC immunization nurse through a site visit for enrolled VFC providers. For new providers, it is required to use standalone freezers and standalone refrigerators for vaccine storage.

## CDC requirements

Absolutely **NO DORMITORY OR BAR STYLE** units will be accepted. Using such units will result in an immediate suspension of vaccine ordering privileges and forced wastage of all VFC vaccine stored in the units.

- All vaccines stored in a dormitory style unit are considered non-viable and must be returned to McKesson Specialty Distribution. Complete and submit a Vaccine Return Form found in Section 6-F.



**The use of dormitory or bar-style refrigerator/freezers is prohibited at all times, and will lead to disenrollment from the VFC program.**

## STORAGE UNITS

**Medical/Pharmaceutical Grade  
Full-sized**



**Standalone Units  
Refrigerator only**



**Under-the-counter**



## Vaccine storage units must be:

- Able to maintain required vaccine storage temperatures year-round (Recording temperatures, Section 6-H).

**Refrigerator: 36.0°F to 46.0°F/2.0°C to 8.0°C**

**Freezer: -58.0°F to 5.0°F/-50.0°C to -15.0°C**

- Large enough to hold the year's largest inventory;
- Defrosted on a monthly basis if freezer unit is not self-defrosting;
- Cleaned every month to discourage bacterial and fungal growth; and
- Placed in a well-ventilated room with appropriate ambient temperature and sufficient space (at least four inches) around the sides and top for air circulation.

## Certified Digital Data Loggers (Section 6-J)

### Pa. VFC requirements

- A digital data logger/continuous temperature monitoring device with an active digital display, current min/max display, a detachable probe encased in a biosafe buffered material, and a valid/current National Institute of Standards and Technology (NIST) certificate of traceability and calibration. **NOTE:** There is a list of digital data logger manufacturers in Section 6-J.
  - VFC highly recommends a biosafe glycol-encased probe, but will accept the following buffered materials if NIST certified:
    - ✓ A vial filled with liquid (i.e., glycol, ethanol or glycerin);
    - ✓ A vial filled with loose media (i.e., sand or glass beads); and
    - ✓ A solid block of material (i.e., Teflon® or aluminum).
- The best calibration is annual, however, the DOH will accept a manufacturer's suggestion not to exceed two years.
- Digital data logger probes must be placed/secured in the center of each storage unit, unless specified otherwise by the manufacturer.
- VFC providers are **required** to have at least one back-up digital data logger at the provider site, with a valid and current certificate of calibration readily available on site to ensure twice-a-day temperature assessment and recordings.
- Providers are responsible for the maintenance and NIST recalibration of all digital data loggers/temperature monitoring devices. Newly purchased units and recalibrations are at the expense of the provider site.
- Digital display on outside of storage unit to allow reading temperatures without opening unit door.
- Alarm to alert out-of-range temperatures.
- Accuracy within +/-1.0°F (+/- .5°C).

- Low battery indicator.
- Continuous monitoring and recording capabilities to track and record temperatures over time.
- Display of current, as well as minimum and maximum temperatures, which indicate the coldest and warmest temperatures recorded since device was reset. Please refer to the digital data logger policy in Section 6-J.
- Logging interval (or reading rate) that can be programmed by the user to measure and record temperatures at least every 30 minutes, if not more often.

### **Setting up your new equipment**

- Notify the immunization nurse in your area there is to be a change in vaccine storage unit.
- Obtain and document four to seven days of in-range temperatures and schedule a site visit to have the unit approved by an immunization nurse before using any new storage unit purchased or transferred.
- Ensure the refrigerator doors are closed properly and the unit is level and in good working order. Notify the VFC contact person immediately if problems occur.
- Advise maintenance and cleaning personnel not to unplug storage units. Post “Do Not Unplug” stickers near the outlet.
- Ensure that only one outlet is used for each individual storage unit.
- Have a safety-lock plug or “DO NOT UNPLUG” sign at the unit.
- Have a “DO NOT DISCONNECT” sign at the breaker box.

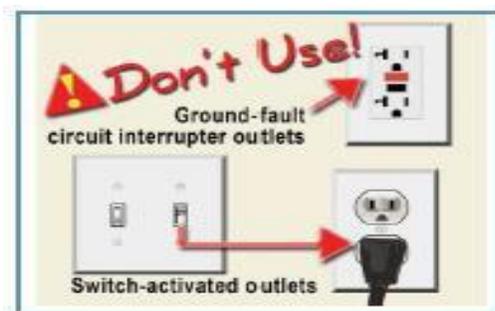


**Safety-lock plug**



**Use outlet covers. Post warning signs and labels.**

- Do not use power outlets with built-in circuit switches and outlets that can be activated by a wall switch.
- Do not use multi-outlet power strips.
- Do not use extension cords.



## Appropriately Trained Staff

### Designate primary and back-up contact individuals who are responsible for:

- Ensuring the VFC Program Provider Handbook and related immunization materials are current and accessible to all staff;
- Training all staff on the proper protocols for receiving vaccine shipments in the absence of the primary and back-up vaccine contact individuals;
- Ordering, receiving and storing vaccine shipments in accordance with requirements;
- Identifying and separating VFC vaccines from privately purchased vaccines; \*
- Monitoring vaccine expiration dates and weekly rotation of vaccine inventory with the shortest expiration date in front, notifying the DOH regarding any short-dated vaccines and removing expired vaccines from the viable vaccine storage units;
- Ensuring digital data loggers used inside both refrigerators and freezers are NIST certified digital data loggers with glycol/buffered probes;
- Ensuring appropriate monitoring and documentation of temperature logs;
- Notifying the DOH immediately regarding any vaccine storage and handling problems to include Incident Report and Vaccine Return and Accountability Form submission for any out of range temperatures (Section 6-F);
- Developing and maintaining a maintenance/cleaning schedule for storage and handling equipment used to store DOH provided vaccines; and
- Only transporting vaccine to other locations using procedures pre-approved by DOH, maintaining the vaccine cold chain (Section 6-I).

\* Clinics/practices serving both VFC and non-VFC eligible children must clearly identify and separate VFC and 317 funded vaccines from private purchased vaccines using VFC and 317 stickers provided by DOH.

### Designate a person to be the primary vaccine coordinator for your facility.

This person will be responsible for ensuring all vaccines are stored and handled correctly.

**Appoint a second staff member to serve as an alternate in the absence of the primary coordinator (this is particularly important in case of after-hours emergencies.) Both coordinators should be fully trained in routine and emergency policies and procedures.**

### Coordinator responsibilities:

- Ordering vaccines;
- Overseeing proper receipt and storage of vaccine deliveries;

- Documenting vaccine inventory information and organizing vaccines within storage units;
- Setting up temperature monitoring devices;
- Reading and recording storage unit temps a minimum of two times each workday;
- Reading and recording current minimum/maximum temps from a digital data logger two times each workday;
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends;
- Rotating stock at least weekly so vaccine with the earliest expiration dates are used first;
- Removing expired vaccine from storage units;
- Responding to out-of-range temperatures (temp excursion);
- Maintaining all documentation, such as inventory and temperature logs;
- Ensuring staff is properly trained;
- Monitoring operation of storage equipment and systems;
- Overseeing proper vaccine transport (when necessary);
- Overseeing emergency preparations, including plans for ensuring safety of vaccine during emergencies;
- Tracking inclement weather conditions; and
- Ensuring appropriate handling of vaccines during disaster or power outage.

### **Training your personnel**

Mandatory personnel training regarding proper vaccine storage and handling guidelines and vaccine administration protocols are required for the primary and back-up VFC coordinator. New coordinators must complete this training requirement during orientation to the position. All office staff (i.e., receptionists, mail handlers, nurses, medical assistants) accepting vaccine shipments or administering vaccines must be trained on vaccine management procedures.

Documentation of training must be added to the educational roster (Section 6-A) and retained for three years. Fax/email copies of completed educational training certificates to the VFC central office:

Fax: 717-214-7223

Email: [Paimmunizations@pa.gov](mailto:Paimmunizations@pa.gov)

**In order to insure appropriate credit is given to person and facility, please include provider's PIN on each individual document.**

Providers must complete the following CDC required educational modules. These two modules must be completed and faxed prior to April 1<sup>st</sup>, each year:

- CDC “You Call the Shots” programs (Print credentials from CDC website and fax/email copies to PA DOI)
  - [Vaccines for Children \(VFC\) JAN 2019](#)  
Scroll to bottom of page and click "continue" to start program
  - [Vaccine Storage and Handling JAN 2019](#)  
Scroll to bottom of page and click "continue" to start program
  - The CDC provides continuing education credits at the following link:  
<http://www2a.cdc.gov/TCEOnline/help.asp>

If you have difficulty printing certificates:

- <https://tceols.cdc.gov/Home/Contact>
- Call 1-800-41-TRAIN.
- Email [CE@CDC.gov](mailto:CE@CDC.gov).

\* If you have any problems with the training, please do not hesitate to contact your district nurse or DOI.

## Optional Training

CDC offers additional online training opportunities for providers on immunizations, storage and handling, and vaccine administration at the following link: <https://tceols.cdc.gov/>

Per provider request, a DOI nurse will perform an on-site educational visit. All education should be documented on the Education Roster (Section 6).

## Clearly Written Procedures (Section 6-E)

**VFC providers are required to:**

Develop and maintain a routine **vaccine management plan**, providing guidelines to ensure the vaccine cold chain is maintained. For this plan:

- Designate staff responsible for all functions of vaccine management.
- Assign functional responsibility for executing the plan.
- Review and document personnel and functions annually.

Develop and maintain a **vaccine emergency handling procedures and disaster recovery plan**. This provides guidelines for developing emergency handling procedures and a vaccine disaster recovery plan to follow when cold storage units malfunction due to mechanical failure or natural disaster to ensure that the vaccine cold chain is maintained. For this plan, providers should:

- Identify an alternative vaccine storage facility, such as a hospital, packing plant or local pharmacy, that has proper refrigerator and freezer units, continuous temperature-monitoring capabilities with twice daily documentation (DDLs or approved continuous temperature monitoring system) and backup power (generator) where vaccine can be stored in an emergency. An alternate site with access available 24/7 is required;
- Call quarterly to make sure the alternate site is still available and will meet Pa. VFC program requirements, and document this information;
- Identify and train staff responsible to pack, monitor and move vaccine during an emergency to a safe location;
- Have a list of emergency phone numbers for local utility companies;
- Make written descriptions of floor plans and vaccine locations available;
- Establish a location of a supply of appropriate packing materials (insulated containers, bubble wrap, cardboard, frozen water bottles, digital data loggers/continuous monitoring devices, temperature logs, etc.);
- Review quarterly with date and signature of reviewer for documentation; and
- Refer to 2019 CDC Storage and Handling Toolkit, pages 25-26.

Providers can find the 2019 Storage and Handling Toolkit at the following CDC link: <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

## **Vaccine Ordering/Delivery/Receiving/Storing**

### **Ordering the vaccine (Section 3)**

- A provider must meet all recommendations and requirements to order VFC vaccine and decrease vaccine wastage. If a noncompliant provider submits an order, the order will be deleted after five business days unless corrective action has been taken. The provider will need to resubmit the order when compliance has been achieved. Ordering instructions are available in Section 3.
- Make sure that your delivery times are up to date in PA-SIIS.
- Providers are expected to order monthly based on patients scheduled to receive vaccine.
- Always tell your front office staff or supply personnel when a vaccine delivery is expected and ask them to notify the appropriate staff when it is received.
- If you have problems or need help ordering vaccine, call the VFC toll-free line 1-888-646-6864 or email questions to [paimmunizations@pa.gov](mailto:paimmunizations@pa.gov). Please include your VFC pin number with any communications.

### **Delivery of the vaccine shipment**

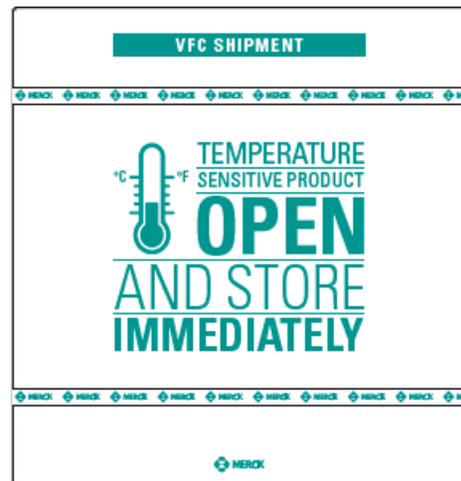
The vaccine orders are shipped from McKesson Distribution for all vaccines except for the frozen vaccines. Frozen vaccines are directly shipped from Merck. Upon

delivery, open the box immediately and inspect the contents for any potential damage that may have occurred during shipment. **If** the shipment cannot be opened and inspected immediately upon delivery:

- Do not refuse delivery;
- Place the entire contents into a bag;
- Place into the proper storage unit (i.e., refrigerator or freezer); and
- Label “do not use” until inspected by designated coordinator.



**McKesson shipping carton**



**Merck shipping carton**

Providers are not required to return the empty shipping cartons to McKesson Specialty Distribution or Merck. Providers may choose to keep some for “emergency transport” or dispose of the boxes.

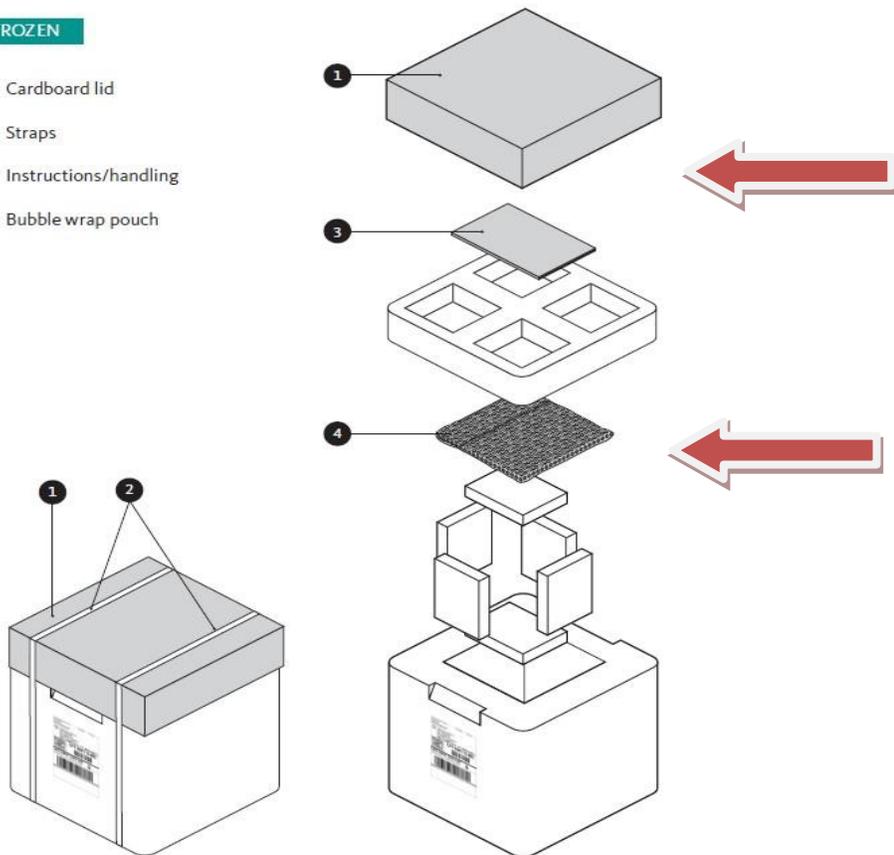
## WHAT'S IN THE VARICELLA/PROQUAD SHIPMENTS

### VACCINE PACKAGING

Axonometric views

#### FROZEN

- 1 Cardboard lid
- 2 Straps
- 3 Instructions/handling
- 4 Bubble wrap pouch



Merck's "Shipping Time" insert will appear inside the shipping container as 1 day, 2 days, or 4 days, indicating the number of days the vaccine shipment delivery can maintain proper temperature. The "Shipping Time" insert shown below indicates that the vaccines delivered will maintain appropriate temperatures from the shipment date that appears on an enclosed "Packing slip."

If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at **1-800-MERCK-RX** (1-800-637-2579).

- 1) **DILUENT** is packaged in the **lid** of the upper compartment of the shipping container.
- 2) **VACCINE** is in the **lower compartment** of the shipping container.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately mark the vaccine and diluent as “DO NOT USE” and store them under the proper conditions.

**1 DAY SHIPPING TIME**  
**FREEZE IMMEDIATELY**  
 Any freezer, including frost-free, that has a separate sealed freezer door and reliably maintains a temperature between -58°F and 5°F (-50°C to -18°C) is acceptable.  
**REPLACEMENT**  
 If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-532-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.

**2 DAY SHIPPING TIME**  
**STORE PRODUCT IMMEDIATELY**  
 Please store product according to product package.  
**FROZEN PRODUCT**  
 Store between -58°F and 5°F (-50°C to -18°C).  
**REFRIGERATED PRODUCT**  
 Store between 36°F and 48°F (2°C to 8°C).  
**REPLACEMENT**  
 If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-532-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.

**4 DAY SHIPPING TIME**  
**STORE PRODUCT IMMEDIATELY**  
 Please store product according to product package.  
**FROZEN PRODUCT**  
 Store between -58°F and 5°F (-50°C to -18°C).  
**REFRIGERATED PRODUCT**  
 Store between 36°F and 48°F (2°C to 8°C).  
**REPLACEMENT**  
 If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at 1-800-MERCK-RX (1-800-532-2579). Requests for replacement must be received by Merck within 15 days of the original shipment.



## WHAT'S IN THE MCKESSON SHIPMENTS

**McKesson**  
**3M MonitorMark**  
 TTT  
 9660C  
 10°C (50°F), 48 hours

**INDEX/INDICE/دليل**  
 0 1 2 3 4 5

*Review this guide to read this temperature indicator.*

**Vaccine Temperature Monitor**  
 A 3M MonitorMark™ Time Temperature Indicator is in this shipment to assure that your vaccines have been shipped under manufacturer-recommended conditions. The indicator shows temperature exposure only – not information about vaccine quality. This monitor must be “turned on” when you receive it. A small white tab on the left side of the monitor with the words “To Activate Fold Up and Pull” has been removed. If you see this tab, please report right away.

**Accepting a Vaccine Shipment**

- On arrival, remove the instruction card with the 3M MonitorMark Time Temperature Indicator from the shipment box right away.
- Follow the guide on the back of this card to read the monitor.
- Examine the vaccines and shipping box for any signs of damage.
- If you have any questions or concerns when reading the monitor, if the monitor is not activated or if you see damage to the package, call 877-TEMP123 (877-836-7123) or your state / local immunization program right away.
- Store vaccines as instructed below.

**Vaccine Storage Requirements**

- Take the vaccines out of the shipping box immediately upon receipt.
- Remove the vaccines from the plastic bag.
- Refrigerate immediately at 35° to 46°F (2° to 8°C).
- Do not freeze or expose to freezing temperatures.

**How to Read the 3M MonitorMark Time Temperature Indicator**  
 As soon as you receive this shipment, remove the 3M MonitorMark Time Temperature Indicator and check the Index. Please note that all pictures below are examples only. Please read the monitor on the other side of this card.

**For all vaccines excluding MMR:**

- If the Index color is 0-2, store the vaccines as instructed and begin use.
- If the Index color is 3-5, store the vaccines as instructed and call 877-TEMP123 (877-836-7123) or your state / local immunization program right away for further instruction before using.

**For MMR vaccines only:**

- If the Index color is 0-1, store the vaccines as instructed and begin use.
- If the Index color is 2-5, store the vaccines as instructed and call 877-TEMP123 (877-836-7123) or your state / local immunization program right away for further instruction before using.

**3M MonitorMark Time Temperature Indicator decision table:**

Indicator Color	Vaccine Type	
	Vaccines (excluding MMR)	MMR
0-1	Ready for Use	
2	Ready for Use	Call 877-TEMP123 (877-836-7123) or your state / local immunization program right away
3-5	Call 877-TEMP123 (877-836-7123) or your state / local immunization program right away	

Call 877-TEMP123 (877-836-7123) or your state / local immunization program right away if you have questions or concerns when reading the temperature indicator or if you see damage to the package.

The McKesson Vaccine Temperature Monitor indicates the temperature of the vaccine and gives vaccine storage guidance

## Receiving the vaccine

- Check the temperature indicator enclosed in the shipment to determine if the vaccines were exposed to temperatures outside the proper range for storage and handling, and immediately notify McKesson Specialty Customer Care directly at 877-TEMP123 (877-836-7123).
- Evaluate the condition of the vaccines and ensure the vaccines are cool to the touch. If the color is odd, the package is damaged or the vaccine seems warm, designate as “DO NOT USE” and properly store the vaccine until a determination has been made on the viability of the vaccine.
- Contact the vaccine manufacturer for further instructions if needed. Complete a Vaccine Incident Report and Worksheet Form, and Vaccine Return and Accountability Form, if necessary (Section 6-F). Fax forms to the DOH at 717-214-7223.
- Compare quantities, lot numbers and expiration dates carefully; **contact the DOH immediately (the same day or next business day) if there is any discrepancy between the contents received and the shipping invoice.**
- Vaccine shipments must be accepted into PA-SIIS inventory. PA-SIIS participating providers should also compare the quantity, lot numbers and expiration dates with the data in the PA-SIIS.
- Re-check the shipping carton and packing materials to ensure that all vaccines and diluents have been removed from the carton.
- Single dose vaccines are packaged in amber bag in lid of upper compartment of shipping container.

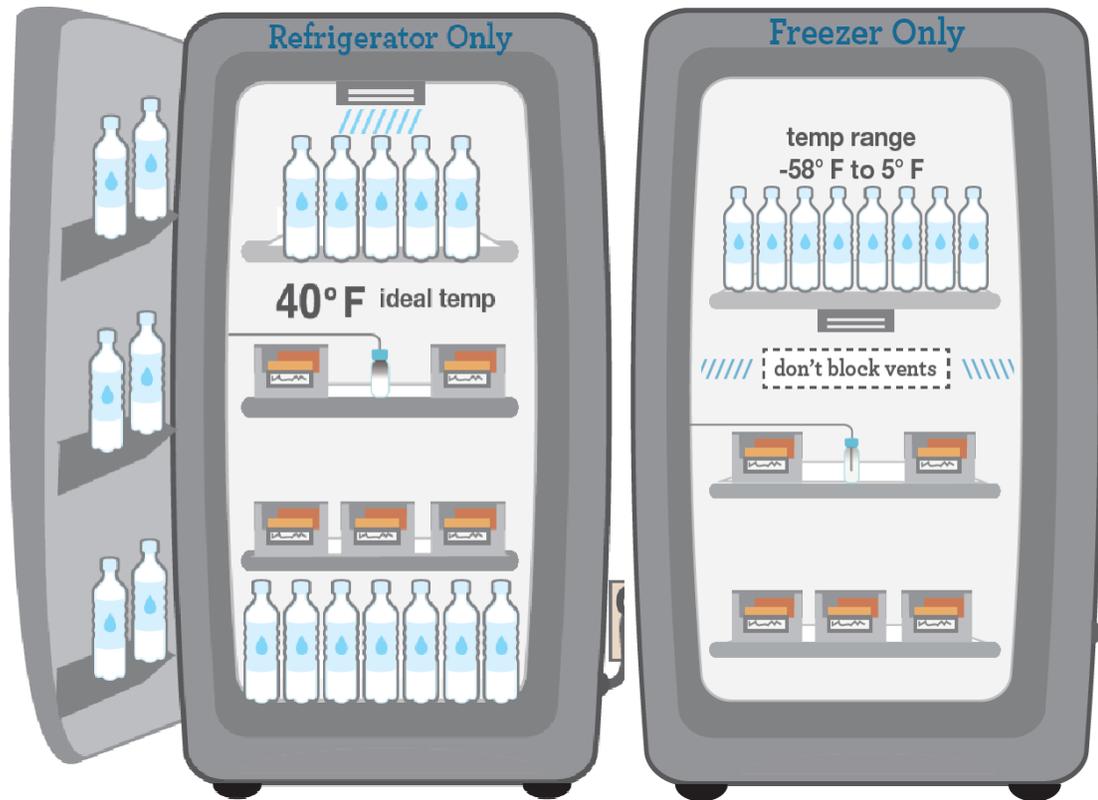
## Storing the vaccines

Proper storage and handling of vaccine is important not only for the shelf life and effectiveness of a vaccine, but also for the safety of the person receiving the vaccine.

Be sure to store vaccine in a well-ventilated room with appropriate ambient temperature and sufficient space (at least four inches) around the sides and top for air circulation.

### Vaccines must:

- Be stored away from cold air vents and coils;
- Have space between vaccines for circulation;
- Be stored with the shortest expiration date in front;
- Be organized and labeled by type (VFC, 317, private);
- Have different vaccine with similar packaging stored in separate locations in the unit to avoid errors in identification;
- Be stored with water bottles in refrigerator unless specified otherwise by refrigerator manufacturer;
- Be stored with water bottles in freezer unless specified otherwise by freezer manufacturer



**Vaccines must never:**

- Be stored with food and beverages because this practice results in frequent opening of the door and destabilization of the temperature;
- Be stored with medications or other biologic products, unless placed below the vaccines on a different shelf to prevent contamination of the vaccines;
- Be stored on the door or floor of the unit; or
- Be stored in crisper drawers. (Remove the crisper drawers and add water bottles.)



## Defrosting manual-defrost freezer units

- Check for frost build-up; if frost exceeds 1 cm or the manufacturer's given limit for frost build-up, follow manufacturer's directions for defrosting unit;
- Frost will build up quickly, when unit's door is open and closed frequently;
- If unit requires defrosting every month or more often than every month, check seals on unit's door and call a technician if needed;
- Always have another storage unit available that is able to maintain correct vaccine temperature, to place vaccine in while defrosting freezer unit.

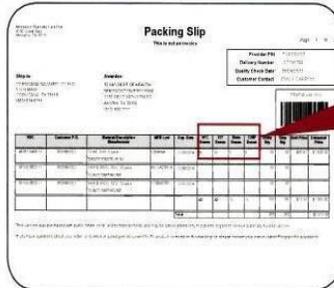


# Separating and Storing Your Vaccine Stock

## 1 How to identify vaccine by public funding type

There are 2 types of public funding:

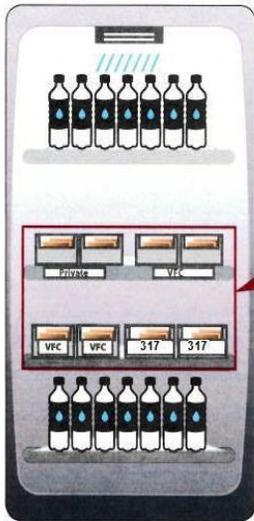
- VFC
- 317



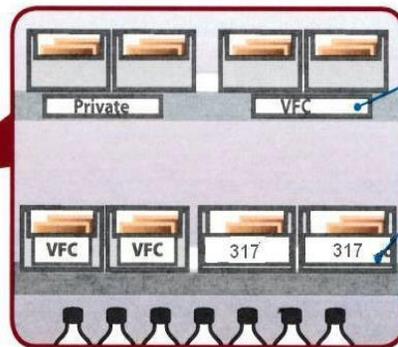
VFC Doses	317 Doses
25	20

The funding type for each public vaccine is listed on the shipment's packing slip. Your private vaccines come in a separate shipment and must be stored apart from public vaccines.

## 2 How to store vaccine with only one fund type in a box



Organize your storage unit so vaccines are separated by VFC, Other Public, and Private. You can either:



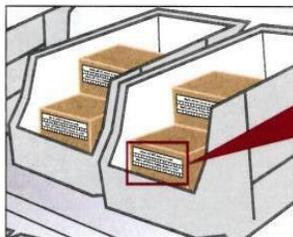
Label the storage unit shelf.

OR

Label the bins.

Place the vaccine in the proper bin.

## 3 How to store vaccine with more than one fund type in a box



Store these boxes in a separate bin. To keep track of your use:

Mark off VFC doses as used.									
×	×	3	4	5	6	7	8	9	
Mark off 317 doses as used.									
×	2	3	4	5	6	7	8	9	

1. Label the box of single-dose or multi-dose vials.
2. Highlight the number of doses from each funding type.
3. Mark off vaccine as you use it.

Be sure you don't cover important information such as vaccine name and lot number. Always keep vaccines in their original packaging with the lid closed to protect them from light.

# Documentation Requirements

## Temperature log requirements

Temperatures are to be checked twice daily (current, minimum and maximum) and recorded on the DOH supplied temperature log with your PIN on it. Temperature logs are to be retained at the provider site for three years and must be made available upon request for review by DOH staff.

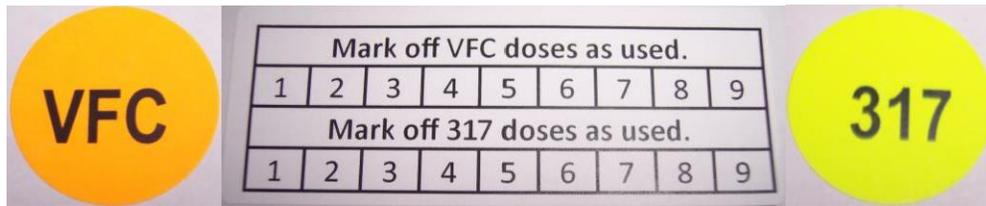
Key points to remember when completing your monthly temperature log:

- Temperature logs must include provider name, pin number, and month and year;
- Include in daily documentation time when temperatures were checked and initials of staff checking the current, minimum and maximum temperatures;
- Manually check and document temperatures twice a day on the temperature log regardless of whether a continuous reading or alarmed units are in use;
- Temperature readings should not be rounded up. Record exactly what is displayed on the digital data logger/continuous temperature monitoring device. If your minimum temperature is **36.24°F** it should be written as such and **not 36.0°F**.
- Once temperatures have been documented, follow instructions provided by manufacturer of temperature monitoring device to clear the temperature data on the display.
- If vaccine temperatures will not be documented for more than 72 hours, contact PA DOI for guidance.
- If the office is going to be closed for a period of time other than holidays or weekends, move the vaccines to the alternate delivery site where they can be monitored and temperatures documented twice daily.
- If the manufacturer states vaccine viability is uncertain and there is any question regarding the vaccine utilization, contact the PA DOI.
- If vaccine temperatures are out of recommended ranges for less than 30 minutes during temperature logging, take immediate action to correct the problem and document the action taken on Step 3 of the temperature log, or attach an explanation of action taken.
- Any time temperatures are out of range, it should be indicated on the temperature log, with corrective action documented.
- For temperatures that are determined to be out of range for more than 30 minutes, mark the vaccine “do not use,” store appropriately and notify the vaccine manufacturer immediately. **You must also complete and submit the Vaccine Incident Report and Worksheet (Section 6-F) to DOH within five days of incident. Fax to 717-214-7223.**
- Submit a copy of the Vaccine Return and Accountability Form to request a return label for shipping unopened vials of expired/wasted vaccines. This is for Federal Excise Tax Credit.

- Notify your local immunization nurse as well. This must be done in conjunction with notifying DOI.

### Maintaining your inventory

- Store and rotate vaccines weekly according to expiration dates. Use vaccines with the shortest expiration dates first.
- Identify any vaccines that will **expire within 90 days**. Contact your immunization nurse for assistance.
- If vaccines are within 90 days of expiration and cannot be used, they may be transferred to a participating VFC provider. Contact your immunization nurse to properly coordinate such transfers.
- Separate vaccines by funding source: VFC, 317 and private. This can be achieved by labeling:
  - Separate bins;
  - Individual vials/syringes; and
  - Vaccine boxes.



### Vaccine accountability

DOI must account for all vaccines. This accountability is achieved through:

- Adhering to the manufacturer’s recommended storage and handling;
- Administering vaccine properly (injection site, recommended schedule, etc.);
- Ensuring authorized personnel track doses administered and reconcile vaccine inventory in PA-SIIS (Section 5) in the site’s Electronic Medical Records or on the PA VFC Dose Tracking Form (Section 6-D);
- Rotating inventory weekly according to expiration date;
- Ordering only vaccine needed for the patients scheduled to receive immunizations in the next month.
- Reporting all expired/wasted vaccines (Section 6-F); and
- Limiting thermostat adjustments to the primary and back-up vaccine contact individuals.

### **Vaccine borrowing**

Borrowing should **only** occur when there is a lack of appropriate stock vaccine (VFC or provider-purchased) due to unexpected circumstances, such as a delayed vaccine shipment, vaccine spoiled in-transit to provider, or new staff who calculated ordering time incorrectly. The reason **cannot** be provider-planned borrowing from either the private stock or the VFC stock. VFC providers who are suspended from ordering vaccine may **not** borrow vaccine to compensate vaccine inventory. Failure to follow proper borrowing protocol may lead to disenrollment.

Two-directional borrowing between VFC and private-stock vaccine must be documented on the VFC Vaccine Borrowing Report (Section 6-D). The VFC Vaccine Borrowing Report must be completed and kept at the provider site for review by the immunization nurse during VFC site visits.

### **Transporting vaccine**

Occasionally, clinics have more vaccine than they can use before it expires. In these situations, transferring vaccine to another clinic to use is a good option. For assistance with this process, please contact the immunization nurse in your area. The transferring site is responsible for ensuring the vaccine is properly shipped or transferred and will be held responsible until the vaccine is appropriately and safely accepted by the receiving facility. VFC cold chain protocol must be maintained at all times.

The following documents **should be reviewed prior to transporting vaccines (Section 6-I)**:

- “Transporting Vaccines” (Vials/syringes must remain in original packaging.)
- “Transporting Frozen Vaccines by Necessity”

- “Vaccine Monitoring Report”



**When transporting/transferring vaccines in ordinary vehicles, use the passenger compartment – NOT the trunk.**

Varicella-containing vaccines are fragile. The CDC **strongly discourages** the transport of varicella-containing vaccines. If these vaccines must be transported, the manufacturer must be contacted to determine if the vaccine is acceptable for use.

### **Expired and wasted vaccines**

**Unopened** vials of **all** vaccines that are expired or have been exposed to out-of-range temperatures, including influenza vaccine, must be returned within six months after the expiration date. However, vaccines that have expired for more than six months will still be accepted. When non-viable vaccine needs to be returned, provider must:

- Remove vaccine(s) from the storage unit and label “Do Not Use”;
- Complete and fax the Vaccine Return and Accountability Form (Section 6-F) to 717-214-7223 (attention: Vaccine Management) to initiate the request for a return label;
- A VTrckS return ID number will be processed and emailed to the primary VFC contact for each vaccine return request;
- Record the ID number on a copy of the vaccine return form. A VTrckS return ID number will be processed and emailed to the primary VFC contact for each vaccine return request. The number must be recorded on a copy of the vaccine return form and placed in the box to be mailed back with the expired/wasted vaccines; and
- Return all unopened vials of vaccines. Unopened vials of all vaccines, including influenza vaccine, should be returned to McKesson Specialty Distribution within six months after the expiration date. However, vaccines that have expired for more than six months will still be accepted.

**\*Diluent is not a vaccine and is not returnable.**

**\*Opened multi-dose vials (including polio and influenza) are also not returnable.**

These must be accounted for on the **Non-Viable, Non-Returnable** form

Providers can receive the UPS return label several ways:

- By email from [pkginfo@ups.com](mailto:pkginfo@ups.com) to a single email address, within one to three hours after return data is received at McKesson;
- By UPS driver at scheduled pick-up time – used especially if you do not have routine UPS service.

Note: If label is not received within 30 days, the process must be repeated.

### **Sample of email message**

The email reads:

UPS Label Delivery, 1Z2R40000097600007

UPS Returns Label Delivery

This notice tells you that a UPS shipper has sent you an electronic label.

You can print and use this label in your outbound shipment or send it to the consignee. The label will be available for 30 days.

Note: When retrieving your label below, we will provide you with both a UPS returns label and commercial invoice if the invoice was prepared by the original shipper.

[View UPS returns documentation instructions](#)

[Retrieve your shipment label](#)

**Note:** If vaccines are wasted as a result of a power outage, failure to properly store, temperatures out of range, etc., the Vaccine Incident Report and Worksheet Form (Section 6-F) must be completed, listing all vaccines exposed to temperature excursion and forwarded to the DOH by fax or email within five days following the incident. Failure to complete these forms will result in immediate suspension of vaccine ordering. Providers will be informed of saved/wasted vaccine doses and cost with every incident report.

## **Vaccine Adverse Event Reporting System (VAERS)**

The National Vaccine Injury Compensation Program (VICP) is a federal “no-fault” system designed to compensate individuals or families of individuals who have been

injured by childhood vaccines administered by private or public providers. VAERS, operated by the Food and Drug Administration (FDA) and the CDC, must be notified of any vaccine-related adverse event by completing a VAERS reporting form:

<https://vaers.hhs.gov/>.

- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see <https://www.hrsa.gov/vaccine-compensation/index.html>).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

## Vaccine Cold Chain Failure

### **Suspected vaccine cold chain failure – Providers must:**

- Refer to the Vaccine Disaster Recovery Plan and the VFC Provider Handbook for vaccine management guidance;
- Contact the appropriate vaccine manufacturers within one workday of a suspected vaccine cold chain failure, to determine viability of the vaccine;
- Request all viability research information be sent from the vaccine manufacturers to the provider, and include with incident report to DOI;
- Complete and submit the Vaccine Incident Report and Worksheet form and fax to the VFC Program at 717-214-7223 within five days of a suspected cold chain failure; and
- Be prepared to provide:
  - ✓ Vaccine name;
  - ✓ Lot number;
  - ✓ Expiration date;
  - ✓ Number of doses at risk;
  - ✓ Documented refrigerator and freezer temperatures; and
  - ✓ Duration of exposure to out of range temperatures

## **Confirmed Vaccine Cold Chain Failure - Providers must:**

- Notify Division of Immunizations (DOI) by completing the Vaccine Incident Report and Worksheet Form within five days of confirmation of the vaccine cold chain failure. The Quality Assurance staff will assist you if needed at 1-888-646-6864.
- Review refrigerator/freezer temperature logs to verify whether other “out-of-range” temperatures occurred that could indicate any other periods of cold chain failure and submit copies with the incident report to DOI.
- Complete a Vaccine Return Form found in the VFC Provider Handbook, section 6. A form is attached and may be copied for use by provider sites.
- Unopened vials of all expired/wasted vaccines, including influenza vaccine, must be returned, preferably within six months, to McKesson Specialty Distribution. Complete the Vaccine Return Form found in section 6 of the VFC Provider Handbook and fax to 717-214-7223 at the Division of Immunizations, and a vaccine return label from McKesson Specialty Distribution will be emailed/mailed to the provider site. When the label arrives, enclose a copy of the Vaccine Return Form with the expired/wasted vaccines in a box and set out for UPS to pick up.
- Any new refrigerator/freezer equipment purchased must be approved by the VFC program through a site visit by the immunization nurse prior to storing vaccine in the unit.
- Within 14 workdays of confirmation of vaccine cold chain failure, review office databases, registries, and patient charts to identify those individuals receiving vaccines during the identified cold chain failure period(s) and determine who needs to be revaccinated.
- Within 21 workdays of confirmed cold chain failure, prepare and submit a Corrective Action Plan to Division of Immunization staff outlining the steps to identify, recall and revaccinate patients who received potentially compromised vaccine.
- Within six weeks of confirmation of cold chain failure, contact identified patients and/or guardians of children by telephone or written correspondence and inform them of the following information:
  - ✓ Purpose of recall;
  - ✓ Need for revaccination;
  - ✓ Information about available clinics and times for revaccination; and
  - ✓ Set appointments to revaccinate individuals who were vaccinated during the cold chain failure timeframe.
- Provide DOI with copy of patient revaccination notification letter template, without patient personal information. If notifying by telephone, please provide copy of script provider staff will use for notification of revaccination.
- Document appropriate vaccination information on the patient’s medical record and/or immunization record.
- Instruct parent/guardian of a revaccinated child to provide revaccination information to the child’s school and/or child care facility.
- Keep an ongoing log of the number of individuals revaccinated and the number of

doses of each vaccine administered

- Submit interim status report and/or final report (Section 6-F) as directed by DOH.

Pennsylvania Department of Health  
Division of Immunizations  
Room 1026, Health and Welfare Building  
625 Forster St.  
Harrisburg, PA 17120  
Fax: 717-214-7223

# SECTION 5 – PA Statewide Immunization Information System

## PA Statewide Immunization Information System (PA-SIIS)

PA-SIIS is a population-based registry that collects vaccination data for all ages and is considered to be part of the medical record. PA-SIIS is a lifelong public health registry.

### PA-SIIS

- Provides a complete and accurate immunization history for new and existing patients;
- Assists with vaccine management;
- Produces immunization records for managed care, child care centers, schools and camps;
- Electronically stores all required immunization data for VFC and the Healthcare Effectiveness Data and Information Set (HEDIS);
- Allows approved facility staff the ability to electronically place vaccine orders; and
- Offers providers that fully participate through a certified electronic health record system the opportunity to attest for public health reporting as required by meaningful use.

In 2013, all DOH vaccine ordering was transitioned from paper to online through PA-SIIS. DOH VFC providers are required to enroll in PA-SIIS in order to place DOH supplied vaccine orders electronically.

### PA-SIIS User Log on Credentials

All newly enrolled facilities with access to the internet are provided a unique PA-SIIS username and password. The logon credentials allow facility staff to order vaccines online, reconcile inventory, update facility address, list vaccine shipping hours, etc.

- Credentials are issued per person, to the individual person who has completed the required CDC modules, and not per site. New personnel will be required to contact Pa. VFC to acquire their individual credentials, upon successful completion of CDC modules.
- Sharing of credentials may result in site suspension or disenrollment from the Pa. VFC program.

## Log into PA-SIIS

Using your web browser, navigate to the PA SIIS website:

PA-SIIS website: <https://siis.health.state.pa.us/siis>

PA-SIIS support: <https://www.health.pa.gov/topics/Reporting-Registries/PA-SIIS/Pages/PA-SIIS.aspx>

Phone number: 877-774-4748

## Online Ordering

Orders for all DOH supplied vaccine must be placed electronically through the PA-SIIS. Provider orders will still be reviewed by the DOH staff and then electronically uploaded to the ordering system through the PA-SIIS.

The following attachments in this section are provided by PA-SIIS to assist providers with online ordering.

## Receiving Shipments in PA-SIIS

NOTE: The electronic receiving process described here will automatically increase your inventory by the amount of each vaccine received in the shipment. This may cause your inventory to be incorrect. You **must** reconcile your inventory prior to each order. Failure to do so may cause problems with ordering vaccine.

1. While on the main screen, click on the **inventory** button. This takes you to the clinic's **edit inventory** page.
2. Scroll down to the bottom of the **edit inventory** page. There are five purple buttons (**add inventory**, **shipments**, **orders**, **batches** and **close inventory**). Click on the second button from the left labeled **shipments**. This takes you to the **edit shipments** page.
3. On the left side of the **edit shipments** page, you will see a miniaturized version of your inventory. On the right side of the page, there are two purple boxes (labelled **receiving** and the other **sending**). If you have any shipments that need to be received, they will be listed under the purple rectangle labeled **receiving**.
4. Click on the blue five-digit number under the left corner of the rectangle. This takes you to the **edit shipment** page.
5. There are three purple buttons at the bottom of the page (**update**, **receive shipment** and **cancel**). Click on the purple button labeled **receive shipment**. This takes you to the **receive shipment** page. On the far right is the volume shipped to your facility. On the far left is a blank box under **total volume received**; click on the box and a flashing cursor will appear.

6. Type in the volume you received for that vaccine. (Most of the time the number will be the same as the **volume shipped**; if it is not, put

- the actual volume received by your facility.)
7. Repeat steps 5 and 6 for each of the vaccines listed on the shipment.
  8. After you have entered all the **total volume received**, click on the downward pointing arrow under “**Is the shipment complete?**” You must choose either **Yes** or **No**.
  9. Once you indicate whether the shipment is complete, click on the left purple button labeled **update**. Selecting this will change your shipment from open to closed status and automatically take you back to the **edit shipment** page.
  10. Click the left purple button labeled **update** on the **edit shipment** page. This will complete the receiving of this shipment, automatically take you to the **edit shipments** page and remove it from the purple **receiving** portion of your **edit shipments** page.
  11. Repeat the above steps until all that have been received by your facility are properly received electronically.

**\*\*\*Again, remember that by receiving your shipment electronically, your inventory increases automatically by the amount of vaccine in each shipment electronically received.\*\*\***

## **Reconciling Inventory in PA-SIIS**

1. Log into PA-SIIS <https://siis.health.state.pa.us/siis>.
2. Generate Clinic Inventory Report from main page. Use this report to write updated number of doses on hand:
  - a. Select **print reports**
  - b. Select **clinic inventory**
  - c. Select **generate**
  - d. Select **submit**
  - e. Select **print**
3. Select **inventory** from main page:
  - a. Select the applicable inventory item by clicking directly on the vaccine (**blue hyperlink**).
  - b. On the **edit inventory item** screen, click the **reconcile** button (bottom of screen).
    - i. In the **type** field, use drop-down arrow to select:
      1. Administered (-) when subtracting doses; or
      2. Unaccountable (+) when adding doses.
    - ii. In the **volume** field, enter the number of doses that were administered.
    - iii. Click **update**.
  - c. Verify all information is correct. (TIP: When **current volume** is zero, uncheck the **active** box)

- d. Click **update**.
- e. Click **ok** to return to the **edit inventory** screen.

\*Please refer to the accompanying training manual for more information.

### **Prior to Sending or Transferring Vaccine:**

**Before any vaccine transfer is considered, please notify the PA DOH Vaccines for Children program at 1-888-646-6864.**

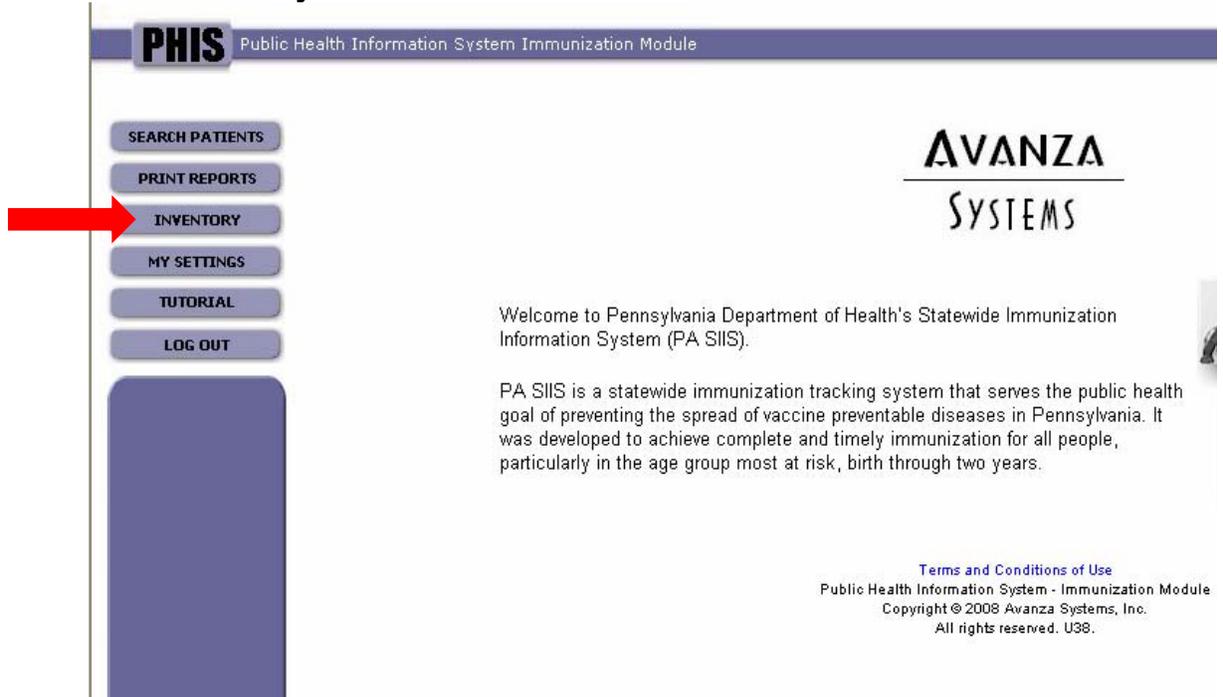
**You are also required to submit three months of temperature logs, along with digital data logger downloads for review.**

**The steps listed below should be used when sending or transferring vaccines.**

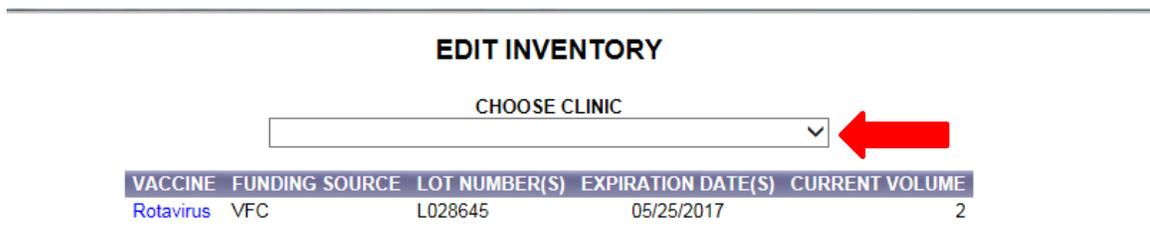
1. Click on the **inventory** menu option and maximize the **edit inventory** screen.
2. Select **shipments**. The **edit shipments** screen is divided into 3 sections (Current Inventory, Receiving, and Sending). Select the **add shipment** button.
3. Within the **add shipment** screen, select the site you are sending the vaccine to, select **open** within the Status field, and select the **next** button.
4. Within the **select inventory** screen, type in the amount you are sending, and select the **associate inventory** button.
5. Make sure all the information is correct within the **edit shipment** screen, and select **update**.
6. The item is added to the **sending** section. Select the **cancel** button to return to **edit inventory**.

# SENDING/TRANSFERRING AN ELECTRONIC SHIPMENT OF VACCINE

1. Select the **Inventory** button on the left-hand side of the screen.



2. Maximize the **Edit Inventory screen** by clicking on the box “□” beside the “x” in the top right-hand corner of the screen (if it isn't already maximized).
3. Verify that “your” clinic name is in the **Choose Clinic** field.



4. Select the **Shipments** button.



5. The **Edit Shipments** screen will appear. Click on the **Add Shipment** button.

**EDIT SHIPMENTS**

CHOOSE CLINIC: Carbon County SHC      STATUS: Not Closed

CURRENT INVENTORY					RECEIVING							
VACCINE	FUNDING SOURCE	LOT #	EXPIRATION DATE(S)	CURRENT VOLUME	#	DATE	FROM	VACCINE	LOT #	EXP DATE	SHIP VOL	RCVD VOL
DT	VFC	DTPa574A2	4/11/2004	5	75	1/13/2004	PA State DOH	DT	DTPa574A2	4/11/2004	10	10
DTaP-IPV-HepB	VFC	01235	11/11/2005	10	77	1/15/2004	PA State DOH	MMR	0192N	2/19/2005	5	5
MMR	Catch-up	0192N	2/19/2005	10	78	1/15/2004	PA State DOH	DTaP-IPV-HepB	01235	11/11/2005	10	

SENDING										
#	DATE	TO	VACCINE	LOT #	EXP DATE	SHIP VOL	RCVD VOL			
76	1/13/2004	Montour County SHC	DT	DTPa574A2	4/11/2004	5				



6. The **Add New Shipment** screen will appear. Select the site to which you are shipping vaccine in the **“Shipped To”** drop-down box. Click on Next.

Note: Site names ending in “BT” are for smallpox shipments only.

**ADD NEW SHIPMENT**

SHIPPED FROM : Carbon County SHC     
 \* SHIPPED TO :      
 SHIPMENT DATE : 2/25/2004     
 \* STATUS : Open

Notes :



7. The **Select Inventory** screen will appear. Type the volume that you are sending in the **“Volume Shipped”** box beside the applicable inventory item. Click on the Associate Inventory button.

### SELECT INVENTORY

VOLUME SHIPPED	VACCINE	FUNDING SOURCE	LOT NUMBER	EXPIRATION DATE	CURRENT VOLUME
<input type="text"/>	DTaP	DOH	C1697AA	7/31/2005	4
<input type="text"/>	DTaP-IPV-HepB	DOH	21936A2	7/10/2005	1760
<input type="text"/>	DTaP-IPV-HepB	DOH	21883B2	3/11/2004	15
<input type="text"/>	Hep A - Child	DOH	VHA724A9	9/25/2004	12
<input type="text"/>	Hep B - Adult	DOH	0640M	8/14/2005	21
<input type="text"/>	Hep B - Adult	DOH	0453M	2/24/2005	8
<input type="text"/>	Hep B - Child	DOH	ENG5557A9	6/12/2005	42
<input type="text"/>	Hep B - Hib	Private	W0196-2	2/14/2005	0
<input type="text"/>	Hib	DOH	0020N	11/15/2005	0
<input type="text"/>	Hib	DOH	UE173AA	2/2/2006	39
<input type="text"/>	IPV - Child	DOH	X0772-2	7/2/2006	70
<input type="text"/>	MMR	DOH	0956N	8/27/2005	11
<input type="text"/>	PNU - Child	DOH	495-222	10/31/2005	40
<input type="text"/>	PNU - Child	DOH	494-754	8/31/2005	0
<input type="text"/>	Td	DOH	U1019AA	10/6/2005	29
<input type="text"/>	Varicella	DOH	0072P	1/9/2006	19

Active ▾

**ASSOCIATE INVENTORY**
**CANCEL**

8. Verify that all information is correct and select **Update**. (The Edit Shipments screen will appear).

9. The transaction should have been added under the Sending section of that screen. Click on **Cancel** and the Edit Inventory screen should appear (with the volumes subtracted from your current inventory).

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Pennsylvania Statewide Immunization Information System

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**Training Manual**

**Vaccine Ordering**

**And**

**Receiving PA-SIIS Electronic**

**Inventory Shipments**

Pennsylvania Statewide Immunization Information System  
Bureau of Health Statistics and Registries  
Division of Statistical Registries  
555 Walnut Street, 6<sup>th</sup> FL  
Harrisburg, PA 17112

(877) 774-4748



## A. Logging In and Logging Out of the PA-SIIS

Every PA-SIIS user is assigned a unique username and password by registry staff. This security measure ensures that only authorized personnel have access to the PA-SIIS database. You must know your username and password to log into PA-SIIS.

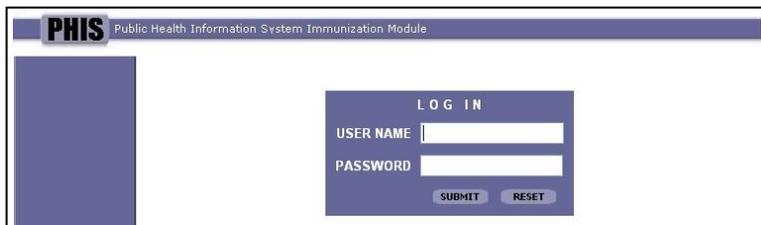
As an additional security measure, the PA-SIIS will time out after a period of inactivity. This is to prevent someone else from using your computer and connection if you step away without logging out. If the system times out, you must re-log in to resume using the system.

### To log into PA-SIIS:

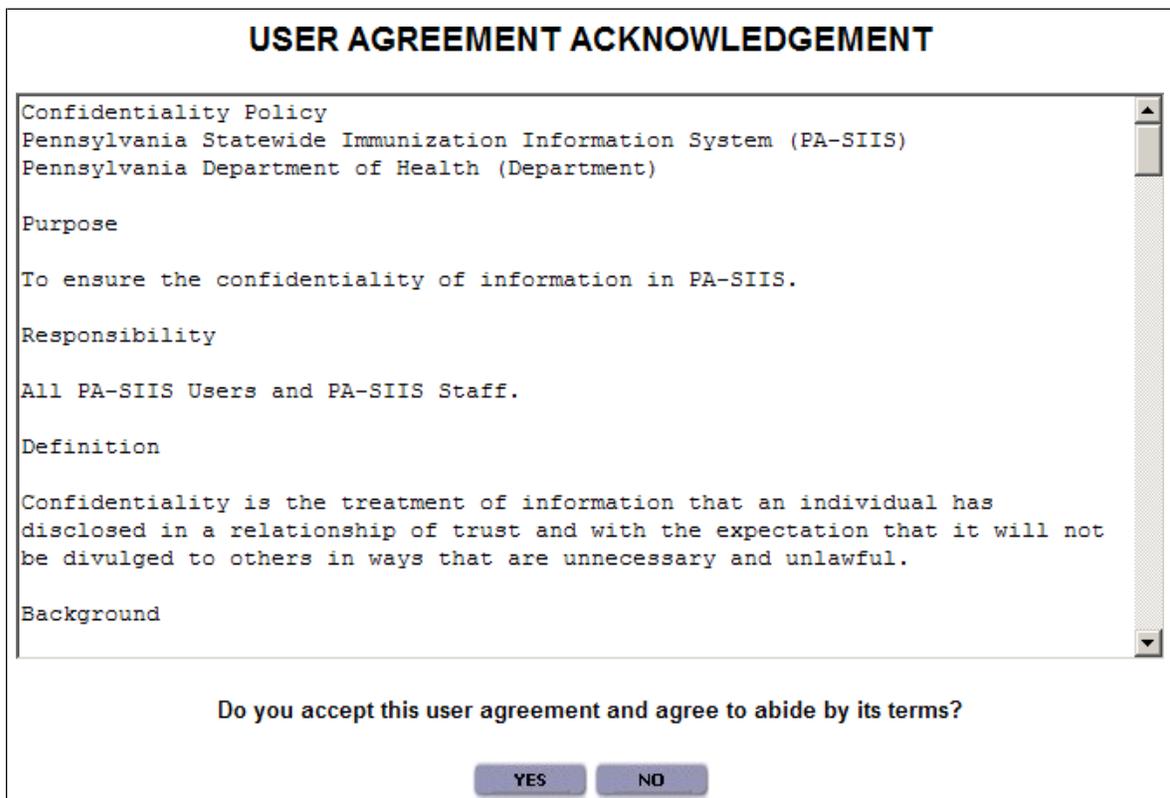
1. Using your Web browser, navigate to the PA-SIIS Web site:

**<https://siis.health.state.pa.us/siis>**

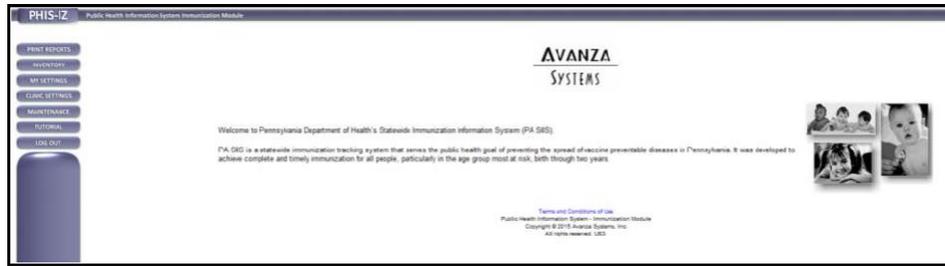
2. When the login screen appears, enter your user name and password into the appropriate fields. The password will display as a series of asterisks (\*\*\*\*) for security purposes.



3. Click **Submit**. Users logging into the PA-SIIS for the first time will receive the user agreement acknowledgement screen. Please review the agreement and accept the agreement by selecting **yes**.



- The Avanza Systems screen displays. From here you can access the print reports, inventory, my settings and clinic settings.



### To log out of the PA-SIIS:

From any screen within the PA-SIIS, click the **Log Out** button. The system logs you out and displays the login screen.

## B. Generate Clinic Inventory Report:

Follow the steps below to generate your clinic inventory report:

- Select the **Print Reports** button on the left-hand side of the Avanza Systems screen.
- Select Clinic Inventory from the select report screen and select **Generate**.
- Verify that your clinic name is in the **Choose Clinic** field and select **Submit**.

### GENERATE REPORT

You can generate a report based on a combination of any criteria below

CLINIC :

STATUS :



### CLINIC INVENTORY

**Clinic:** Sample Clinic  
**Address:** 555 Walnut Street  
 Floor 6  
 Harrisburg, Pennsylvania  
 17101  
**Phone:** 717-783-2548  
**Fax:** 717-772-3258

VACCINE	FUNDING SOURCE	LOT #	EXPIRATION DATE	VOLUME	REFRIGERATOR COUNT	MANUFACTURER	VENDOR
DTaP-IPV-HepB	VFC	AHAVB667CB	03/22/2015	20	<input type="text"/>	SmithKline	State
Hep B - Child	VFC	55698	07/23/2015	30	<input type="text"/>	Merck	State
Varicella	VFC	H016238	04/11/2015	50	<input type="text"/>	Merck	State

Generated April 28, 2015
Page 1

## C. Clinic Settings:

Every practice must validate all of the clinic information contained on this screen for content accuracy to assure a timely approval and delivery of vaccines for every order that is placed.

Follow the steps below to verify clinic properties.

1. Select the **Clinic Settings** button on the left-hand side of the Avanza System screen.
2. Verify that your practice name is in the **Clinic Name** field and update any additional information as needed.
3. Click on the **Update** button to save the updates.
4. Click on the **Ok** button to confirm the Edit Clinic was accepted and then **Cancel** at the bottom of the Edit Clinic Screen.

**EDIT CLINIC**

<b>CLINIC NAME *</b> Sample Clinic	<b>CLINIC TYPE</b> Private	<b>VFC PIN</b> 123854	
<b>CLINIC PHONE *</b> 7177832548	<b>EXTENSION</b> 	<b>CLINIC FAX</b> 7177723258	
<b>PRIMARY VFC CONTACT</b>			
<b>LAST NAME *</b> Duck	<b>FIRST NAME *</b> Shirley	<b>MIDDLE NAME</b> 	<b>EMAIL ADDRESS</b> 
<b>BACKUP VFC CONTACT</b>			
<b>LAST NAME *</b> Duck	<b>FIRST NAME *</b> Shirley	<b>MIDDLE NAME</b> 	<b>EMAIL ADDRESS</b> 
<b>Clinic Address * <a href="#">EDIT</a></b> 555 Walnut Street Floor 8 Harrisburg, Pennsylvania 17101		<b>Shipping Address <a href="#">EDIT</a></b>	
<b>Associated Providers <a href="#">EDIT</a></b>		<b>Delivery Times <a href="#">EDIT</a></b> Mon Tue Wed Thu Fri	
<b>Patient Population <a href="#">EDIT</a></b> Total (0) Enrolled in MA (0) Uninsured (0) American Indian (0) Underinsured (0)		<b>VFC Acknowledgement <a href="#">EDIT</a></b> Physician Name: License #: MA ID: VFC Enrollment Signature Date:	

\* Required

## D. Reconciling Inventory:

Follow the steps below to adjust the current volume of a given inventory item due to spoilage, waste, unaccountability, etc.:

1. Select the **Inventory** button on the left-hand side of the Avanza System screen.
2. Verify that your clinic name is in the **Choose Clinic** field.

3. Select the applicable inventory item by clicking directly on the vaccine (blue hyperlink). The *Edit Inventory Item* screen will appear.
4. Click on the **Reconcile** button at the bottom of the *Edit Inventory Item* screen. The *Add New Reconciliation Note* screen will appear.

**ADD NEW RECONCILIATION NOTE**

DATE *	TYPE *	VOLUME *
4/16/2015	Administered (-) ▼	
NOTES		
<div style="border: 1px solid #ccc; padding: 5px;"> <!-- Placeholder for notes content --> </div>		

\* Required

5. The **date** field will default to today's date. This date can be modified if necessary.
6. In the **Type** field, select the appropriate reconciliation type:
  - If subtracting doses from the inventory item, use reconciliation type **Administered (-)**, **Wasted (-)**, **Spoiled (-)**, or **Unaccountable (-)**.
  - If adding doses to the inventory item, use reconciliation type **Unaccountable (+)**.
7. Enter the number of doses that were administered, wasted, spoiled, unaccountable (-), or unaccountable (+) in the **Volume** field.
8. Click on the **Update** button to save the transaction. The *Edit Inventory Item* screen will appear.
9. Verify that all information is correct and select the **Update** button on the bottom of the *Edit Inventory Item* screen and then select OK to return to the Edit Inventory Screen and then select Close Inventory to return to the Avanza System Screen.

### Inactivating Inventory Items

When the CURRENT VOLUME of a vaccine item reaches zero (0):

1. Select the **Inventory** button on the left-hand side of the Avanza System screen.
2. Maximize the *Edit Inventory* screen by clicking on the box "□" beside the "x" in the top right-hand corner of the screen (if it is not already maximized).
3. Verify that your clinic name is in the **Choose Clinic** field.
4. Select the applicable inventory item by clicking directly on the vaccine (**blue hyperlink**). The *Edit Inventory Item* screen will appear.

**EDIT INVENTORY ITEM**

CLINIC : Sample Clinic	VACCINE : Influenza	SOURCE/VENDOR : State	FUNDING SOURCE : Non-VFC
CURRENT VOLUME : 0	ADMIN VOLUME : 490	DOSAGE VOLUME : 1	MINIMUM VOLUME : 0
<input checked="" type="checkbox"/> ACTIVE	NOTES :		
<input checked="" type="checkbox"/> RECOMMEND			

**LOT INFORMATION**

LOT NUMBER	EXPIRATION DATE	MANUFACTURER
58794	6/30/2010	Lederle

**RECONCILIATION INFORMATION**

DATE	TYPE	VOLUME	NOTES
8/18/2009	In Transit	500	Shipped By PA State DOH
8/18/2009	Received (+)	500	Received
8/18/2009	Spoiled (-)	-10	

- Uncheck the “**Active**” box (as appears above) and select **Update** on the bottom of the *Edit Inventory Item* screen to save the changes.

## E. Inventory Management:

### Part 1: Ordering Vaccines

Follow the steps below to electronically order vaccines within PA-SIIS:

- Select the **Inventory** button on the left-hand side of the Avanza System screen. The *Edit Inventory* screen will appear.

**EDIT INVENTORY**

CHOOSE CLINIC

Sample Clinic

VACCINE	FUNDING SOURCE	LOT NUMBER(S)	EXPIRATION DATE(S)	CURRENT VOLUME
DTaP-IPV-HepB	VFC	A121B326AA	11/08/2013	20
Hep B - Child	VFC	0131AE	10/26/2014	30
Varicella	VFC	00369AA	01/12/2014	50

Active

- Verify that your clinic name is in the **Choose Clinic** field.
- Click on the **Orders** button at the bottom of the *Edit Inventory* screen. The *Edit Orders* screen will appear.

**EDIT ORDERS**

CLINIC : Sample Clinic	STATUS : Incomplete				
CLINIC DATE	ORDER ID	STATUS	VACCINE TRADE NAME	FUNDING SOURCE	VOLUME ORDERED



5. Locate the vaccine and trade name of vaccine requested. Enter the vaccine doses quantity being ordered under the “**VFC**” funding source of the vaccine requested.
6. Select the **Update** button on the bottom of the *Add New Order* screen.
7. Select the **Ok** button on the *Add New Order* screen. The *Edit Orders* screen will appear.
8. The order will now appear in the *Edit Orders* screen with a status of “Pending Approval”. Click on **Cancel** button and the *Edit Inventory* screen will appear.

After your vaccine order is created in the PA-SIIS, the order will be reviewed and processed by the PA Department of Health, Division of Immunizations. You will receive an email notification after the order is approved and shipped. Also, an electronic shipment will automatically be created in the PA-SIIS for your approved order. Please review the instructions in **Part 2: Receiving PA-SIIS Electronic Inventory Shipments** for receiving your electronic shipment within the PA-SIIS.

## Part 2: Receiving PA-SIIS Electronic Inventory Shipments

Follow the steps below to receive a PA-SIIS electronic inventory shipment:

1. Select the **Inventory** button on the left-hand side of the Avanza System screen.
2. Verify that your clinic name is in the **Choose Clinic** field. The new inventory item will appear on your list of current active inventory, the current volume will be “0” (if you don’t already have that lot number in your inventory).
3. Select the **Shipments** button on the bottom of the *Edit Inventory* screen. The *Edit Shipments* screen will appear.

**EDIT SHIPMENTS**

CHOOSE CLINIC:       STATUS:

CURRENT INVENTORY					RECEIVING							
VACCINE	FUNDING SOURCE	LOT #	EXPIRATION DATE(S)	CURRENT VOLUME	#	DATE	FROM	VACCINE	LOT #	EXP DATE	SHIP VOL	RCVD VOL
DTaP	Private	00001	12/31/2010	72	17763	8/18/2009	PA State DOH	Influenza	58794	6/30/2010	500	
Hep B - Child	VFC	0053X	7/28/2010	195								
Influenza	Non-VFC	58794	6/30/2010	0								

SENDING											
#	DATE	TO	VACCINE	LOT #	EXP DATE	SHIP VOL	RCVD VOL				

4. Under the **Receiving** section, select the blue hyperlink of the shipment number for the shipment that you are receiving into the PA-SIIS (e.g., [11763](#)). The *Edit Shipment* screen will appear.

**EDIT SHIPMENT**

SHIPPED FROM :	SHIPPED TO :	ORDER ID :	SHIPMENT DATE :	STATUS :
PA State DOH	Sample Clinic		8/18/2009	Open

Notes :

---

VACCINE :	FUNDING SOURCE :	ITEMS SHIPPED LOT NUMBER :	EXPIRATION DATE :	VOL SHIPPED :	VOL RECEIVED :
Influenza	Non-VFC	58794	6/30/2010	500	

5. Click on the **Receive Shipment** button on the bottom of the *Edit Shipment* screen. The *Receive Shipment* screen will appear.

### RECEIVE SHIPMENT

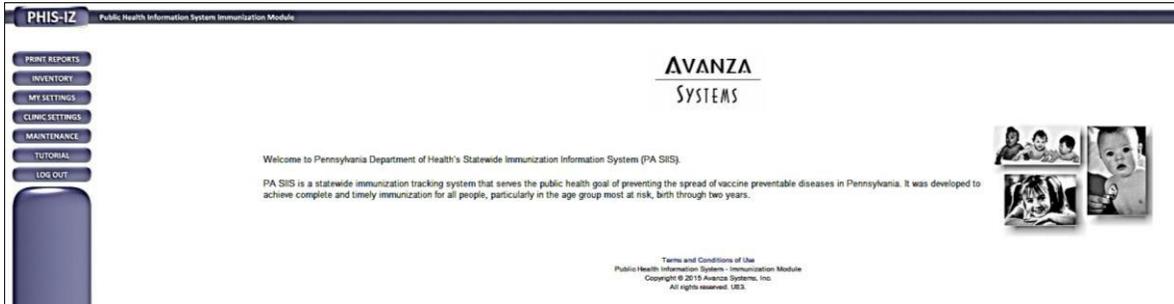
TOTAL VOL RECEIVED :	VACCINE :	FUNDING SOURCE :	LOT NUMBER :	EXPIRATION DATE :	VOL SHIPPED :
<input type="text" value="500"/>	Influenza	Non-VFC	58794	6/30/2010	500

Is this shipment complete ?

6. Type the volume that you received in the **"Total Vol. Received"** column.
7. Select **Yes** under the question, "Is this shipment complete?" and then click on the **Update** button on the bottom of the *Receive Shipment* screen. The *Edit Shipment* screen will appear.
8. Verify that all information is correct and select the **Update** button. The *Edit Shipments* screen will appear.
9. The shipment that was received will have disappeared from the Receiving section of the *Edit Shipments* screen. Click on **Cancel** and the *Edit Inventory* screen will appear (with the new volumes added to your current inventory).

# Initial PA-SIIS User set up prior to placing your first VFC Vaccine order

After logging into the PA-SIIS and accepting the on-line User Agreement you will land on the Avanza home screen as shown below.



Please go directly to My Settings and enter a new Password, and confirm your new Password. Select update and then select Okay and then select close my settings to return to the Avanza home page.

### EDIT MY SETTINGS

<b>FIRST NAME</b> Donald	<b>MIDDLE NAME</b> 	<b>LAST NAME</b> Duck
<b>LOGIN ID</b> fcaniglia2	<b>PASSWORD</b> ●●●●●●●●	<b>CONFIRM PASSWORD</b> ●●●●●●●●

**IMMN. PROVIDER**  
SELECT ▼

**USER NOTES**

**SIGNATURE BLOCK**

# Initial PA-SIIS User set up prior to placing your first VFC Vaccine order

From the Avanza home screen **select Clinic Settings** and the following screen will appear. Please select the maximize button located at the top right corner of the Edit Clinic screen to expand the Edit Clinic screen.

**EDIT CLINIC**

<b>CLINIC NAME *</b> Sample Clinic	<b>CLINIC TYPE</b> Private	<b>VFC PIN</b> 123654	
<b>CLINIC PHONE *</b> 7177832548	<b>EXTENSION</b> 	<b>CLINIC FAX</b> 7177723258	
<b>PRIMARY CLINIC CONTACT</b>			
<b>LAST NAME *</b> Smith	<b>FIRST NAME *</b> Mary	<b>MIDDLE NAME</b> 	<b>EMAIL ADDRESS</b> msmith@pa.com
<b>PRIMARY VFC CONTACT</b>			
<b>LAST NAME *</b> Duck	<b>FIRST NAME *</b> Shirley	<b>MIDDLE NAME</b> 	<b>EMAIL ADDRESS</b> 
<b>BACKUP VFC CONTACT</b>			
<b>LAST NAME *</b> Duck	<b>FIRST NAME *</b> Donald	<b>MIDDLE NAME</b> 	<b>EMAIL ADDRESS</b> 
<b>Clinic Address * <a href="#">EDIT</a></b> 555 Walnut Street Floor 6 Harrisburg, Pennsylvania 17101		<b>Shipping Address <a href="#">EDIT</a></b>	
<b>Associated Providers <a href="#">EDIT</a></b>		<b>Delivery Times <a href="#">EDIT</a></b> Mon Tue Wed Thu Fri	
<b>Patient Population <a href="#">EDIT</a></b> Total (0) Enrolled in MA (0) Uninsured (0) American Indian (0) Underinsured (0)		<b>VFC Acknowledgement <a href="#">EDIT</a></b> Physician Name: License #: MA ID: VFC Enrollment Signature Date:	

\* Required

Please validate the information that is presented for accuracy. If changes are needed please make the required changes for every field and include any information that is missing. Particular attention to the following fields is necessary as any incorrect information may cause a delay in your VFC order approval and shipment.

## Clinic phone, Clinic fax

**Primary VFC contact:** Last Name, First Name, and Email Address

**Secondary VFC Contact:** Last Name, First Name, and Email Address

Select **Edit** to open the following sections of the Edit Clinic screen:

## Clinic Address, Shipping Address, Delivery Times, Patient Population, and VFC Acknowledgment

The above information is required by the CDC and will cause orders to be rejected if not properly completed.

## SECTION 6 – FORMS/PLANS/RESOURCES

This section includes the following:

- Education Roster 6-A
- Enrollment in the Vaccines for Children Program 6-B
  - Instructions for Completing the 2019 Pa. VFC Program Provider Agreement
  - Pa. VFC Program Provider Agreement
- Insurance and VFC Eligibility 6-C
  - Chip MA Card Comparison
  - Eligibility Vs. Health Care Coverage
  - Pa. VFC Eligibility Screening Record
- Ordering and Accountability 6-D
  - Pa DOH Supplied Vaccine Order, Inventory and Accountability Form
  - Pa. VFC Borrowing Report
  - Pa. VFC Dose Tracking Form
- Required Plans 6-E
  - Emergency Handling Procedures and Vaccine Disaster Recovery Plan
  - Pa. VFC Vaccine Management Plan
  - Designated Responsible Staff
  - Vaccine Storage Maintenance Reminder
- Required Reporting 6-F
  - Vaccine Incident Report and Worksheet Instructions
  - Vaccine Incident Report and Worksheet

Vaccine Return and Accountability Forms

Interim/Final Status Report Following Cold Chain Failure

Frequently Asked Questions 6-G

- Temperatures and Monitoring 6-H
  - Recording Vaccine Temperatures
  - Fahrenheit Refrigerator Temperature Log
  - Fahrenheit Freezer Temperature Log
  - Celsius Refrigerator Temperature Log
  - Celsius Freezer Temperature Log
  
- Transporting Vaccines 6-I
  - Transporting Frozen Vaccines
  - Transporting Refrigerated Vaccines
  - Vaccine Transport Inventory Sheet and Monitoring Sheet
  
- Best Practices and Resources 6-J
  - NIST Certified Data Logger Manufacturers
  - Pa. VFC Digital Data Logger (DDL) Policy
  - Pre-Purchase Worksheet for Data Loggers
  - Best Practices in Vaccine Storage
  - Vaccine Coordinator Roles and Responsibilities
  - Handling a Temperature Excursion in Your Vaccine Storage Unit
  - Cold Storage Unit Manufacturers
  - Lithium Battery Suppliers
  - Resources and Websites
  - AAP Refusal to Vaccinate Form
  - Acronyms



# Instructions for Completing the 2019 PA VFC Program Provider Agreement

The 2019 procedures and forms have been revised to meet Centers for Disease Control (CDC) requirements for new enrollment, reactivation and updates to participate in the VFC Program. Prior to completing the forms ensure that you have the “2019 PA VFC Program Provider Agreement Form.”

## PA Vaccines for Children Program Provider Agreement

### TYPE OF AGREEMENT:

1. **Types of Agreement** – Please indicate by checking either New, or Update.

### FACILITY INFORMATION:

2. **VFC PIN Number** – Provider Identification Number (PIN) assigned by the PA VFC Program to providers to indicate on vaccine orders, phone inquiries, and during application renewal. It is important to place your PIN on every VFC form that is sent to the PA VFC program. New providers that have not been assigned a PIN, please leave blank.
3. **Facility Name** – Provide the business name or “legal business name”
4. **Primary Vaccine Coordinator Name** –VFC providers must designate a Vaccine Coordinator and Back-up Vaccine Coordinator fully trained to oversee and manage the clinic’s vaccine supply.
5. **Primary Vaccine Coordinator Email** – Please indicate the work email account of the primary vaccine coordinator. This email address will be utilized to receive vaccine alerts and educational materials. It is important that this email is related to the medical practice and routinely accessed during working hours.
6. **Back-up Vaccine Coordinator Name** – (*see above*)
7. **Back-up Vaccine Coordinator Email** – Please indicate the work email account of the back-up vaccine coordinator. This email address will be utilized to receive vaccine alerts and educational materials. It is important that this email is related to the medical practice and routinely accessed during working hours.
8. **Facility Address** – Provide the street name and street number, suite number, or other important delivery information, where you would like to receive mail correspondence. Post office boxes are allowed for mail correspondence.
9. **City** – The city where you would like to receive mail correspondence.

10. **Zip Code** – The five-digit code assigned to your mailing address by the U.S. Postal Service.
11. **County** – The County assigned to your mailing address.
12. **Shipping Address** – Provide the street address if different than facility address, including floors, buildings or suites where you intend to receive vaccine deliveries (Post office boxes are NOT allowed).
13. **City** – The city where you would like to receive vaccine deliveries.
14. **Zip Code** – The five-digit code assigned to your vaccine delivery address by the U. S. Postal Service.
15. **County** – The County assigned to your delivery address.
16. **Telephone** – Provide the main switchboard or office/facility area code and telephone number.
17. **Fax** – Provide the main office/facility fax number including area code.
18. **Access to Internet?** – If your medical facility has access to office internet (Circle one) “Yes or No”.
19. **Office Email** – if you indicated “Yes” above please indicate the work email account.

## **FACILITY TYPE**

20. **Type of Facility** – select the type of facility that best describes your practice.
21. **Annual Patient Population** – Please carefully read each requested item based upon the number of individuals currently enrolled in your practice by “years of age.” **Please do not count a child in more than one category listed below:**
  - a. Total Number Enrolled in the Practice – is the total VFC eligible and non-VFC eligible (private insurance)
  - b. Number of Children Enrolled in Medical Assistance
  - c. Number of Uninsured Children
  - d. Number of American Indian/Alaska Native Children
  - e. Number of Underinsured Children

**Next, select the type of data used to determine child population from choices provided.**

- A. **Benchmarking** – A process of collecting patient population data, usually over a year, to estimate patient population.
  - B. **Medical Claims** – A retrospective collection of data derived from medical claims that are used to calculate an estimated patient population, generally over a year period.
  - C. **Doses Administered** – number of patients receiving vaccine doses during past 12 months. For example, one TDAP administered counts as one dose.
  - D. **Provider Encounter** – A retrospective collection of the number of children who went to a specific provider, regardless of whether or not they received any immunizations.
  - E. **Registry** – Represents PA-SIIS electronic data to determine their vaccine enrollment.
  - F. **Other** – A retrospective collection of any data that is derived by a method that is not listed in the above source data listing.
22. **Provider Vaccine Delivery Hours** – Please indicate for each day in military time/24 hour clock the hours when appropriate vaccine staff will be available to receive and properly store vaccines and supplies at the indicated vaccine delivery address. Example: Monday 0800 – 1200, 1300 – 1600
23. **Annual Training (page 2)** – Check to indicate if your facility’s VFC Coordinator has completed the annual VFC training requirement.
24. **Vaccines Offered-** Please indicate if “All ACIP vaccines are offered” or if only “Offers Select Vaccines” is checked, please indicate which vaccines are offered by checking each type from the list. **(The “Offers Select Vaccines” is only available for facilities designated as Specialty Providers by the VFC Program).**
- A “Specialty Provider” is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g. OB/GYN; Secure Treatment; Youth Detention) or (2) a specific age group within the general population of children from birth to age 18. **Local health departments and pediatricians are not considered specialty providers.** The VFC Program has authority to designate VFC providers as specialty providers. At the discretion of the VFC Program, enrolled providers such as pharmacies and mass vaccinators may offer only influenza vaccine.
25. **Providers Practicing at this facility (page 3)** – List **all** licensed health care providers (MD, DO) at your facility who have prescribing authority. Provide title, license number and Medicaid or NPI number. Employee Identification Number (EIN) is optional.

26. **Changes to Practice Staff** – After the initial enrollment process, any changes in physician practice staff should be indicated in the “Add” or “Delete” section.
27. **Provider Agreement (pages 4 & 5)** – In order to participate in the PA VFC Program and or receive federally procured vaccine provided at no cost, a facility’s medical director or equivalent must read and agree to each of the requirements listed.

## **MEDICAL DIRECTOR OR EQUIVALENT**

**First, MI, Last Name and Email Address** – The name and email of the official VFC registered physician provider signing the agreement must be a practitioner, M.D. or D.O., authorized to administer pediatric vaccines under state law. This physician will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the PA VFC Program Provider Agreement

**Title** – Provide the title of the person listed as Medical Director.

**Specialty** – Provide the specialty of person indicated as Medical Director.

**Physician License #** – Provide the Pennsylvania Physician license number for the person listed as Medical Director.

**Medicaid or NPI #** – Provide the Medicaid or NPI Number for the person listed as Medical Director.

28. **Electronic Signature** - On behalf of the applying medical facility, the Medical Director (or equivalent) must acknowledge by checking the box. If completing via hard-copy please, check the box and hand sign below to comply with the policies and procedures stated on the enrollment form.
29. **Provider’s Signature** – Enter the name of the Medical Director (or equivalent). If manually completing, provide his/her hand signature.
30. **Date** – The date the indicated Medical Director (or equivalent) signed the “2019 PA VFC Program Provider Agreement”.

Any questions or concerns please contact the PA VFC line at 888-646-6864.

## **SUBMISSION OF THE COMPLETE INFORMATION**

Once completed, the enrollment form must be submitted electronically to: Pennsylvania Department of Health, Division of Immunizations, 625 Forster Street, Room 1026, Harrisburg, PA 17120. Fax: 717-214-7223, Phone: 717-787-5681

Following the processing of the completed enrollment form, an on-site enrollment visit and training session will be scheduled for new enrollments or re-enrollments. The enrollment training will include a review of VFC Program requirements, and give the provider the opportunity to ask questions regarding any segment of the VFC Program.

**A copy of the original enrollment form should be retained by the primary contact person.**

**Note:**

Section 1928 (c) (1) (A) of the Social Security Act (42 U.S.C. 1396s (c) (1) (A) states that the following providers qualify to be VFC program-registered providers: those healthcare providers "licensed or otherwise authorized for administration of pediatric vaccines under the law of the State in which the administration occurs" (subject to section 333 (e) of the Public Health Service Act, which authorizes members of the Commissioned Corps to practice).

## 2019 Pennsylvania Vaccines for Children Program Provider Agreement

**All** pages of this form must be completed for providers to be able to participate in the Vaccines for Children (VFC) Program. A form must be completed for each site where vaccines will be shipped. This document provides shipping information and helps determine the amount of vaccine supplied through the VFC program to each provider site. A copy of this form will be kept on file at the Pennsylvania Department of Health (DOH). Questions call 717-787-5681.

**The PA VFC Program Provider Agreement (PPA) must be updated annually or more frequently if:**

- 1) The number of children served changes
- 2) The type of facility changes (i.e., proper documentation must be forwarded to the DOH before a change in status is made); or
- 3) A provider is added or deleted from the practice

Check one: <input type="radio"/> NEW <input type="radio"/> REACTIVATION <input type="radio"/> UPDATE			<b>VFC Pin#:</b>	
Facility Name:				
Primary Vaccine Coordinator Name:			Email:	
Back-up Vaccine Coordinator Name:			Email:	
Facility Address:				
City:		Zip Code:		County:
Shipping Address (if different than facility address):				
City:		Zip Code:		County:
Telephone:			Fax:	
Does your medical facility have access to the internet? ( <i>check one</i> )			<input type="radio"/> Yes <input type="radio"/> No	Office Email:
Type of facility: ( <i>please only check one</i> ):				
<input type="checkbox"/> Family Practice/General Practitioner; Internal Medicine; <input type="checkbox"/> OB/GYN; <input type="checkbox"/> Pediatrician; <input type="checkbox"/> Federally Qualified Health Center (FQHC); <input type="checkbox"/> Rural Health Clinic (RHC); <input type="checkbox"/> Other:				
<b>Annual Patient Population</b> For a 12-month period, report the number of children who received vaccines at your facility, by age group. Only count a child once based on the status of the last immunization visit, regardless of the number of visits made.				
Years of age	<1	1-6	7-18	>19**
Total Number Enrolled in the Practice (VFC & Non-VFC)				
<i>DO NOT COUNT A CHILD IN MORE THAN ONE CATEGORY LISTED BELOW.</i>				
Number of Children Enrolled in Medical Assistance				
Number of Uninsured Children				
Number of American Indian/Alaskan Native Children				
*Number of Underinsured Children (children whose health insurance does not cover vaccines)				
*Underinsured children are only eligible through the PA VFC program if vaccinated at an FQHC or RHC or approved deputized provider. **Persons 19 and older are not VFC Eligible.				
Check type of data used to determine profile:				
<input type="checkbox"/> A. Benchmarking <input type="checkbox"/> B. Medical Claims Data <input type="checkbox"/> C. Doses Administered <input type="checkbox"/> D. Provider Encounter Data <input type="checkbox"/> E. PA-SIIS Registry <input type="checkbox"/> F. Billing System <input type="checkbox"/> G. Other				
<b>PROVIDER VACCINE DELIVERY HOURS, NOT OFFICE HOURS: INCLUDE LUNCH / TIME STAFF IS NOT AVAILABLE</b>				
Monday:				
Tuesday:				
Wednesday:				
Thursday:				
Friday:				

**2019 Pennsylvania Department of Health  
Vaccines for Children Program Provider Agreement Form**

VFC PIN#

**ANNUAL TRAINING REQUIREMENT (please check box to indicate compliance)**

At a minimum, a facility's VFC primary and back-up coordinators must complete the annual training requirement by April 1, of each calendar year or have a VFC compliance site visit. For more information concerning CDC's requirement for annual training, please refer to Section 4 "Vaccine Storage and Handling" of the VFC provider handbook or visit our website at: <https://www.health.pa.gov/topics/programs/immunizations/Pages/VFC.aspx> and scroll to the subheading "VFC Training".

**VACCINES OFFERED (select only one box)**

- All Advisory Committee on Immunization Practices (ACIP) Recommended Vaccines for children 0 through 18 years of age.  
 Offers Select Vaccines (**This option is only available for facilities designed as Specialty Providers by the VFC Program**)

A "Specialty Provider" is defined as a provider that only serves (1) a defined population due to the practice specialty (e.g. OB/GYN; STD clinic; family planning) or (2) a specific age group within the general population of children ages 0-18. Local health departments and pediatricians are not considered specialty providers. The VFC Program has authority to designate VFC providers as specialty providers. At the discretion of the VFC Program, enrolled providers such as pharmacies and mass vaccinators may offer only influenza vaccine.

**SELECT VACCINES OFFERED BY SPECIALTY PROVIDER:**

- |                                      |  |  |
|--------------------------------------|--|--|
| <input type="checkbox"/> DTaP        | <input type="checkbox"/> Meningococcal Conjugate     | <input type="checkbox"/> TD              |
| <input type="checkbox"/> Hepatitis A | <input type="checkbox"/> MMR                         | <input type="checkbox"/> Tdap            |
| <input type="checkbox"/> Hepatitis B | <input type="checkbox"/> Pneumococcal Conjugate      | <input type="checkbox"/> Varicella       |
| <input type="checkbox"/> HIB         | <input type="checkbox"/> Pneumococcal Polysaccharide | <input type="checkbox"/> Other, specify: |
| <input type="checkbox"/> HPV         | <input type="checkbox"/> Polio                       |  |
| <input type="checkbox"/> Influenza   | <input type="checkbox"/> Rotavirus                   |  |

**2019 Pennsylvania Department of Health  
Vaccines for Children Program Provider Agreement Form**

VFC Pin#:

**PROVIDERS PRACTICING AT THIS FACILITY**

*Instructions: List below all licensed health care providers (MD, DO) at your facility who have prescribing authority. Attach information if needed.*

Provider Name	Title	License #	MA ID or NPI#

*Please indicate any changes to practice staff below:*

Add Delete	Provider Name	Title	License #	MA ID or NPI#
Add <input type="checkbox"/> Delete <input type="checkbox"/>				
Add <input type="checkbox"/> Delete <input type="checkbox"/>				
Add <input type="checkbox"/> Delete <input type="checkbox"/>				
Add <input type="checkbox"/> Delete <input type="checkbox"/>				
Add <input type="checkbox"/> Delete <input type="checkbox"/>				
Add <input type="checkbox"/> Delete <input type="checkbox"/>				

Vaccines will be shipped to the vaccine delivery address indicated on the provider site profile within 30 days of receipt of your order.

**PROVIDER AGREEMENT**

*To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent:*

1. I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2. I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:
  - A. Federally Vaccine-eligible Children (VFC eligible)
    1. Are an American Indian or Alaska Native;
    2. Are enrolled in Medicaid;
    3. Have no health insurance;
    4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.
  - B. State Vaccine-eligible Children
    1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible" I will screen for such eligibility as listed in the addendum to this agreement, and will administer state-funded doses (including 317 funded doses) to such children.

Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are **not** eligible to receive VFC-purchased vaccine.
3. For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:
  - a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
  - b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4. I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5. I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6. I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceed the administration fee cap of **\$23.14** per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
7. I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8. I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).

9.	<p>I will comply with the requirements for vaccine management including:</p> <ul style="list-style-type: none"> <li>a) Ordering vaccine and maintaining appropriate vaccine inventories;</li> <li>b) Not storing vaccine in dormitory-style units at any time;</li> <li>c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet Pennsylvania Department of Health storage and handling recommendations and requirements;</li> <li>d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.</li> </ul>
10.	<p>I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR §455.2, and for the purposes of the VFC Program:</p> <p><b>Fraud:</b> is 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.</p> <p><b>Abuse:</b> 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 healthcare. It also includes recipient practices that result in unnecessary cost to the Medicaid program.</p>
11.	<p>I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.</p>
12.	<p>For providers with a signed deputization Memorandum of Agreement between a FQHC or RHC and the Pennsylvania Department of Health to serve underinsured VFC-eligible children, I agree to:</p> <ul style="list-style-type: none"> <li>a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit;</li> <li>b) Vaccinate "walk-in" VFC-eligible underinsured children; and</li> <li>c) Report required usage data.</li> </ul> <p><i>Note: "Walk-in" in this context refers to any underinsured child who presents requesting a vaccine, not just established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to underinsured patients as well.</i></p>
13.	<p>I understand this facility or the Pennsylvania Department of Health may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the Pennsylvania Department of Health.</p>
<p>Medical Director (Physician) or Equivalent Physician Name and Email:</p>	
<p>Title:</p>	<p>Specialty:</p>
<p>Physician License#:</p>	<p>Medicaid or NPI#</p>
<p><i>By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable for compliance with these requirements.</i></p> <p><input type="checkbox"/> Checking this box acknowledges my signature below.</p>	
<p>Medical Director (Physician) Signature:</p>	<p>Date:</p>

After completing the “2019 VFC Program Provider Agreement Form” mail to the Pennsylvania Department of Health, Division of Immunizations, 625 Forster St., Room 1026, Harrisburg, PA 17120-0701 or fax to 717-214-7223.

# CHIP vs. Medicaid Insurance Cards: What's the Difference?



**CHIP Patients are not eligible for VFC vaccines**

**Medicaid patients are eligible for VFC vaccines**



**Aetna Better Health**

**CHIP Card:**

- "Kids"

**Medicaid Card:**

- Aetna Better Health



**Blue Cross of NEPA**

**CHIP Card:**

- "First Priority Health for Kids"
- "Y-18"

**Medicaid not offered by this Carrier**



**Keystone Health Plan Central**

**CHIP Card:**

- "Capital Cares 4 Kids" logo

**Medicaid not offered by this Carrier**



**HighMark Keystone Health Plan West**

**CHIP Card:**

- "Y-18"

**Medicaid not offered by this Carrier**



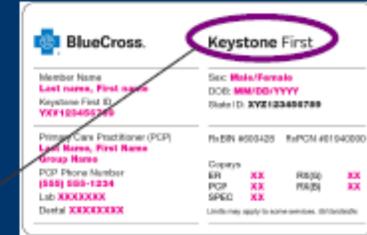
**Keystone Health Plan East**

**CHIP Card:**

- "PA Kids" logo

**Medicaid Card:**

- "Keystone First" logo

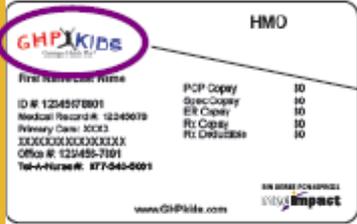


# Continued: CHIP vs. Medicaid Insurance Cards



**CHIP Patients are not eligible for VFC vaccines**

**Medicaid patients are eligible for VFC vaccines**



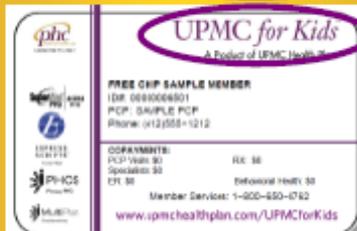
**Geisinger Health Plan**  
**CHIP Card:**  
 • "GHP Kids"  
**Medicaid Card:**  
 • Geisinger Health Plan



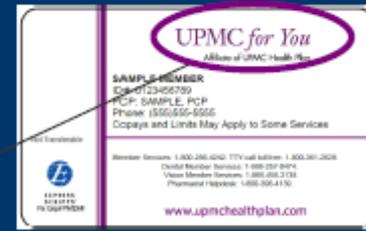
**Health Partners**  
**CHIP Card:**  
 • "Kidz Partners"  
**Medicaid Card:**  
 • HP Health Partners



**United Healthcare**  
**CHIP Card:**  
 • Community Plan for Kids  
**Medicaid Card:**  
 • United Healthcare Community Plan for Families



**UPMC**  
**CHIP Card:**  
 • "UPMC for Kids"  
**Medicaid Card:**  
 • "UPMC for You"



**CHIP not offered by the following Medicaid carriers**



## Pa. VFC Eligibility/Insurance

### Vaccines for Children Program Eligibility vs. Health Care Coverage/Insurance

When a child (0-18 years old) presents at a VFC provider site, please refer to the chart below to determine if he/she is eligible for the PA VFC Program.

Coverage Type	Eligible for PA VFC
Uninsured No insurance	<b>YES</b>
Medicaid/ MA *	<b>YES</b> * See chart with specific plans.
Alaskan Native	<b>YES</b> Regardless of insurance coverage
American Indian	<b>YES</b> Regardless of insurance coverage
Underinsured Limited health coverage/insurance Immunizations not covered	<b>YES</b> Must receive vaccines at: Federally Qualified Health Center (FQHC), Rural Health Center (RHC) or Deputized State Health Center (SHC)
CHIP	<b>NO</b> ** Considered private insurance See listing of specific plans.
Private insurance	<b>NO</b>

\*A Medicaid eligible child is eligible for PA VFC vaccines even if they have any other type of primary health care coverage/insurance plan.

MA Managed Care Organization (MCO)	MA MCO business line/product name
Aetna Better Health	Aetna Better Health
AmeriHealth Caritas	AmeriHealth Caritas Partnership, in collaboration with Keystone First
Gateway Health	Gateway Health Plan
Geisinger Health Plan	Geisinger Health Plan
Health Partner Plan	Health Partners of Philadelphia, Inc.
Keystone First	Keystone First
United Health Care	United Health Care
UPMC Health Plan	UPMC

\*PA Medical Assistance and Medical Assistance Managed Care Plans.

### \*\*CHIP Contractors 2019

Aetna: Aetna Better Health Kids/BlueCross of Northeastern PA (BCNEPA): First Priority Health For Kids/Capital BlueCross: Keystone Health Plan Central: Capital Cares 4 Kids/Geisinger Health Plan: GHP Kids/Health Partners Plans: KidzPartners, Highmark: Keystone Health Plan West: Keystone Blue Y-18/Highmark Blue Shield: PPO Plus Y-18/Keystone Health Plan East: Independence Blue Cross: PA Kids/United Healthcare: United Healthcare Community Plan/UPMC Health Plan: UPMC for kids

CHIP children are insured and not eligible for Pa. VFC vaccine unless a vaccine is not covered by CHIP insurance, which would make the child underinsured, in which case he/she should receive vaccines at an FQHC, RHC or deputized SHC.

## PA Vaccines for Children (VFC) Program Patient Eligibility Screening Record

A record of all children 18 years of age or younger who receive immunizations must be kept in the health care provider's office for three years or longer depending on state law. The record may be completed by the parent, guardian, individual of record or the health care provider. VFC eligibility screening and documentation of eligibility status must take place with each immunization visit to ensure the child's eligibility status has not changed. While verification of responses is not required, it is necessary to retain this or a similar record for each child receiving vaccine. Providers using a similar form (paper-based or electronic) must capture all reporting elements included in this form.

1. Child's name: \_\_\_\_\_  

Last name
First name
MI
2. Child's date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_
3. Parent/guardian/individual of record: \_\_\_\_\_  

Last name
First name
MI
4. Primary provider name: \_\_\_\_\_  

Last name
First name
MI
5. To determine if a child (0 through 18 years of age) is eligible to receive federal vaccine through the VFC and state programs, at each immunization encounter/visit, enter the date and mark the appropriate eligibility category. If Column A-D is marked, the child is eligible for the VFC program. If column E, F or G is marked the child is not eligible for federal VFC vaccine.

	Eligible for VFC Vaccine				Not Eligible for VFC Vaccine		
	A	B	C	D	E	F	G
<b>Date</b>	<b>Medicaid enrolled</b>	<b>No health insurance</b>	<b>American Indian or Alaska Native</b>	<b>*Underinsured served by FQHC, RHC or deputized provider</b>	<b>Has health insurance covering vaccines</b>	<b>**Other underinsured</b>	<b>***Enrolled in CHIP</b>

\*Underinsured includes children with health insurance that does not include vaccines or only covers specific vaccine types. Children are only eligible for vaccines that are not covered by insurance. In addition, to receive VFC vaccine, underinsured children must be vaccinated through a Federally Qualified Health Center (FQHC), Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate underinsured children.

\*\* Other underinsured are children that are underinsured but are not eligible to receive federal vaccine through the VFC program because the provider or facility is not a FQHC/RHC or a deputized provider. However, these children may be served if vaccines are provided by the state program to cover these non-VFC eligible children.

\*\*\*Children enrolled in separate state Children's Health Insurance Program (CHIP) are considered insured and are not eligible for vaccines through the VFC program. Each state provides specific guidance on how CHIP vaccine is purchased and administered through participating providers.

PENNSYLVANIA DEPARTMENT OF HEALTH SUPPLIED VACCINE ORDER, INVENTORY and ACCOUNTABILITY FORM



I take full responsibility for the information on this form and attest that there is a current temperature log at this practice site.

Signature of person completing this form: \_\_\_\_\_

PIN #:		Vaccine delivery times (Include times closed for lunch.):			FROM:	TO:		
Date:					Monday			
					Tuesday			
Name of physician's office, practice, clinic, etc.:					Wednesday			
					Thursday			
					Friday			
Address:								
City/State/Zip:				PHONE:	FAX:			
Fax Order to: 717-441-3800 or email to: <a href="mailto:paimmunizations@pa.gov">paimmunizations@pa.gov</a>								
VACCINE	CURRENT INVENTORY			NEW VACCINE ORDER				
	DOSES ON HAND	LOT#	EXPIRATION DATE	MANUF	BRAND	NDC	PKG DESCRIPTION	DOSES ORDER ED
DTaP				Sanofi	Daptacel	49281-0286-10	(10 pk) 1-dose vials	
				GSK	Infanrix	58160-0810-11	(10 pk) 1-dose vials	
				GSK		58160-0810-52	(10 pk) 1-dose syringes	
DTaP/Hep B/IPV				GSK	Pediarix	58160-0811-52	(10 pk) 1-dose syringes	
DTaP/IPV/Hib				Sanofi	Pentacel	49281-0510-05	(5 pk) 1-dose vials	
DTaP/IPV				GSK	Kinrix	58160-0812-11	(10 pk) 1-dose vials	
				GSK		58160-0812-52	(10 pk) 1-dose syringes	
				Sanofi	Quadracel	49281-0562-10	(10 pk) 1-dose vials	
EIPV				Sanofi	IPOL	49281-0860-10	(1 pk) multi-dose vials	
HEP A				Merck	Vaqta	00006-4831-41	(10 pk) 1-dose vials	
				Merck		00006-4095-02	(10 pk) 1-dose syringes	
				GSK	Havrix	58160-0825-11	(10 pk) 1-dose vials	
				GSK		58160-0825-52	(10 pk) 1-dose syringes	
HEP B				Merck	Recombivax	00006-4981-00	(10 pk) 1-dose vials	
				Merck		00006-4093-02	(10 pk) 1-dose syringes	
				GSK	Engerix	58160-0820-52	(10 pk) 1-dose syringes	
Hib				Merck	PedvaxHIB	00006-4897-00	(10 pk) 1-dose vials	
				Sanofi	ActHIB	49281-0545-03	(5 pk) 1-dose vials	
				GSK	Hiberix	58160-0818-11	(10 pk) 1-dose vials	
HPV				Merck	Gardasil 9	00006-4121-02	(10 pk) 1-dose vials	
Meningococcal conjugate				Sanofi	Menactra	49281-0589-05	(5 pk) 1-dose vials	
				GSK	Menveo	58160-0955-09	(5 pk) 1-dose vials	
Meningococcal B				Pfizer	Trumenba	00005-0100-10	(10 pk) 1-dose syringes	
				GSK	Bexsero	58160-0976-20	(10 pk) 1-dose syringes	
MMR				Merck	MMR-II	00006-4681-00	(10 pk) 1-dose vials	
MMR-V				Merck	ProQuad	00006-4171-00	(10 pk) 1-dose vials	
Pneumococcal Polysaccharide				Merck	Pneumovax (PPV23)	00006-4837-03	(10 pk) 1-dose vials	
Pneumococcal conjugate				Pfizer	Prevnar 13	00005-1971-02	(10 pk) 1-dose syringes	
Rotavirus				Merck	RotaTeq	00006-4047-41	(10 pk) 1-dose tube	
				Merck		00006-4047-20	(25 pk) 1-dose tube	
				GSK	Rotarix	58160-0854-52	(10 pk) 1-dose vials	
Td				Grifols	Td	13533-0131-01	(10 pk) 1-dose vials	
				Sanofi	Tenivac	49281-0215-10	(10 pk) 1-dose vials	
				Sanofi		49281-0215-15	(10 pk) 1-dose syringes	
Tdap				Sanofi	Adacel	49281-0400-10	(10 pk) 1-dose vials	
				Sanofi		49281-0400-20	(5 pk) 1-dose syringes	
				GSK	Boostrix	58160-0842-11	(10 pk) 1-dose vials	
				GSK		58160-0842-52	(10 pk) 1-dose syringes	
Varicella				Merck	Varivax	00006-4827-00	(10 pk) 1-dose vials	

Facility name:

Pin #:

## VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non-VFC-eligible patients. **Planned borrowing of VFC vaccine, including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory, is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

### COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child; or
- A dose of privately-purchased vaccine is administered to a VFC-eligible child.

### HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed.
- The provider must sign and date at the bottom of this report.
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7 Other or 13 Other) is entered in the Vaccine Borrowing Report Table.

### Reason for vaccine borrowing and replacement coding legend

Reason for Borrowing VFC Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order on time/delay in shipping)	1	VFC vaccine shipment delay (order on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose exchanged with VFC dose	4	Short-dated VFC dose exchanged with private dose	11
Accidental use of VFC dose for a private patient	5	Accidental use of a private dose for a VFC eligible patient	12
Replacement of private dose with VFC when insurance plan did not cover vaccine	6	Other – Describe:	13 Other
Other – Describe:	7 Other		

### WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and made available to the state/local or territorial immunization program upon request.







## PA VFC DOSE TRACKING FORM



Complete this form each time you administer PA VFC vaccines. This form will help you track the vaccines by manufacturer, lot number and the name of child who received the vaccine. This one record will also have all the information that you will need in the event of a vaccine recall. We have included the manufacturer's name when there is only one manufacturer for the particular vaccine. Refer to the legend on the bottom of this form.

- ♥ When you receive a vaccine order, enter the manufacturer (if necessary), lot number and expiration date of each vaccine in the appropriate column.
- ♥ Enter the name of the child and place a hash mark in the column of the vaccine(s) administered.
- ♥ Retain this form for future reference.

# Vaccine Emergency Handling Procedures and Disaster Recovery Plan

Provider Site Name: \_\_\_\_\_

Address: \_\_\_\_\_  
\_\_\_\_\_

Telephone: \_\_\_\_\_

Date: \_\_\_\_\_ Person Completing Form: \_\_\_\_\_

VFC Coordinator: \_\_\_\_\_ Title: \_\_\_\_\_ Phone: \_\_\_\_\_

Cell #: \_\_\_\_\_ Email: \_\_\_\_\_

Back-up: \_\_\_\_\_ Title: \_\_\_\_\_ Phone: \_\_\_\_\_

Cell #: \_\_\_\_\_ Email: \_\_\_\_\_

Physician: \_\_\_\_\_ Title: \_\_\_\_\_ Phone: \_\_\_\_\_

Cell #: \_\_\_\_\_ Email: \_\_\_\_\_

This document offers guidance for developing emergency handling procedures and a vaccine disaster recovery plan to follow when cold storage units malfunction due to mechanical failure or natural disaster.

## Advanced Planning and Preparations Prior to Emergency

### All Providers Must:

- Identify and establish an agreement with an alternative vaccine storage facility with proper refrigerator and freezer units, proper temperature-monitoring capabilities and backup generator where vaccine can be stored in an emergency. An alternate site that is available 24/7 is preferred; an example would be a hospital. Call quarterly to make sure this facility is still available.
- Designate staff to be responsible for packing and moving the vaccine to a safe location. Ensure written descriptions of floor plans and vaccine locations are available, as well as 24-hour access to the building and vaccine storage units.
- Have the appropriate packing material on hand at all times, including insulated containers, cold/ice packs, bubble wrap, conditioned frozen water bottles and illustrated instructions for packing vaccines for transport. Have flashlights and spare batteries easily accessible.
- Develop a written emergency vaccine retrieval and storage plan which includes how to access the facility and storage area. Create protocols for proper handling of vaccines during transportation using VFC policy guides with Vaccine Transport Hourly Monitoring form and written transportation route to the alternate storage facility.
- Create an emergency call chain including provider staff, cold storage unit service contact information and local utility company emergency phone numbers.

- Track inclement weather conditions
- Set up and maintain a monitoring/notification system especially during times of inclement weather or other conditions creating a power shutdown to ensure the appropriate handling of vaccine during disaster or power outage.
- Verify sufficient fuel is on hand to continuously run a backup generator for at least 72 hours or transfer vaccines to designated alternate storage facility.

### Vaccine Storage Unit Specifications

Type of Unit (Refrigerator or Freezer)	Brand	Model Number	Serial Number

#### During Emergency Event:

- Determine if the equipment failure is mechanical (i.e., no lights in the refrigerator or freezer, no fan noise, digital temperature is above or below the specific target range) or power related.
- Activate the emergency call chain.
- Monitor vaccine storage equipment function.
- If the building has lost electrical power, check with maintenance/security staff to confirm the generator is operational and activated.
- If a time frame for electrical power restoration cannot be determined, implement the emergency disaster recovery plan for transporting vaccines to the designated alternate storage facility.
- Conduct a vaccine inventory before transporting to alternate storage facility using the Vaccine Transport Hourly Monitoring form.
- Alert the alternate storage facility prior to transporting vaccines.
- Pack vaccines to assure the cold chain is maintained and monitored during transportation. Signatures of the person transporting the vaccine and the person receiving the vaccine are required on the transport form.

- Verify proper temperatures were maintained for 24 hours prior to returning the vaccines to the main storage facility.
- Conduct a vaccine inventory prior to transporting the vaccines to the main storage facility, verify temperatures maintained in range during stay at alternate facility and complete the transport form.

Ensure that staff including housekeeping, security and maintenance have read, understand, signed and dated the emergency handling procedures for vaccine disaster/ recovery. The emergency handling plan must be updated annually or when changes occur and reviewed by all staff.

In an emergency, call the following people immediately:

Primary Contact: \_\_\_\_\_ Phone: \_\_\_\_\_ Cell: \_\_\_\_\_

Backup Contact: \_\_\_\_\_ Phone: \_\_\_\_\_ Cell: \_\_\_\_\_

Physician Contact: \_\_\_\_\_ Phone: \_\_\_\_\_ Cell: \_\_\_\_\_

Reviewed & understood by:	Date:	Alternate Site Check-Initial & Date:

Original Emergency Handling Procedures Date: \_\_\_\_\_

Revision of Emergency Handling Procedures Date: \_\_\_\_\_

Company	Name	Telephone
Maintenance/Refrigerator Company		
Electrical power provider		
Flammable Fuel Supplier		
Refrigerator Repair		
Freezer Repair		
Security Alarm Contact		
Backup vaccine storage facility		
Transportation to Back up storage facility		
Emergency Generator repair		
National Weather Service		
<a href="http://www.nws.noaa.gov">http://www.nws.noaa.gov</a>		
<a href="http://www.nhc.noaa.gov">http://www.nhc.noaa.gov</a>		
<a href="http://www.goes.noaa.gov">http://www.goes.noaa.gov</a>		
<a href="https://www.fema.gov/">https://www.fema.gov/</a>		

# PA VFC Vaccine Management Plan and Designated Responsible Staff

VFC PIN#: \_\_\_\_\_ NAME: \_\_\_\_\_

Update Vaccine Management Plan and Designated Responsible Staff document annually.

1. Each staff member/provider that has direct contact with VFC vaccine must review and sign the updated Vaccine Management Plan and the Disaster Recovery Plan annually and keep posted at the site.
2. VFC vaccine shipments are received and inventoried by \_\_\_\_\_ [designated person].
3. Upon receipt, VFC vaccines are labeled (to differentiate them from private vaccine stock), received in PA-SIIS and stored appropriately.
4. DTaP, Td, Tdap, HepA, HepB, Hib, HPV, influenza, meningococcal, MMR, pneumococcal, polio and rotavirus vaccines are stored in the refrigerator with temperatures maintained at 36.0° to 46.0°F/2.0°C to 8.0°C.
5. Frozen vaccines (varicella and MMRV) must be stored in the freezer with temperatures maintained at 5.0°F to negative 58.0°F/negative 15.0°C to negative 50.0°C. MMR may be stored in the freezer. Diluents are stored at refrigerator 36.0°F to 46.0°F/2.0°C to 8.0°C or, if the manufacturer's instructions allow it, room temperatures 68.0°F to 77.0°F/20.0°C to 25.0°C.
6. Stand-alone/medical grade storage units are required for any new/replacement purchases. It is **never** permissible to use dormitory style units (freezer section located within the refrigerator section) to store VFC vaccine. Vaccine found in a dormitory style unit will be considered non-viable.
7. Warning signs are posted to assure vaccine storage units are plugged in at all times and circuit breaker boxes must identify vaccine storage unit switches to prevent turning off the power supply without prior notification given to \_\_\_\_\_ [designated person].
8. Calibrated digital data loggers with current certificate of NIST/ILAC traceability and calibration, as well as probes, are located in the central compartment of each VFC vaccine refrigerator and freezer storage unit. Digital data loggers are due for recalibration on \_\_\_\_\_ [date]. Certificates are kept and maintained by [designated person].
9. Temperature logs are maintained on site for three years. Failure to maintain temperature logs will result in suspension of your VFC vaccine ordering privileges.
10. Temperatures are recorded twice a day at the beginning and end of day by \_\_\_\_\_ [designated person]. Min/max temperatures are to be recorded twice daily.

11. Document any actions taken for out-of-range temperatures on the temperature log. Recheck the temperature in 30 minutes and record. If still out of range after 30 minutes, immediately contact the manufacturers for recommendations on the viability of the vaccine.
12. If temperatures are out of range, \_\_\_\_\_ [designated person] will be notified and determine what actions will be taken. Vaccine Incident Report and Worksheets (and Vaccine Return Form if applicable) located in section 6 of VFC Handbook must be completed and submitted to the VFC Program within five days.
13. Vaccine is stored in the central shelving of the units. No vaccine is permitted in the crisper bins or on the doors/floor of the storage unit. Crisper bins are removed and jugs of water are placed in crisper space. No food or drink is permitted in vaccine storage units.
14. Vaccine vials/syringes must be stored in the manufacturer original packaging.
15. Vaccine inventory is reviewed weekly by \_\_\_\_\_ [designated person].
16. Vaccine stock is rotated with short-dated vaccines used first. Expired vaccines are removed from the storage unit and labeled to be returned to McKesson. The Vaccine Return and Accountability Form is completed listing all wasted, open and expired vaccine, then submitted to the VFC Program in order to receive the vaccine Return Shipping Label. **No opened multi-dose vials may be returned; dispose of open vials according to your biohazard waste disposal process.**
17. Notify your VFC immunization nurse for assistance if vaccine will expire within 90 days.
18. Vaccine borrowing is documented on Vaccine Borrowing Report Form (Section 6). This important information is documented and maintained for three years for review by the VFC program.
19. Procedures for vaccine relocation in the event of a power outage, mechanical difficulty or emergency are reviewed and updated annually. Attach site specific Vaccine Disaster Recovery Plan or adapt the sample in Section 6 of VFC Handbook with a detailed plan of the alternative storage site, documentation of temperatures twice daily, directions to the site, and instructions of how to pack and maintain temperatures in the transport coolers.
20. The Vaccine Storage Maintenance Reminder should be posted on the VFC storage unit and be completed by \_\_\_\_\_ [designated person].
21. Vaccine orders are to be placed online using PA SIIS (Section 5).
22. Primary and backup coordinators must complete annual training (Section 4). All office staff are recommended to complete training.



# Vaccine Storage Maintenance Reminder

**\*\* Post on Storage Unit \*\***

## **Defrost Freezer Unit Monthly**

January	February	March	April	May	June
July	August	September	October	November	December

**Certificate of NIST digital data loggers**

Date \_\_\_\_\_

Date \_\_\_\_\_

**Model/Serial #**

Date \_\_\_\_\_

Date \_\_\_\_\_

## **Annual/biannual recalibration of NIST digital data loggers**

	<u>Due date</u>	<u>Completed date</u>
<b>Refrigerator:</b>	_____	_____
	_____	_____
<b>Freezer:</b>	_____	_____
	_____	_____

**Yearly service of storage unit**

\_\_\_\_\_

**(Recommended)**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## **Vaccine Incident Report and Worksheet Instructions**

**Refrigerator: 36.0° to 46.0° Fahrenheit/2.0° to 8.0° Celsius  
Aim for 40.0° Fahrenheit (5.0° Celsius).**

**Freezer: - 58.0° to 5.0° Fahrenheit/-50.0° to -15.0° Celsius  
Aim for below 0° Fahrenheit (-20.0°Celsius).**

If recorded temperatures are **not** within acceptable ranges and are indicated by “Too Warm” or “Too Cold” on the temperature log:

### **Please Follow the Steps Below**

1. If vaccine temperatures are out of recommended ranges for **less** than 30 minutes during temperature logging, you **must** take immediate action to correct the problem and document the action taken on the temperature log or attach an explanation of action taken.
  - Document corrective action taken on the temperature log and recheck temperatures every 30 minutes to ensure temperatures have returned to acceptable ranges. If there is not enough space on the temperature log to document corrective action taken, please write action taken on a separate sheet of paper and attach to temperature log. Retain for three years.
  
2. For temperatures that remain out of range for **more** than 30 minutes, **immediately** call the manufacturers and complete the Vaccine Incident Report and Worksheet forms (pages 1-4). Also complete a Vaccine Return and Accountability form (Section 6 – Forms) if vaccines are wasted and submit to Pa. VFC Program within five days of the incident.
  - List all details on the incident report.
  - Include a description of incident.
  - Describe incident resolution.
  - Include a corrective action plan.
  - Answer all questions on the report.
  - List all vaccines that were in the affected storage unit at the time of the incident (i.e., name, lot number, expiration, doses).
  - Write manufacturers recommendations, along with case number if available. (Record doses keeping, destroying and returning).
  - Attach copy of temperature log to incident report and fax to 717-214-7223.

**Notify the Pa. VFC Program at 888-646-6864 in the event of a cold chain failure, if you have any questions or need assistance.**

Vaccine Incident Report and Worksheet  
 Pennsylvania Department of Health  
 Vaccines for Children Program

Date	Pin #
<b>Demographics</b>	
Practice name	
Address	Phone #
	County <span style="float: right;">District</span>
<b>Incident Criteria</b>	
Date/time of incident	
Type of incident (Power failure, refrigerator/freezer failure, improperly stored, digital data logger malfunction, shipping/transporting error, etc.)	
Reported by	Reported to
<b>Temperature Data</b>	
<b>Refrigerator</b> -- circle appropriate unit below	<b>Freezer</b> -- circle appropriate unit below
Pharmaceutical    Commercial    Standalone	Pharmaceutical    Commercial    Standalone
Make/model	Make/model
Date/time                      Temperature	Date/time                      Temperature
Min                                  Max	Min                                  Max
Temperatures are reviewed and documented twice daily during operating hours? <b>YES NO</b>	
Water bottles are stored in both refrigerator and freezer? <b>YES NO</b>	
<b>Description of Incident</b> (Write a narrative giving details of incident; attach additional sheet of paper if needed.)	
<b>Incident Resolution</b> (Circle all appropriate responses and/or write a narrative giving details of actions taken after a problem was detected; attach additional sheet of paper if needed.)	
Fridge, Freezer, digital data logger    repaired    replaced    Date _____ Notified VFC immunization nurse of storage repairs/replacements    Date _____ Manufacturers contacted immediately and completed incident report faxed within five days <b>YES NO</b>  Other/additional information:          	
Call and notify Division of Immunizations of incident at 1-888-646-6864. You must also complete all four pages of worksheet and fax within five days to 717-214-7223.	

Vaccine Incident Report and Worksheet  
 Pennsylvania Department of Health  
 Vaccines for Children Program

Date	Pin #
------	-------

**Temperature log and calibration certificate**

NIST-certified temperature monitoring device/buffered probes are placed in the center of each unit

Current calibration certificate included with incident report; provide expiration date: \_\_\_\_\_

Temperature logs complete and copy included with the incident report

Action taken with OOR temperature noted on Step 3 of temperature log

**Vaccine waste**

Was it necessary to waste vaccine because of the incident?    **YES    NO**

Details of contact with manufacturers are documented on vaccine worksheet.

Vaccine Return and Accountability Forms are completed for all wasted vaccine doses.

**Revaccination (Complete only if revaccination is necessary.)**

Were any compromised vaccines administered to patients requiring revaccination?    **YES    NO**  
 If revaccination is necessary, how many patients need revaccination? \_\_\_\_\_

Were patients notified of need for revaccination?    **YES    NO**

Interim/Final Status Report of Corrective Actions Following Cold Chain Failure completed?  
 Note: All letters and emails must be approved by the DOI prior to being sent out    **YES    NO**

**Corrective action plan (Write a narrative giving details of actions taken; attach additional sheet of paper if needed.)**



Vaccine Incident Report and Worksheet  
 Pennsylvania Department of Health  
 Vaccines for Children Program

**Vaccine Incident Report and Worksheet Instructions**

**If temperatures are out of range less than 30 minutes:**

Take immediate action to correct the problem.

Document corrective action on Step 3 of temperature log.

Recheck temperatures every 30 minutes to ensure temperatures have returned to acceptable range.

**If temperatures are out of range more than 30 minutes:**

Mark vaccine "Do Not Use." Immediately contact manufacturers.

VACCINE	MANUFACTURER	TELEPHONE #
<b>DTaP</b> (Daptacel), <b>DTaP-IPV-Hib</b> (Pentacel) <b>IPOL</b> (Polio), <b>Flu, Hib</b> (ActHib), <b>Meningococcal</b> (MCV4), <b>Td, Tdap</b> (Adacel)	Sanofi Pasteur <a href="https://www.sanofi.us/en">https://www.sanofi.us/en</a>	1-800-822-2463
<b>Hep A</b> (Vaqta), <b>Hep B</b> (Recombivax), <b>Hib</b> (PedvaxHib), <b>HPV</b> (Gardasil9), <b>MMR, MMRV</b> (Proquad), <b>Pneumococcal PPV23</b> (Pneumovax), <b>Rotavirus</b> (RotaTeq), Varicella (Varivax)	Merck <a href="http://www.merck.com">www.merck.com</a>	1-800-672-6372
<b>DTaP</b> (Infanrix), <b>DTaP-IPV-HepB</b> (Pediarix), <b>DTaP-IPV</b> (Kinrix), <b>Flu, Hep A</b> (Havrix), <b>Hep B PF</b> (Engerix) <b>Tdap</b> (Boostrix), Shingrix, Twinrix, <b>Rotavirus</b> (Rotarix), <b>Meningococcal</b> (Menveo) <b>Meningococcal B</b> (Bexsero)	GlaxoSmithKline <a href="http://www.gsk.com">www.gsk.com</a>	1-888-825-5249
<b>PNU13</b> (Prevnar PCV 13), <b>Meningococcal B</b> (Trumenba)	Pfizer <a href="http://www.pfizer.com">www.pfizer.com</a>	1-800-572-8221
<b>FluMist</b>	AstraZeneca <a href="http://www.astrazeneca.com/">www.astrazeneca.com/</a>	1-877-633-4411
<b>Flucelvax, Afluria, Fluvirin, Fluad</b>	Seqirus <a href="http://www.seqirus.com">www.seqirus.com</a>	1-855-358-8966

Vaccine worksheet is completed to document manufacturer recommendation.

Vaccine Return and Accountability Forms document vaccine waste to be returned to distributor.

Complete all four pages of the Vaccine Incident Report and Worksheet within five days.

Fax completed paperwork and supporting documentation to 717-214-7223.

All paperwork for the VFC program is to be retained for three years.

# VACCINE RETURN AND ACCOUNTABILITY

## PENNSYLVANIA DEPARTMENT OF HEALTH

**Terms used in accountability of vaccines and determining the proper form to complete and submit to the Division of Immunizations (wasted-nonviable-nonreturnable or returnable-nonviable vaccines) for returning of expired/wasted vaccines for Federal Excise Tax Credit**

**EXPIRED:** Is any vaccine that has not been administered prior to the expiration date indicated on the vial or syringe.

**OPENED:** Is a partially used multi-dose vial;  
A vial that has been punctured;  
A syringe with an opened safety cap; or  
A vial missing the plastic cap.

**UNOPENED:** Is a box of 10 single dose vials with three doses administered – the remaining seven doses are considered “unopened”;  
  
Is a five-pack of syringes with only two doses administered, the remaining three syringes are considered “unopened”; and  
  
Includes situations in which the original packaging (box) of any vaccine is missing, but the vial/syringe still has the plastic cap/safety cap on and has not been punctured.

**SPOILAGE:** Is any vaccine in a multi-dose vial, single dose vial or syringe that has been exposed to temperatures out of the recommended range, power outages or unit failure.

**WASTED:** Is any vaccine that has been drawn up but not administered;  
  
Is a vial or syringe that is accidentally broken;  
  
Includes open/partial vials exposed to out-of-range temperatures, power outages, unit failures or expired vaccines.

The above descriptions should be considered when completing the Vaccine and Return Accountability Form.

All **unopened**, non-viable vaccine, including influenza vaccine, if ordered through the Department of Health, should be returned to McKesson ARS Specialty for Federal Excise Tax credit **within six months after the expiration date**. However, vaccines that have expired more than six months previously will still be accepted.

**Diluent is not a vaccine and does not need to be returned.**

If the vaccine being returned is a result of anything other than “expired,” a Vaccine Incident Report and Worksheet (Section 6-F) **must** be submitted to the Department of Health with a copy of the Vaccine Return and Accountability Form within **five** days of the incident.

## To return expired/non-viable vaccine to McKesson, follow these steps:

1. Fax a copy of the completed Vaccine Return and Accountability Form to the vaccine manager 717-214-7223. Faxing this form will initiate a request for a return label. If you call FedEx or UPS directly, you will be charged for the retrieval of the box(es).
2. Check the appropriate box on the return form to indicate if you have routine UPS service at this facility; facilities that do not have routine UPS service will not be sent their labels via email.
3. McKesson will be forwarding UPS return labels in one of three ways:
  - By email to the primary VFC Contact indicated in PA-SIIS from [uoltsupport@ups.com](mailto:uoltsupport@ups.com) with a subject line – UPS Shipping API. Providers should receive UPS return label within one to three hours after Division of Immunizations staff enters the return into the appropriate system (VTrckS)
    - One unique return label will be included per email.
    - The return label will be coded with an internal tracking number used by McKesson – IT WILL NOT include the VTrckS return ID number required on the return form.
    - Return labels cannot be photocopied or reprinted for multiple uses.
    - If it is indicated that three boxes will be used to return vaccines, the provider will receive three separate emails with one label per email – the labels are not specific to any of the three boxes.
    - Unused labels **must be discarded** and cannot be used on future returns.
  - By routine U.S. mail addressed to the primary VFC Contact indicated in PA-SIIS – approximately seven to 10 business days
  - By the UPS driver at the time of scheduled pick-up for those without routine UPS service

### Sample of the email

The email reads:

[UPS Label Delivery, 1Z2R43839097612737](#)

UPS Returns Label Delivery

This notice tells you that a UPS shipper has sent you an electronic label. You can print and use this label to include in your outbound shipment or send it to the consignee. The label will be available for 30 days.

Note: When retrieving your label below, we will provide you with both a UPS Returns Label and commercial invoice if the invoice was prepared by the original shipper.

[View UPS Returns Documentation Instructions](#)

[Retrieve Your Shipment Label.](#)

4. Returns can be sent in the McKesson shipping container or a container of your own. If you use your own container, ensure that vials are secure so they don't break during transport.
5. You **must** include a copy of the completed Vaccine Return and Accountability Form in each box with the non-viable vaccines being returned to McKesson. The **Vaccine Return ID number must** be included on this form. VFC Program staff will fax or email the Vaccine Return ID information to the VFC contact once the Vaccine Return and Accountability Form is received by the VFC Program.
6. **DO NOT** return any vaccines **not** included on the original Vaccine Return and Accountability Form. A separate request must be submitted for additional returns.
7. Keep a copy of the completed form for your records.
8. UPS will pick up all boxes to return to McKesson, even when packages are shipped to you via FedEx, UPS or DHL.
9. Once you have the label and affix it to the box, simply give it to your UPS driver the next time he/she is at your facility **within 30 days of receiving the return label**.
10. **IF** you indicated on the Vaccine Return and Accountability Form that your facility does not have routine UPS service, staff at McKesson will make arrangements for a pickup. The label will be created at the time of pickup by the UPS driver.
11. **Do not** return vaccines prior to the expiration date **unless** they were exposed to temperatures outside of the recommended range for storing vaccines.

**VACCINE RETURN AND ACCOUNTABILITY FORM  
PENNSYLVANIA DEPARTMENT OF HEALTH**

**WASTED / DESTROYED**

**NON-VIABLE, NON- RETURNABLE VACCINE FORM**

**VTckS Waste ID:** \_\_\_\_\_

(Note: by submitting this form, you are indicating that the vaccines have been destroyed and will not be returned to McKesson ARS Specialty)

Date: _____	Person reporting _____	VFC PIN #: _____
Site name: _____		Phone #: _____
Was an incident report submitted for these vaccines?	Yes <input type="checkbox"/> No <input type="checkbox"/>	<b>NOTE:</b> You must submit an incident report if wasted vaccine is connected to a temperature excursion
Will an incident report be submitted for these vaccines?	Yes <input type="checkbox"/> No <input type="checkbox"/>	

**ACCOUNTABILITY OF WASTED, NON-VIABLE—NON-RETURNABLE VACCINES  
(COMPLETION OF ALL COLUMNS IS REQUIRED)**

NDC #**	Vaccine	Manufacturer	Lot #	Exp. Date	# Doses	Reason Code

**\*\* The NDC number can be found on each individual vaccine vial/syringe.**

Although wasted non-viable, non-returnable vaccines are not returned to McKesson ARS specialty, the VFC Program must account and document these vaccines. **All** vaccines deemed non-viable, non-returnable must be properly disposed of according to the policy at your facility. Use this wasted, non-viable-non-returnable form to account for vaccine.

Wasted, Non-Viable – Non-Returnable Vaccines Reason Code Includes:

- a) Vaccine drawn up but not administered
- b) Broken vial or syringe
- c) Lost or unaccounted for
- d) Open/partial vial exposed to out of range temperatures, unit failures or power outages
- e) Open/partial vial that has pass the expiration date
- f) Non-vaccine product i.e. IG, HBIG, Diluent

Open/partial vials should not be returned. Please complete a wasted, non-viable, non-returnable form. **Please fax completed wasted, non-viable—non-returnable form to 717-214-7223**

**VACCINE RETURN AND ACCOUNTABILITY FORM  
PENNSYLVANIA DEPARTMENT OF HEALTH  
SPOILED / EXPIRED RETURNABLE**

**NON-VIABLE RETURNABLE VACCINE FORM**

**VTrckS Return ID:** \_\_\_\_\_

(Note: **ALL** fields below must be completed legibly. Forms with missing information will be delayed in processing, or not be processed.)

Date: \_\_\_\_\_ Person reporting \_\_\_\_\_ VFC PIN #: \_\_\_\_\_  
 Site name: \_\_\_\_\_ Phone #: \_\_\_\_\_

Was an incident report submitted for these vaccines? Yes  No   
 Will an incident report be submitted for these vaccines? Yes  No   
 Does this facility have routine UPS service? Yes  No   
 If yes, do you prefer UPS shipping label sent via email? Yes  No   
 If facility does not have UPS service, would you prefer UPS shipping label sent via email? Yes/No  
 Email address: \_\_\_\_\_ # of shipping labels needed \_\_\_\_\_

**NOTE:** You must submit an incident report if this vaccine return is connected to a temperature excursion.

\*VTrckS return ID number will be provided to VFC contact via email.

**NON -VIALE VACCINES TO RETURN TO MCKESSON; COMPLETION OF ALL COLUMNS IS REQUIRED**

(Note: Open/partial vials and/or diluents should not be returned; destroy them and complete a wasted, non-viable--non-returnable form.)

NDC #**	Vaccine	Manufacturer	Lot #	Exp. Date	# Doses	Reason Code

\*\* The NDC number can be found on each individual vaccine vial/syringe.

**Non-Viable returnable vaccines Reason Code includes:**

- a) Expiration date has passed.
- b) Failure to store or handle properly (e.g., Vaccine left out overnight, not put away upon arrival)
- c) Mechanical failure (refrigerator/freezer failure)
- d) Power outage/Natural disaster
- e) Refrigerator/Freezer too warm
- f) Refrigerator/Freezer too cold
- g) Spoilage of vaccine in transit

\*\*Open/partial vials should not be returned. Please complete a wasted, non-viable, non-returnable form.

**Please fax completed returnable, non-viable returnable form to 717-214-7223**

**Pennsylvania Department of Health**  
**Division of Immunizations**  
**Room 1026 Health and Welfare Building**  
**625 Forster St.**  
**Harrisburg, PA 17120-0701**

**Interim/Final Status Report Following Cold Chain Failure**

Pin # \_\_\_\_\_ Date cold chain failure discovered \_\_\_\_\_

Name and address of provider site:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Based on compromised vaccines, the number of clients who need revaccinated \_\_\_\_\_

Method used to contact clients: Phone  Letter  Other

(Attach a copy of the letter if applicable.)

Number of clients revaccinated \_\_\_\_\_ Number of clients not revaccinated \_\_\_\_\_

(Do not include patients counted on any previous status reports for this incident.)

Why were clients not revaccinated? Client refusal  Physician refusal  Other

(Physician refusal to revaccinate: DOH must be notified for further actions.)

Number of doses of each vaccine administered to date:

(Do not include doses counted on any previous status reports for this incident.)

_____ Tdap	_____ Hepatitis A and B	_____ HIB
_____ DTaP	_____ Influenza	_____ MMR
_____ Varicella	_____ Pneumococcal	_____ IPV
_____ Rotavirus	_____ Meningococcal	_____ Meningococcal B
_____ Other (Specify)		

Overall progress toward completion of revaccination per physician: \_\_\_\_\_

Any further action needed? \_\_\_\_\_  
\_\_\_\_\_

Signature of Physician: \_\_\_\_\_

Date: \_\_\_\_\_

## **VFC Frequently Asked Questions**

**Question:** If the refrigerator temperature is 46.1°F is this considered out of range?

**Answer:** Yes. Temperatures below 36.0°F and above 46.0°F are in DANGER. Temperatures between 36.0°F to 46°F are OK. You must notify manufacturer of cold chain failure.

**Question:** Are we allowed to round up temperatures when taking temperature log?

**Answer:** No. Do not round up the temperature. Record temperatures exactly as they appear on the data logger.

**Question:** My combination refrigerator broke, do I get another combination unit?

**Answer:** PA VFC requires that all new enrollee and replacement purchases be stand-alone medical/pharmaceutical grade units.

**Question:** How do I know which vaccine storage unit to buy?

**Answer:** VFC does not endorse any specific product. However, recommendations can be found in section 6-J of the handbook or at this site

<https://www.health.pa.gov/topics/programs/immunizations/Pages/VFC.aspx>

**Question:** Why do I have to update my patient population in SIIS?

**Answer:** This is a requirement from the CDC. It holds VFC and providers accountable for the vaccines that they receive by making sure that the number used corresponds with the patients served.

**Question:** Where do I get my patient population numbers?

**Answer:** Usually your office manager should be able to help with this.

**Question:** My VFC coordinator has been changed. Do I need to notify DOI?

**Answer:** Yes. You must notify DOI of all changes including address change, hours of operation, new VFC staff/providers and when cold chain failure occurs.

**Question:** When do I have to reconcile my vaccine inventory in PA-SIIS?

**Answer:** You must always reconcile vaccine inventory before placing any vaccine order. If this isn't done, your vaccine order will not be approved.

### **Enrollment and VFC Eligibility**

#### **1. What are the requirements for enrolling with VFC?**

- You cannot charge a fee for VFC supplied vaccine.
- Complete and return the provider profile and enrollment forms.

- Agree to provider site visits.
- Screen all patients to establish VFC eligibility and maintain a record of screenings.
- Comply with the recommended immunization schedule as established by the ACIP and state law.
- Immunize eligible children with VFC supplied vaccine.

**2. Is there a fee to enroll with VFC?**

No. There is no fee to enroll with VFC, and you must not charge any fee for VFC vaccines. However, you may charge an administration fee for administering VFC vaccines.

**Note:** Providers may not deny administration of a qualified pediatric vaccine to a VFC eligible child due to the inability of the child's parents to pay an administration fee.

**3. My patient has health insurance but has not met the deductible, is he/she eligible to receive VFC vaccine?**

Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration is denied payment by the insurance carrier because the plan's deductible has not been met.

**4. I already enrolled with VFC, do I have to re-enroll?**

Yes. CDC requires that VFC perform annual re-enrollment of providers into the VFC program to:

- Verify provider eligibility (licensure in the jurisdiction and non-inclusion on the LEIE list);
- Determine the number of VFC-eligible children and non-VFC eligible children served by VFC providers; and
- Ensure that provider still has the capacity to order, receive, and manage public vaccine, including proper vaccine storage and temperature monitoring measures.

**Note:** VFC enrollment and renewal paperwork may be completed electronically.

**5. Which patients are eligible to receive VFC vaccines?**

Children 0 through 18 years of age (under 19) who meet at least one of the following criteria:

- Medicaid-eligible: A child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms "Medicaid-eligible" and "Medicaid-enrolled" are used interchangeably and refer to children who have health insurance covered by a state Medicaid program);
- Uninsured: A child who has no health insurance coverage;

- American Indian or Alaska Native (AI/AN): As defined by the Indian Health Care Improvement Act (25 U.S.C. 1603); or
- Underinsured: \* A child who has health insurance, but the coverage does not include vaccines, or a child whose insurance does not cover all Advisory Committee on Immunization Practices (ACIP) recommended vaccines. The child would be eligible to receive those vaccines not covered by the insurance.

\*Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC), or under an approved deputization agreement. With the implementation of the Affordable Care Act (ACA), it is rare for a child to meet the underinsured eligibility criteria for the VFC program. Therefore, unless insurance coverage\*\* for vaccines is verified by the provider prior to administration of vaccine, for the purposes of the VFC program, these children are considered insured and not eligible to receive VFC vaccines at that immunization encounter.

\*\*Insurance Coverage: Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines. This applies even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible has not been met.

**6. Do I have to update my patient population in SIIS?**

Yes. This is a requirement from the CDC. It serves to ensure that VFC and providers are accountable for the vaccines that they receive; by making sure that the number of vaccines requested/used tallies with the number of patients served.

**7. Where do I get my patient population numbers?**

Usually your office manager should be able to help with this.

**8. What happens if I dis-enrolled from the VFC program but wish to participate in the program again?**

If a former provider believes that the circumstances regarding his disenrollment from the VFC program has changed and wishes to participate in the VFC program, provider should complete a provider profile form and be sure to check the reactivate box. Provider should also indicate the pin number that was assigned to them in the past.

**9. Where can I go to get vaccines if I am not, or my children, are not insured? Please call local health offices to find out if they are a part of the VFC Program. Your county health department may also be able to provide you with locations to upcoming clinics.**

**10. Does VFC provide vaccines to adults?**

No. However, CDC makes a limited quantity of vaccines for eligible adults available through the VFC.

**Storage and Handling**

**11. What are the VFC requirements for vaccine storage?**

VFC requires all providers to utilize properly functioning equipment, including vaccine storage units and certified digital data loggers. All DOH-supplied vaccine must be stored in one of the following:

- Stand-alone units with enough space to accommodate your maximum inventory without crowding. (Medical/pharmaceutical grade units are highly recommended but not required); and
- Digital data logger (DDL) with a current and valid Certificate of Calibration Testing (also known as a Report of Calibration) for each unit and at least one backup digital data logger in case of a broken or malfunctioning device.

**12. How do I know which vaccine storage unit to buy?**

VFC does not endorse any specific product. However, recommendations can be found in section 6-J of the handbook or at this site

<https://www.health.pa.gov/topics/programs/immunizations/Pages/VFC.aspx>

**13. My combination refrigerator broke; do I get another combination unit? PA VFC**

requires that all new enrollee and replacement purchases be stand-alone units with space to accommodate your maximum inventory without crowding. Dormitory style or combo style units are not allowed for storage of VFC vaccines. Medical/pharmaceutical grade units are highly recommended, but not required.

**14. If the refrigerator temperature is 46.1°F, is this considered out of range? Yes.**

Temperatures below 36.0°F and above 46.0°F are in DANGER. Temperatures between 36.0°F to 46°F are OK. You must notify manufacturer of cold chain failure.

**15. Are we allowed to round up temperatures when logging temperatures? No.**

Do not round up the temperature. Record temperatures exactly as they appear on the data logger i.e. if temperature reads 34.2°F, do not record it as 34°F.

**16. When and how often should I defrost my vaccine storage freezer?**

CDC recommends you defrost manual-defrost freezers when the frost exceeds either 1 cm or the manufacturer's suggested limit. You should follow the manufacturer's instructions regarding the defrost process. While defrosting, store vaccines temporarily in another unit with appropriate freezer temperatures. You can learn more about this from the Storage and Handling Toolkit.

**17. I need to report a temperature excursion, what do I do?**

- Contact the manufacturer immediately to confirm viability of the vaccines.
- Contact your immunization nurse to notify DOI of the incident. Provider may have to submit an incident report (IR) form. To make sure that your IR investigation is completed in a timely manner, be sure to provide the nurses with ALL required information.

**18. I need to submit an incident report, what do I do?**

- Contact the manufacturer immediately to confirm viability of the vaccines.
- Contact your immunization nurse to notify DOI of the incident. Provider may have to submit an incident report (IR) form. To make sure that your IR investigation is completed in a timely manner, be sure to provide the nurses with ALL required information.

**19. Is it necessary that I have a digital data logger?**

Yes. PA VFC requires all providers to have a properly functioning temperature monitoring device, and at least one backup temperature monitoring system with a current certificate of calibration.

**Note:** Effective January 2018, CDC will require all VFC providers to purchase a digital data logger/continuous temperature monitoring system with an active temperature display, continuous monitoring and recording capabilities, and a detachable probe encased in a bio-safe buffered material (glycol-encased probe recommended) in all VFC storage units. VFC providers will also be required to have at least one backup digital data logger/continuous temperature monitoring system with a valid and current certificate of calibration, readily available at the site, to ensure that temperature assessment and recordings are performed twice a day.

**20. Does VFC supply free data loggers to providers?**

No. VFC does not supply data loggers to providers. Recommendations may be made on the types of data loggers that are available for purchase by providers, but VFC does not endorse any.

**Statewide Immunization Information System - SIIS**

**21. My VFC coordinator has been changed, do I need to notify division of immunization (DOI)?**

Yes. You must notify DOI of all changes including address change, hours of operation, new VFC staff/providers, and changes to contact emails and phone numbers. You must also notify DOI when cold chain failure occurs.

**22. The name of my facility has changed, what do I do?**

You must notify DOI of this change and provide the new address (if any) of your facility as well. You should provide the name(s) of new providers from the merger. Make sure that you reference your pin number in all correspondence.

**23. My facility will be merging with another healthcare provider, what do I do?** You must notify DOI of the merger, and provide the new name, and new address (if any) of your facility as well. Make sure that you reference your pin number in all correspondence.

**24. Can VFC provide me with my patient's vaccination history?**

No. VFC does not keep records of individual patients' immunization records and does not provide the public with such information.

**Requesting for VFC Vaccines**

**25. How often should I request for vaccines?**

It is recommended that you put in your request for vaccines every month; usually between the 1st and 15th. You should only request for vaccines that you will use for the month.

**26. It has been a week, why have I not received the vaccines I requested?**

McKesson requires 5 to 9 business days to ship vaccines to providers. However, there are several other reasons why your vaccine request may be pending:

- Provider's inventory may not be reconciled;
- Previous provider shipment may not have been accepted properly; or
- Provider may have an incident report (IR) under investigation. To make sure that your IR investigation is completed in a timely manner, be sure to provide the nurses with ALL required information.

**27. How do I reconcile vaccine inventory in PA-SIIS?**

Inventory on hand should match what is in your refrigerator and freezer. Contact VFC personnel for assistance at 1-888-646-6864 or to request a training aid.

**28. When do I have to reconcile vaccine inventory in PA-SIIS?**

You must always reconcile vaccine inventory before placing any request for vaccines. If this isn't done, your vaccine request will not be approved.

**29. How do I accept shipment correctly in PA-SIIS?**

To accept shipments correctly in PA-SIIS you must enter the total volume received and be sure it matches total volume shipped. Then select yes, so it populates into your inventory. Contact VFC personnel for assistance at 1-888-646-6864 or to request training aid.

**30. Why did I receive my refrigerated vaccines but not the frozen vaccines?**

Refrigerated vaccines are shipped separate from frozen vaccines. The frozen vaccines are shipped directly to providers and not from the warehouse, so the delivery times may vary even though your request was placed at the same time.

**31. My frozen vaccine did not come with diluents, what should I do?**

Call Division of Immunization and we will follow up with McKesson and Merck.

**32. My vaccine shipping box is damaged, what should I do?**

- Label the vaccines as "do not use" and place them in the refrigerator.
- Contact the manufacturer immediately to confirm viability of the vaccines.
- Contact your immunization nurse to notify DOI of the incident. Provider may have to submit an incident report (IR) form. To make sure that your IR investigation is completed in a timely manner, be sure to provide the nurses with ALL required information.

**33. The vaccines I received were out of temperature range, what should I do?**

- Label the vaccines as "do not use" and place them in the refrigerator.
- Contact the manufacturer immediately to confirm viability of the vaccines.
- Contact your immunization nurse to notify DOI of the incident. Provider may have to submit an incident report (IR) form. To make sure that your IR investigation is completed in a timely manner, be sure to provide the nurses with ALL required information.

**34. I didn't receive all the doses that I requested, what should I do?**

Contact Division of Immunizations and they will follow up with McKesson and/or Merck. Make sure you fax in the shipping label and indicate what vaccine(s) were missing or more than what you requested for. Also specify the number of doses.

**35. I put in a request for the wrong vaccine and it has been approved, what should I do?**

Contact your local immunization nurse. They will attempt to find another clinic in need of the vaccine. If you do not know how to contact your local immunization nurse, Division of Immunizations can provide that information.

**36. How can I change my vaccine request/order?**

To change your order, you make sure that it is still in "pending approval" status:

- Log into SIIS, click on the "View Clinic's Orders" button which is at the bottom of your "Edit Clinic" page.
- If the order status is "pending approval", you may click anywhere on the blue hyperlink; this opens the order and allows you to make changes.

**Note:** Please be sure to click on the update button once all changes are made.

**37. How do I know what quantity of vaccines to request for?**

Always make sure that vaccine requests are commiserate with your patient population and historical monthly usage.

**Note:** Vaccines should be requested by number of doses and not by packages.

# Recording Vaccine Temperatures

Record **CURRENT, MIN, AND MAX** temperatures in vaccine units twice a day.

Keep temperature logs for **3 years**.

Set Mode Display to **36.0°F Lo and 46.0°F Hi (2°C Lo and 8°C Hi)**

The **Current** temp is the temperature **now**. But **MIN** (minimum) and **MAX** (maximum) temperatures are also very important! The **MIN** shows the **coldest** temperature in the unit since the memory was cleared or data was downloaded.

The **MAX** shows the **warmest** temperature in the unit since the memory was cleared or data was downloaded. MIN/MAX numbers tell you if temperatures were ever in the DANGER Zone since you last checked the temperature. (See Step 2 for example)



**Refrigerator units: Temperatures 35.9°F or lower are out of range and require incident report to PA VFC program.**

**Temperatures 46.1°F or higher are out of range and require incident report to PA VFC program.**

Be sure to record a.m. temperatures **before** opening the refrigerator or doing inventory.



## Step 1

Start a new log at the beginning of every month.  
Write the **month** and **year** and **VFC Pin #**.  
Write the **Facility Name**

\_\_\_\_\_

Month/Year \_\_\_\_\_ VFC Pin # \_\_\_\_\_

Facility Name \_\_\_\_\_

Find the proper date and time (AM or PM), and record temp in °F or °C.

**Mark** sure to use correct log, **F or C**.

**Initial** on correct line for am or pm. \_\_\_\_\_

Day	Time: AM	Refrigerator AM Temp	Refrigerator Min/Max Temp	Staff Initials	Temp in Range (Y/N)
1					

## Step 2

Read the **MIN and MAX** temperatures on the digital data logger display.  
Write the temperatures in the space provided.

Refrigerator Min/Max Temp	Staff Initials	Temp in Range (Y/N)
38.2°F/44.7°F		

Check if the temperatures you recorded are OK or in the DANGER Zone.

**Refrigerated vaccine safety zone is 36.0°F to 46.0°F (2°C to 8°C).**

**Note that 35.9°F is IN the DANGER Zone. Note that 46.1°F is IN the DANGER Zone.**

Circle all the temperatures that are in DANGER Zone (even if they are due to temporary causes, such as taking inventory). Then go to Step 3.

Refrigerator Min/Max Temp	Staff Initials	Temp in Range (Y/N)
38.2°F/47.5°F		N

If ALL the temps are OK, go to Step 4.

(Continued on next page)

# Recording Vaccine Temperatures (cont'd)

## Step 3

If temperatures are in a DANGER Zone, immediately take these actions.

### If you ever see temps in Danger Zone (above 5.0°F), even for a short time:

- Put a “Do Not Use Vaccine” sign on the vaccines and alert your supervisor immediately.
- If temps are in the DANGER Zone over 30 minutes – **Call the manufacturers immediately, then complete the Incident Report. You must notify Division of Immunization of all cold chain failure.**

You may see warmer temperatures after taking inventory or stocking vaccine. After you’re done, temperatures should be OK within 30 minutes. But if any temperatures remain too warm, it could mean that there is a problem with your freezer. Then, you must take the action steps above!

Document actions. Attach an extra sheet of paper to the log. See example here:

**Action Taken:** *(attach additional pages as needed) 9/6/13, 5pm warm temps due to taking inventory. Called VFC. Vaccines OK. Temps ok in 30 minutes.*

When you record MIN/MAX temperatures, you may see more temps in the DANGER Zone than you did when you only recorded CURRENT temps. It is important to call the manufacturer and document temps in the DANGER Zone **every time** as indicated in this step.

## Step 4

**For a digital min/max on data logger** press the MEMORY CLEAR\* button **every time** you finish logging temperatures.

**For a digital data logger or continuous monitoring device** weekly/monthly downloads from the device to a computer file are required.

\*Some Digital Data Loggers (DDL) may not have the **Memory Clear** button.



## Step 5

At the end of the day repeat Steps 1 - 4.

**PA VFC Fahrenheit Refrigerator Temperature Log**

Facility Name \_\_\_\_\_

Month/Year \_\_\_\_\_

VFC Pin # \_\_\_\_\_

Call Vaccines for Children immediately at 1-888-646-6864 for ANY temperatures found outside of the safety zones.

Refrigerated vaccine safety zone is 36.0° to 46.0°F. 40°F is ideal.

**Record CURRENT, MIN, and MAX temperatures twice a day. Document temps are IN RANGE by 'Y' or 'N'.**

**Exact time, exact temperature on display, and initials are REQUIRED for each entry**

Day	Time: AM	Refrigerator AM Temp	Refrigerator Min/Max Temp	Staff Initials	Temp in Range (Y/N)	Time: PM	Refrigerator PM Temp	Refrigerator Min/Max Temp	Staff Initials	Temp in Range (Y/N)
1										
2										
3										
4										
5										
6										
7										
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**Action Taken:**

Attach additional \_\_\_\_\_  
pages as needed.

**PA VFC Fahrenheit Freezer Temperature Log**

Facility Name \_\_\_\_\_

Month/Year \_\_\_\_\_

VFC Pin # \_\_\_\_\_

Call Vaccines for Children immediately at 1-888-646-6864 for ANY temperatures found outside of the safety zones.

Freezer vaccine safety zone is 5.0°F or lower. 0°F or colder is ideal.

**Record CURRENT, MIN, and MAX temperatures twice a day. Document temps are IN RANGE by 'Y' or 'N'.**

**Exact time, exact temperature on display, and initials are REQUIRED for each entry**

Day	Time: AM	Freezer AM Temp	Freezer Min/Max Temp	Staff Initials	Temp in Range (Y/N)	Time: PM	Freezer PM Temp	Freezer Min/Max Temp	Staff Initials	Temp in Range (Y/N)
1										
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**Action Taken:**

Attach additional \_\_\_\_\_  
pages as needed.

\_\_\_\_\_

**PA VFC Celsius Refrigerator Temperature Log**

Facility Name \_\_\_\_\_

Month/Year \_\_\_\_\_

VFC Pin # \_\_\_\_\_

Call Vaccines for Children immediately at 1-888-646-6864 for ANY temperatures found outside of the safety zones.

Refrigerated vaccine safety zone is 2° to 8°C.

**Record CURRENT, MIN, and MAX temperatures twice a day. Document temps are IN RANGE by 'Y' or 'N'.**

**Exact time, exact temperature on display, and initials are REQUIRED for each entry**

Day	Time: AM	Refrigerator AM Temp	Refrigerator Min/Max Temp	Staff Initials	Temp in Range (Y/N)	Time: PM	Refrigerator PM Temp	Refrigerator Min/Max Temp	Staff Initials	Temp in Range (Y/N)
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**Action Taken:**

Attach additional \_\_\_\_\_  
pages as needed.

\_\_\_\_\_

**PA VFC Celsius Freezer Temperature Log**

Facility Name \_\_\_\_\_

Month/Year \_\_\_\_\_

VFC Pin # \_\_\_\_\_

Call Vaccines for Children immediately at 1-888-646-6864 for ANY temperatures found outside of the safety zones.

Freezer vaccine safety zone is -15°C or colder.

**Record CURRENT, MIN, and MAX temperatures twice a day. Document temps are IN RANGE by 'Y' or 'N'.**

**Exact time, exact temperature on display, and initials are REQUIRED for each entry**

Day	Time: AM	Freezer AM Temp	Freezer Min/Max Temp	Staff Initials	Temp in Range (Y/N)	Time: PM	Freezer PM Temp	Freezer Min/Max Temp	Staff Initials	Temp in Range (Y/N)
1										
2										
3										
4										
5										
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**Action Taken:**

Attach additional \_\_\_\_\_  
pages as needed.

\_\_\_\_\_

## TRANSPORTING FROZEN VACCINES BY NECESSITY

CDC and Merck do NOT recommend transporting varicella-containing vaccines.

Varicella-containing vaccine is to be transported in the original box in a portable freezer (preferred by CDC and Merck) or in a cooler with frozen water bottles for *less than one hour.*

Varicella-containing vaccine is to be transported in the original box in a portable freezer (preferred by CDC and Merck) or in a cooler with frozen water bottles for *more than one hour.*

Documentation of time and temperatures in the transport unit need to be monitored and documented at the beginning and end of transport.

Documentation of time and temperatures in the transport unit need to be monitored and documented at the beginning, end and every 30 minutes *during transport.*

If temperatures are maintained at the recommended range  $-58.0^{\circ}\text{F}$  to  $+5.0^{\circ}\text{F}$  ( $-50.0^{\circ}\text{C}$  to  $-15.0^{\circ}\text{C}$ ), then no further action is needed.

If the temperature is outside of the recommended range  $-58.0^{\circ}\text{F}$  to  $+5.0^{\circ}\text{F}$  ( $-50.0^{\circ}\text{C}$  to  $-15.0^{\circ}\text{C}$ ) at any time, or if temperature in the transport unit is not documented, additional action is required.

1. Place vaccine in permanent freezer unit between  $-58.0^{\circ}\text{F}$  to  $+5.0^{\circ}\text{F}$  ( $-50.0^{\circ}\text{C}$  to  $-15.0^{\circ}\text{C}$ ).
2. Label "DO NOT USE" and keep it separate by placing in a clearly labeled paper bag.
3. Call Merck to report. Include description of incident, time and temperature at beginning, during and end of transport; report vaccine type, expiration date and lot number. Inform Merck if this vaccine lot has been previously exposed to temperatures outside of recommended range  $-58.0^{\circ}\text{F}$  to  $+5.0^{\circ}\text{F}$  ( $-50.0^{\circ}\text{C}$  to  $-15.0^{\circ}\text{C}$ ).
4. Merck National Service Center phone number is 1-800-672-6372. This number is open 7 a.m. to 8 p.m. If call is placed after hours, leave a message, and Merck will call back in the morning.
5. Merck will give guidance on the use of this vaccine. Document what Merck reports.
6. You must complete an incident report within five days and fax it to the PA VFC program at 717-214-7223.

# TRANSPORTING REFRIGERATED VACCINES

**The number of times vaccines are handled and transported should be minimized.**

The provider should contact district/county nurses when vaccine is within 90 days of expiration for assistance with transfer.

Check three months of temperature logs before transferring vaccine between provider offices to assure vaccine is usable.

Vaccine is transported in the original box, and it is critical that vaccine potency is protected by maintaining the cold chain at all times.

If vaccine is transported to an off-site clinic, temperatures must be recorded every 30 minutes during transport and throughout the duration of the clinic. Diluent should travel with its corresponding vaccine and should never be frozen.

**Materials for transport must be readily available at all times.**

**Cooler:** The CDC recommends hard sided coolers or the reuse of original vaccine shipping containers. Enough coolers should be available to transport your typical supply of refrigerated vaccine. A label attached to the outside of the cooler should state “keep refrigerated,” vaccine type, quantity, date, time and originating facility. Do not use soft-sided collapsible coolers. Equipment designed specifically for transporting vaccine may have varying instructions; please contact manufacturer for guidance on these occasions.

**Temperature monitoring:** The CDC and the PA DOI require digital data loggers for all temperature monitoring, including vaccine transport. The buffered probe of the available monitoring device should be kept refrigerated. The date, time and temperature must be recorded at beginning and end of transport. You should also document temperatures every 30 minutes.

**Coolant:** The CDC recommends use of conditioned frozen water bottles. Frozen water bottles should be prepped in freezer at all times in case of immediate need. Frozen water bottles are conditioned by placing in a sink of lukewarm water until the ice inside the bottle spins freely when rotated in your hand.

**Insulating materials:** Premeasure two pieces of corrugated cardboard and two one-inch layers of bubble wrap or packing foam to place above and below the vaccines in each cooler.



## HOW TO PACK VACCINE

1. Conditioned frozen water bottles should be spread over the bottom of the cooler.
2. Completely cover conditioned frozen water bottles with one sheet of corrugated cardboard.
3. Completely cover cardboard with at least one inch of bubble wrap or packing foam when using conditioned frozen water bottles.
4. Vaccine is placed on top of insulating materials with the refrigerated buffered probe of the monitoring device nestled between the layers of vaccine; the temperature display is placed outside the cooler.
5. Completely cover vaccine with at least one inch of bubble wrap or packing foam.
6. Completely cover bubble wrap with one sheet of corrugated cardboard.
7. An additional layer of conditioned frozen water bottles is added to the cooler.
8. If there is excess space, fill the cooler to the top with packing materials to prevent shift.
9. Close lid and secure the temperature display to the lid of the container.
10. Temperatures between 36.0° F and 46.0° F will be maintained up to eight hours using this method if container is not opened or closed repeatedly.
11. At end of transfer, assure appropriate storage to a refrigerator that has maintained a temperature between 36.0° F and 46.0° F for at least five days.

## Vaccine Transport Inventory Sheet

VFC Provider Site Name: \_\_\_\_\_ Pin #: \_\_\_\_\_

Vaccine packed by: \_\_\_\_\_ Date: \_\_\_\_\_ Time prepared: \_\_\_\_\_

Type of vaccine (Circle one) Frozen / Refrigerated

Are diluents enclosed? (Circle one) Yes / No / NA

Acceptable refrigerator temp: 36.0° to 46.0°F / 2.0°C to 8.0°C

Acceptable freezer temp: - 58.0° to 5.0° F / -50.0° to -15.0°C

Vaccine	Brand name and number of doses				Lot number
DTaP	Daptacel		Infanrix		
DTaP-HepB-IPV	Pediarix				
DTaP-IPV-Hib	Pentacel				
DTaP-IPV	Kinrix		Quadracel		
Hep A-Peds	Havrix		Vaqta		
Hep B	Engerix-B		Recombivax		
Hib	ActHIB		PedvaxHIB	Hiberix	
HPV	Gardasil				
IPV polio	IPV				
MCV4	Menactra		Menveo		
Meningitis	Bexsero		Trumenba		
MMR	MMR				
MMRV	ProQuad				
PCV 13	Pevnar				
Pneumovax 23	PPV 23				
Rotavirus	Rotateq		Rotarix		
Td	Tenivac		Td (Grifols)		
Tdap	Adacel		Boostrix		
Varicella	Varivax				
Other					

Facility accepting vaccine: \_\_\_\_\_

Date received: \_\_\_\_\_ Time received: \_\_\_\_\_

Type of vaccine (Circle one) Frozen / Refrigerated

Are diluents enclosed? (Circle one) Yes / No / NA

The above vaccine has been transported in accordance with CDC guidelines and has been accepted and stored appropriately following transport.

Signature of person storing vaccine: \_\_\_\_\_

Signature of person accepting vaccine: \_\_\_\_\_

## Vaccine Transport Monitoring Sheet

VFC provider site name: \_\_\_\_\_ PIN #: \_\_\_\_\_

Vaccine packed by: \_\_\_\_\_ Date: \_\_\_\_\_ Time prepared: \_\_\_\_\_

Type of vaccine (Circle one.)      Frozen/refrigerated

Are diluents enclosed? (Circle one.)      Yes/No/NA

Is inventory sheet attached? (Circle one.)      Yes/No/NA

Acceptable refrigerator temp:                      36.0° to 46.0°F / 2.0°C to 8.0°C

Acceptable freezer temp:                              - 58.0° to 5.0° F / -50.0° to -15.0°C

<b>Time (Circle one: a.m./p.m.)</b>		<b>Temperature</b>			
<small>**Temperatures should be recorded every 30 minutes.</small>		<small>**Temperatures should be recorded every 30 minutes.</small>			
a.m./p.m.		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
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am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	
am / pm		°C		°F	

Facility accepting vaccine: \_\_\_\_\_

Date received: \_\_\_\_\_ Time received: \_\_\_\_\_

Type of vaccine (Circle one.)      Frozen/refrigerated

Are diluents enclosed? (Circle one.)      Yes/No/NA

Is inventory sheet attached? (Circle one.)      Yes/No/NA

The above vaccine has been transported in accordance with CDC guidelines and has been accepted and stored appropriately following transport.

Signature of person storing vaccine: \_\_\_\_\_

Signature of person accepting vaccine: \_\_\_\_\_

Are these signatures on inventory sheet? (Circle one.) Yes/No/NA

**\*\* Temperatures should be recorded every 30 minutes. This is to ensure that there is no cold chain failure. All vaccine transport sheets must be kept on file for three years and be made available upon request.**

## NIST-CERTIFIED DIGITAL DATA LOGGER MANUFACTURERS

The PA VFC program does NOT recommend or endorse products or manufacturers.  
This list is provided as a courtesy and is not inclusive of all manufacturers.

COMPANY	WEBSITE	PHONE #
Berlinger USA LLC	<a href="http://www.berlinger.com">www.berlinger.com</a>	508-366-0084
Control Solutions	<a href="http://www.vfcdataloggers.com">www.vfcdataloggers.com</a>	888-311-0636
Delta Trak	<a href="http://www.deltatrak.com">www.deltatrak.com</a>	800-962-6776
Dickson	<a href="http://www.dicksondata.com">www.dicksondata.com</a>	800-757-3747
Fisher Healthcare	<a href="http://www.fishersci.com">www.fishersci.com</a>	800-766-7000
Grainger	<a href="http://www.grainger.com">www.grainger.com</a>	800-472-4643
LabRepCo	<a href="http://www.labrepco.com">www.labrepco.com</a>	800-521-0754
Lascar Electronics	<a href="http://www.lascarelectronics.com">www.lascarelectronics.com</a>	814-835-0621
Madgetech	<a href="http://www.madgetech.com">www.madgetech.com</a>	603-456-2011
Onset	<a href="http://www.onsetcomp.com">www.onsetcomp.com</a>	800-564-4377
Sper Scientific	<a href="http://www.sperdirect.com">www.sperdirect.com</a>	480-948-4448
Supply Link Inc.	<a href="https://www.supply-link.co/ddl">https://www.supply-link.co/ddl</a>	740-972-2582
Traceable Products	<a href="http://www.traceable.com">www.traceable.com</a>	281-482-1714
VWR	<a href="http://www.vwrsp.com">www.vwrsp.com</a>	800-932-5000
Weber Scientific	<a href="http://www.weberscientific.com">www.weberscientific.com</a>	800-328-8378



## **Pennsylvania Vaccines for Children (VFC) DIGITAL DATA LOGGER (DDL) POLICY**

PA VFC program recommends the use of continuous temperature monitoring devices/DDLs, which must adhere to the following policy:

### **Continuous Monitoring Devices:**

CDC and PA DOI require the use of a continuous temperature monitoring device for each storage unit. These devices can provide an indication of length of time a unit has been operating outside the recommended vaccine storage temperature (excursion) and when an excursion occurred. Unlike a simple min/max thermometer, which provides only information about warmest and coldest temperatures that were reached, the continuous monitoring device provides detailed information on all temperatures recorded at preset intervals.

### **Temperature Monitoring:**

1. Record time of recording and initials of person taking temperature.
2. Record current, minimum, and maximum temperature on paper temperature log with your VFC PIN number on the form. Blank forms are available in Section 6 Provider Handbook.
3. Record temperatures twice daily (a.m. and p.m.).
4. Take immediate action for out-of-range (OOR) temperatures and document on temperature logs.

### **Data Logger Settings:**

1. If not already preset, alarm limits for min/max temperatures should be:
  - **Refrigerator** min 36.0° F/max 46.0° F (min 2.0° C/max 8.0° C)
  - **Freezer** min -58.0° F/max 5.0° F (min -50.0° C /max -15.0° C)
2. Set recording duration intervals (every 15 minutes is recommended, but intervals of up to every 30 minutes are accepted)

### **Data Storage and Download Requirements:**

1. Weekly downloads from the data logger to a computer file are required to be completed. Once data is downloaded it should be reviewed by staff. This downloaded data should be kept for at least three years and be accessible by staff members.
2. Keep temperature logs for at least three years
  - The PA VFC Program may randomly request this information for Quality Assurance (QA) requirements

## **Digital Data Logger Minimum Requirements:**

1. Capable of displaying current, minimum and maximum temperatures in Fahrenheit or Celsius
2. Must have an active digital display that can be easily read from outside of the unit
3. Must have an alarm for OOR temperatures (recommend both visual and audible)
4. Low battery indicator
5. Accuracy of +/- 1.0° F (+/- 0.5° C)
6. Memory storage of a least 4,000 readings
7. Does not record over old data when log is full
8. User programmable logging interval or reading rate (every 15 minutes is recommended, but up to every 30 minutes is acceptable)
9. Must have user-programmable alarm thresholds
10. Must be able to download data on to either a computer or website
11. Must have current NIST certificate and calibrated per manufacturer's recommendations or at least every two years by an accredited laboratory and include:
  - Name of device (optional)
  - Model number
  - Serial number
  - Date of calibration (report or issue date)
  - Measurement results indicate passing with uncertainty = +/- 1.0° F (0.5° C)
  - Statement that calibration testing conforms to ISO 17025
12. Detachable probe to be encased in a biosafe buffered material
  - Biosafe glycol buffer highly recommended by VFC also, acceptable buffered materials (only if NIST certified):
    - A vial filled with liquid (i.e., glycol, ethanol or glycerin)
    - A vial filled with loose media (i.e., sand or glass beads)
    - A solid block of material (i.e., Teflon® or aluminum)

## **Cold Chain Failure Protocol/Out-of-Range Recordings:**

1. Follow the VFC Cold Chain Failure Policy in Section 4 Provider Handbook.
2. Address the problem.
  - Document reason/action taken on temperature log.
3. Call the manufacturers if greater than 30 minutes OOR; complete incident report.
4. Call the Division of Immunizations directly.
  - Report the incident for further instructions.
  - Phone 1-888-646-6864 and ask for the VFC QA nurse.

## **Maintaining Temperatures and the Cold Chain:**

1. Maintain proper temperature for vaccine storage.
  - Refrigerator: 36.0° to 46.0° Fahrenheit/ 2.0° to 8.0° Celsius
    - Average 40.0° Fahrenheit (5.0° Celsius)
  - Freezer: - 58.0° to 5.0° Fahrenheit/-50.0° to -15.0° Celsius
    - Average 0° Fahrenheit (-18.0° Celsius)
2. Ensure working digital data loggers are used inside both refrigerators and freezers. NIST certified digital data loggers, calibrated per manufacturer's recommendations, are required for vaccine storage. Data logger probes must be placed/secured in the center of each compartment.
3. Manually check and document temperatures twice a day on the temperature log regardless of whether a continuous reading or alarmed units are in use. Daily documentation should include the time when temperatures were checked and initials of staff checking the temperatures.
4. If vaccine temperatures are out of recommended ranges for less than 30 minutes during temperature logging, take immediate action to correct the problem and document the action taken on the temperature log or attach an explanation of action taken.
5. If vaccine temperatures are out of recommended ranges for more than 30 minutes the vaccine manufacturers must be called. Complete and submit the Vaccine Incident Report and Worksheet within five days of incident. Instructions and forms are available in Section 6F Provider Handbook.
6. Providers are responsible for the maintenance and NIST recalibration of all temperature monitoring devices/digital data loggers. Newly purchased units and recalibrations are at the expense of the provider site.
7. Providers are required to maintain paper or electronic versions of digital data logger downloads for three years.

# Pre-Purchase Worksheet for Digital Data Logger

Digital Data Loggers (DDLs) and Continuous Temperature Monitoring Systems (CTMS) are readily available for use in VFC vaccine monitoring. This worksheet should help you learn which unit/system is best for your office. Please refer to section 6-J of the VFC Provider Handbook for a list of suggested manufacturers and the DDL Policy.

Instructions for using this worksheet:

- Write device information in the top portion of each column i.e. Section 1
- Place a checkmark in each column if the DDL meets the requirement
- Checkmark must appear in each column of section 2 to meet PA VFC Program requirements

<b>1. Information About Device</b>			
Vendor Name			
Make/Model number			
Phone number			
Price			
<b>2. PA VFC Requirements</b>			
Capable of displaying current, minimum, and maximum temperatures in Fahrenheit or Celsius			
Must have an active visual temperature display outside of the unit			
Must have an alarm for OOR temperatures (recommend both visual and audible)			
Low battery indicator			
Accuracy of +/- 1.0° F (+/- 0.50° C)			
Memory storage of a least 4,000 readings			
Does not record over old data when log is full			
User programmable logging interval or reading rate (every 15 minutes is recommended; but will accept up to every 30 minutes)			
Must have user-programmable alarm thresholds			
Must be able to download data on to either a computer or website			
Must have current NIST certificate and calibrated per manufacturer's recommendations or at least every two years by an accredited laboratory			
Detachable probe must be encased in a bio safe buffered material			
<b>3. Other Considerations</b>			
Battery life of one year (Lithium preferred)			
Requires software? (IT may need to download)			
Automatic alerts (text, email, phone)			
Buffered probe included (glycol preferred)?			
Return or exchange if DDL malfunctions?			
Detailed and summary reports downloadable and printable?			
Multiple unit purchase discount?			
Buffered probe included?			
NIST Calibration one or two years?			
Single unit capable of monitoring 2 storage units (if close enough and electrical outlet available)?			
Additional accessories required?			
<b>Are you Ready?</b>			
Management or IT authorization needed for software installation?			
Cloud space/account needed for data storage?			
Who will train your staff?			

# BEST PRACTICES IN VACCINE STORAGE

The Pa. Vaccines for Children (VFC) Program does NOT recommend or endorse any products or manufacturers.

## **DOH-supplied vaccine must be stored in one of the following:**

Stand-alone storage units (medical/pharmaceutical grade, highly recommended);  
Household combination unit (refrigerator portion only; must have separate stand-alone freezer); or  
Medical/pharmaceutical grade combination units.

## **All storage units must be approved by the VFC program for enrolled VFC providers.**

Medical/pharmaceutical grade stand-alone freezers and stand-alone refrigerators are strongly recommended for vaccine storage. Dormitory style units are prohibited for storage of VFC vaccine.

DOH-approved household combination units are no longer permitted for new/replacement unit purchases.

If a DOH-approved household combination unit is not accompanied by a stand-alone freezer, providers will be immediately suspended from ordering all VFC vaccines.

Providers will remain suspended until a stand-alone freezer is acquired and approved by VFC.

Any new providers enrolling in the VFC program will be required to use stand-alone refrigerators and stand-alone freezers for vaccine storage. New vaccine storage equipment must be approved by the VFC program through a site visit by the immunization nurse prior to storing vaccine in the unit.

## **The cold storage unit selected must be:**

Dedicated to vaccines only with limited access and locks if possible;

Large enough to accommodate the year's largest inventory;

Capable of maintaining refrigerator temperature of 2.0 to 8.0 degrees C or 36.0 to 46.0 degrees F;

Capable of maintaining freezer temperature of -50.0 to 15.0 degrees C or -58.0 to +5.0 degrees F;

Enough space to store water bottles in the refrigerator to reduce temperature deviations;

Enough space to store frozen water bottles in the freezer to hold temperature;

Capable of housing a calibrated digital data logger accurate to +/- 0.5 degrees C or +/- 1.0-degree F;

Equipped with a calibrated digital display/data logger with probe centrally located in the storage unit;

Capable of accepting baskets and/ or racks to separate vaccine and promote air flow;

Cleaned/defrosted monthly;

Able to rotate inventory on a weekly basis;

Identified in the circuit breaker box; Labelled with do NOT unplug stickers; and

The provider should have maintenance/service contacts established.

### Vaccine Manufacturer/Distributor Contact List

Manufacturer/Distributor Websites	Telephone/E-mail	Products
ACAM2000 Sanofi Pasteur <a href="https://www.sanofi.us/en/products-and-resources/vaccines">https://www.sanofi.us/en/products-and-resources/vaccines</a>	800-822-2463 <a href="http://www.sanofi.us/en/products-and-resources/vaccines">www.sanofi.us/en/products-and-resources/vaccines</a>	Smallpox
bioCSL <a href="https://www.seqirus-us.com/">https://www.seqirus-us.com/</a>	855-358-8966 <a href="mailto:cs.flu@seqirus.com">cs.flu@seqirus.com</a>	IIV cclIV4, aIIIVE
Centers for Disease Control and Prevention <a href="https://www.cdc.gov/ncezid/dsr/index.html">https://www.cdc.gov/ncezid/dsr/index.html</a> <a href="https://www.cdc.gov/laboratory/drugservice/index.html">https://www.cdc.gov/laboratory/drugservice/index.html</a>	404-639-3670 <a href="mailto:drugservice@cdc.gov">drugservice@cdc.gov</a>	Distributor for anthrax vaccine adsorbed (AVA), diphtheria antitoxin, smallpox vaccine
CSL Limited (Merck distributor) <a href="http://www.merckvaccines.com/">www.merckvaccines.com/</a>	800-637-2590	IIV
Emergent BioDefense Operations Lansing, Inc. <a href="http://www.biothrax.com/">http://www.biothrax.com/</a>	877-246-8472 <a href="mailto:productsafety@ebsi.com">productsafety@ebsi.com</a>	Anthrax vaccine adsorbed (AVA)
GlaxoSmithKline (GSK) <a href="http://www.gskvaccines.com/">www.gskvaccines.com/</a>	866-475-8222 <a href="mailto:vaccine.service-center@gsk.com">vaccine.service-center@gsk.com</a>	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, Hib, IIV, JE, MenB-4C, MenACWY-CRM, Rabies, RV1, RZV, Tdap
Massachusetts Biological Labs <a href="https://www.umassmed.edu/massbiologics/">https://www.umassmed.edu/massbiologics/</a>	800-457-4626	Td
AstraZeneca <a href="https://www.astrazeneca.com/">https://www.astrazeneca.com/</a>	800-236-9933	LAIV, RSV

Manufacturer/Distributor Websites	Telephone/E-mail	Products
Merck & Co., Inc. <a href="http://www.Merckvaccines.com">www.Merckvaccines.com</a>	877-829-6372	HepA, HepB, Hib, 9vHPV, ZVL, MMR, MMRV, PPSV23, RV5, VAR
Novartis <a href="https://www.novartis.com/">https://www.novartis.com/</a>	862-778-2100	IIV
PaxVax <a href="https://www.paxvaxconnect.com/vivotif">https://www.paxvaxconnect.com/vivotif</a>	888-483-9053	Cholera (oral) Typhoid (oral)
Pfizer <a href="http://www.pfizer.com/products">http://www.pfizer.com/products</a>	800-438-1985	MenB-FHbp, PCV13
Sanofi Pasteur <a href="https://www.sanofi.us/en/products-and-resources/vaccines">https://www.sanofi.us/en/products-and-resources/vaccines</a>	800-822-2463	DT, DTaP, DTaP-IPV/Hib, DTaP-IPV, Hib, IIV, IPV, MenACWY-D, Rabies, Td, Tdap, Typhoid, YF
Seqirus <a href="http://www.seqirus-us.com/">www.seqirus-us.com/</a>	855-358-8966 <a href="mailto:Customerservice.us@seqirus.com">Customerservice.us@seqirus.com</a>	IIV, ccIIV4, aIIV3
Valneva (Intercell distributor) <a href="https://www.valneva.com/en/">https://www.valneva.com/en/</a>	301-556-4500	Japanese Encephalitis, Cholera

## **Vaccine Coordinator roles and responsibilities**

**Designate a person to be the primary vaccine coordinator for your facility.** This person will be responsible for ensuring all vaccines are stored and handled correctly. Appoint a second staff member to serve as an alternate in the absence of the primary coordinator (this is particularly important in case of after-hours emergencies). Both coordinators should be fully trained in routine and emergency policies and procedures.

Coordinator responsibilities:

- Ordering vaccines
- Overseeing proper receipt and storage of vaccine deliveries
- Documenting vaccine inventory information and organizing vaccines within storage units
- Setting up temperature monitoring devices
- Reading and recording storage unit temps a minimum of two times each workday
- Reading and recording current minimum/maximum temps from a digital data logger two times each workday
- Reviewing and analyzing temperature data at least weekly for any shifts in temperature trends
- Rotating stock at least weekly so vaccine with the earliest expiration dates are used first
- Removing expired vaccine from storage units
- Responding to out-of-range temperatures (temp excursion)
- Maintaining all documentation, such as inventory and temperature logs
- Ensuring staff is properly trained
- Monitoring operation of storage equipment and systems
- Overseeing proper vaccine transport (when necessary)
- Overseeing emergency preparations, including plans for ensuring safety of vaccine during emergencies
- Tracking inclement weather conditions
- Ensuring appropriate handling of vaccines during disaster or power outage.

### **Staff Training**

All staff members who receive deliveries and/or handle or administer vaccines should be familiar with storage and handling policies and procedures at your facility. Keep standard operating procedures for storage and handling near storage units and make sure staff knows where to find them.

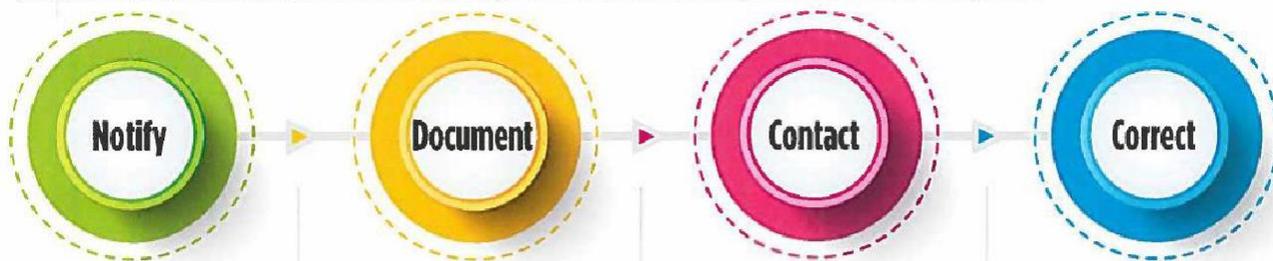
CDC recommends that storage and handling training should be done:

- As part of new employee orientation;
- Annually as a refresher for all staff involved in immunization activities;
- Whenever new vaccines are added to inventory; and
- Whenever recommendations are updated.

**The coordinator will also maintain the Vaccines for Children email ([RA-PAVFC@pa.gov](mailto:RA-PAVFC@pa.gov)) on your safe senders list to ensure you receive the important communications from the VFC program.**

## Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



- » Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.
- » Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

- » Document details of the temperature excursion:
  - Date and time
  - Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
  - Room temperature, if available
  - Name of the person completing the report
  - General description of the event (i.e., what happened)
  - If using a digital data logger (DDL), determine the length of time vaccine may have been affected
  - Inventory of affected vaccines
  - List of items in the unit other than vaccines (including water bottles)
  - Any problems with the storage unit and/or affected vaccines before the event
  - Other relevant information

- » Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
- » Be prepared to provide the manufacturer or immunization program with documentation and DDL data so they can offer you the best guidance.

### Contact manufacturer for excursions:

<b>Merck</b>	1-800-672-6372
<b>Sanofi Pasteur</b>	1-800-822-2463
<b>GlaxoSmithKline</b>	1-888-825-5249
<b>Pfizer</b>	1-800-438-1985
<b>Seqirus</b>	1-855-358-8966

- » If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- » Check the basics, including:
  - Power supply
  - Unit door(s)
  - Thermostat settings
- » If the excursion was the result of a temperature fluctuation, refer to the chapter, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's *Vaccine Storage and Handling Toolkit* for detailed guidance on adjusting storage unit temperature to the appropriate range.
- » If you believe the storage unit has failed, implement your emergency vaccine SOPs. Never allow vaccines to remain in a nonfunctioning unit.



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention

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## COLD STORAGE UNIT MANUFACTURERS

The following are some Manufacturers of freezers and refrigerators suggestions for vaccine storage. This list is not exhaustive and is intended for reference only.

**Please notify your immunization nurse consultant prior to purchasing your desired make/model.** The nurse will let you know if the chosen model is acceptable for VFC vaccine storage. Once you receive your new unit, one week of stable temperature logs should be faxed or emailed to your immunization nurse consultant. A visit to approve the unit can then be scheduled.

Per CDC commissioned studies by the National Institute of Standards & Technology (NIST) household style single compressor combination refrigerator/freezer units have less capability to simultaneously maintain proper storage temperatures in the refrigerator & freezer because of the chilled air being diverted from freezer to refrigerator compartment. Separate units decrease the risk of freezing refrigerated vaccine.

Storage unit recommended features:

- Adjustable wire shelves
- Locks on outside door
- Digital thermostat controls
- Forced air circulation
- Door ajar alarm
- Port for external temperature probe wire
- Glass doors offer the ability to view inventory without opening the door but lose temperature quicker in the event of a power outage; this requires emergency vaccine plan consideration.

Aegis	<a href="http://www.aegisfridge.com">www.aegisfridge.com</a>	1-800-796-2344
American BioTech Supply	<a href="https://www.americanbiotechsupply.com/">https://www.americanbiotechsupply.com/</a>	1-800-648-4041
Fisher Scientific	<a href="http://www.fishersci.com">www.fishersci.com</a>	1-800-640-0640
Follett	<a href="http://www.follettice.com">www.follettice.com</a>	1-800-523-9361
Geneva Scientific	<a href="http://www.Geneva-Scientific.com">www.Geneva-Scientific.com</a>	1-877-436-3827
Haier (not all models acceptable)	<a href="http://www.haier.com">www.haier.com</a>	1-877-337-3639
Helmar	<a href="http://www.helmerinc.com">www.helmerinc.com</a>	1-800-743-5637
LAB RepCo	<a href="http://www.labrepco.com">www.labrepco.com</a>	1-800-521-0754
Migali Scientific	<a href="http://www.migaliscientific.com">www.migaliscientific.com</a>	1-855-464-4254
Minibar RX	<a href="http://minibarrx.com/">http://minibarrx.com/</a>	1-215-583-3022
Panasonic purchased Sanyo	<a href="https://www.phchd.com/us/biomedical/">https://www.phchd.com/us/biomedical/</a>	1-800-858-8442
Sears (not all models acceptable)	<a href="http://www.sears.com">www.sears.com</a>	1-800-349-4358
Summit	<a href="http://www.summitmedicalrefrigerators.com">www.summitmedicalrefrigerators.com</a>	1-718-893-3900
Sun Frost	<a href="http://www.sunfrost.com">www.sunfrost.com</a>	1-707-822-9095
Thermo Scientific	<a href="http://www.thermoscientific.com">www.thermoscientific.com</a>	1-800-556-2323

# 1/2 AA 3.6V Lithium Battery Suppliers

The PA VFC program does NOT recommend or endorse products or manufacturers. This list is provided as a courtesy and is not inclusive of all manufacturers.

Lithium batteries are used for different types of digital data loggers. The cost for each battery varies depending on the supplier. Batteries should last for approximately one year. It is recommended to have a spare battery available if a new battery is needed in your data logger.

Amazon	<a href="http://www.amazon.com">www.amazon.com</a>	1-888-280-4331
AtBatt	<a href="http://www.atbatt.com">www.atbatt.com</a>	1-877-528-2288
Control Solutions	<a href="http://www.vfcdataloggers.com">www.vfcdataloggers.com</a>	1-503-410-5996
Supply Link, Inc.	<a href="mailto:supply-link@hotmail.com">supply-link@hotmail.com</a>	1-614-565-2084
Lascar Electronics	<a href="http://www.lascarelectronics.com">www.lascarelectronics.com</a>	1-814-835-0621
RadioShack	<a href="http://www.radioshack.com">www.radioshack.com</a>	1-800-843-7422
Walmart	<a href="http://www.walmart.com">www.walmart.com</a>	1-800-925-6278

Examples of common batteries:



## RESOURCES AND WEBSITES

RESOURCE	TELEPHONE #	FAX #	WEBSITE
Division of Immunizations (DOI)	<p style="text-align: center;">717-787-5681</p> <p style="text-align: center;"><u>Toll Free</u> 1-888-646-6864</p>	<p style="text-align: center;">DOI office 717-214-7223</p> <p style="text-align: center;">Vaccine orders 717-441-3800</p>	<p style="text-align: center;">General E-Mail Account: <a href="mailto:PAIMMUNIZATIONS@PA.GOV">PAIMMUNIZATIONS@PA.GOV</a></p>
Pa. Department of Health	1-877-PAHEALTH		<a href="http://WWW.HEALTH.PA.GOV">WWW.HEALTH.PA.GOV</a>
Centers for Disease Control and Prevention (CDC)	1-800-232-2522		<a href="http://www.cdc.gov/vaccines/">http://www.cdc.gov/vaccines/</a>
Vaccine Adverse Event Reporting System (VAERS)	1-800-822-7967		<a href="http://vaers.hhs.gov/index">http://vaers.hhs.gov/index</a>
Statewide Immunization Information System	1-717-783-2548		<a href="http://www.health.pa.gov">www.health.pa.gov</a>
Pa. Department of Human Services			<a href="http://WWW.DHS.PA.GOV">WWW.DHS.PA.GOV</a>

RESOURCE	TELEPHONE #	FAX #	WEBSITE
GlaxoSmithKline (Novartis)	1-866-475-8222	215-599-9179	<a href="https://us.gsk.com/en-us/products/our-vaccines/">https://us.gsk.com/en-us/products/our-vaccines/</a>
Merck & Co., Inc.	1-877-829-6372		<a href="http://WWW.MERCKVACCINES.COM">WWW.MERCKVACCINES.COM</a>
Pfizer	1-800-438-1985		<a href="http://www.pfizer.com/products">http://www.pfizer.com/products</a>
Sanofi Pasteur	1-800-822-2463		<a href="https://www.sanofi.us/en/products-and-resources/vaccines">https://www.sanofi.us/en/products-and-resources/vaccines</a>
Seqirus	1-855-358-8966		<a href="https://www.seqirus-us.com/">https://www.seqirus-us.com/</a>
Advisory Committee on Immunization Practices			<a href="https://www.cdc.gov/vaccines/acip/index.html">https://www.cdc.gov/vaccines/acip/index.html</a>
American Academy of Pediatrics			<a href="http://WWW.AAP.ORG">WWW.AAP.ORG</a>
Immunization Action Coalition			<a href="http://WWW.IMMUNIZE.ORG">WWW.IMMUNIZE.ORG</a>

RESOURCE	TELEPHONE #	FAX #	WEBSITE
American Academy of Family Physicians			<a href="http://WWW.AAFP.ORG">WWW.AAFP.ORG</a>
General Recommendations on Immunizations			<a href="http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf">http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf</a>
Guide to Contraindications to Vaccinations			<a href="http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm">http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm</a>
VFC-ACIP Vaccine Resolutions			<a href="https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html">https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html</a>
VFC Provider Handbook			<a href="https://www.health.pa.gov/topics/programs/immunizations/Pages/VFC.aspx">https://www.health.pa.gov/topics/programs/immunizations/Pages/VFC.aspx</a>



## Documenting Parental Refusal to Have Their Children Vaccinated

345 Park Blvd  
Itasca, IL 60143  
Phone: 630/626-6000  
Fax: 847/434-8000  
E-mail: kidsdocs@aap.org  
www.aap.org

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All parents and patients should be informed about the risks and benefits of preventive and therapeutic procedures, including vaccination. In the case of vaccination, the American Academy of Pediatrics (AAP) strongly recommends and federal law mandates that this discussion include the provision of the Vaccine Information Statements (VISs). Despite our best efforts to educate parents about the effectiveness of vaccines and the realistic chances of vaccine-associated adverse events, some will decline to have their children vaccinated. This often results from families misinterpreting or misunderstanding information presented by the media and on unmonitored and biased Web sites, causing substantial and often unrealistic fears.

Within a 12-month period, 74% of pediatricians report encountering a parent who refused or delayed one or more vaccines. A 2011 survey of children six months to six years of age reported that 13% of parents followed an alternative vaccination schedule. Of these, 53% refused certain vaccines and 55% delayed some vaccines until the child was older. Seventeen percent reported refusing all vaccines. In a 2009 survey, 11.5% of parents of children 17 years and younger reported refusing at least one vaccine. The use of this or a similar form in concert with direct and non-condescending discussion can demonstrate the importance you place on appropriate immunizations, focuses parents' attention on the unnecessary risk for which they are accepting responsibility, and may in some instances induce a wavering parent to accept your recommendations.

Providing parents (or guardians) with an opportunity to ask questions about their concerns regarding recommended childhood immunizations, attempting to understand parents' reasons for refusing one or more vaccines, and maintaining a supportive relationship with the family are all part of a good risk management strategy. The AAP encourages documentation of the health care provider's discussion with parents about the serious risks of what could happen to an unimmunized or under-immunized child. Provide parents with the appropriate VIS for each vaccine at each immunization visit and answer their questions. For parents who refuse one or more recommended immunizations, document your conversation and the provision of the VIS(s), have a parent sign the Refusal to Vaccinate form, and keep the form in the patient's medical record. The AAP also recommends that you revisit the immunization discussion at each subsequent appointment and carefully document the discussion, including the benefits to each immunization and the risk of not being age-appropriately immunized. For unimmunized or partially immunized children, some physicians may want to flag the chart to be reminded to revisit the immunization discussion, as well as to alert the provider about missed immunizations when considering the evaluation of future illness, especially young children with fevers of unknown origin.

This form may be used as a template to document that the health care provider had a discussion with the parent signing the form about the risks of failing to immunize the child. It is not intended as a substitute for legal advice from a qualified attorney as differing state laws and factual circumstances will impact the outcome. While it may be modified to reflect the particular circumstances of a patient, family, or medical practice, practices may want to consider obtaining advice from a qualified attorney. If a parent refuses to sign the refusal form such refusal along with the name of a witness to the refusal should be documented in the medical record.

The AAP Section on Infectious Diseases and other contributing sections and committees hope this form will be helpful to you as you deal with parents who refuse immunizations. It is available on the AAP Web site on the Section on Infectious Diseases Web site (<http://www2.aap.org/sections/infectdis/resources.cfm>), and the Web site for the AAP Childhood Immunization Support Program (<http://www2.aap.org/immunization/pediatricians/refusaltovaccinate.html>).

Sincerely,

/s/

Tina Tan, MD, FAAP

Chairperson

AAP Section on Infectious Diseases

/s/

Ed Rothstein, MD, FAAP

AAP Section on Infectious Diseases

## Refusal to Vaccinate

Child's Name \_\_\_\_\_ Child's ID# \_\_\_\_\_

Parent's/Guardian's Name \_\_\_\_\_

My child's doctor/nurse, \_\_\_\_\_ has advised me that my child (named above) should receive the following vaccines:

Recommended	Declined
<input type="checkbox"/> Hepatitis B vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria tetanus (DT or Td) vaccine	<input type="checkbox"/>
<input type="checkbox"/> <i>Haemophilus influenzae</i> type b (Hib) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Pneumococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Inactivated poliovirus (IPV) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Measles-mumps-rubella (MMR) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Varicella (chickenpox) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Influenza (flu) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Meningococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Hepatitis A vaccine	<input type="checkbox"/>
<input type="checkbox"/> Rotavirus vaccine	<input type="checkbox"/>
<input type="checkbox"/> Human papillomavirus (HPV) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Other _____	<input type="checkbox"/>

- That some vaccine-preventable diseases are common in other countries and that my unvaccinated child could easily get one of these diseases while traveling or from a traveler.
- If my child does not receive the vaccine(s) according to the medically accepted schedule, the consequences may include
  - Contracting the illness the vaccine is designed to prevent (the outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness requiring hospitalization, death, brain damage, paralysis, meningitis, seizures, and deafness; other severe and permanent effects from these vaccine-preventable diseases are possible as well).
  - Transmitting the disease to others (including those too young to be vaccinated or those with immune problems), possibly requiring my child to stay out of child care or school and requiring someone to miss work to stay home with my child during disease outbreaks.
- My child's doctor and the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all strongly recommend that the vaccine(s) be given according to recommendations.

Nevertheless, I have decided at this time to decline or defer the vaccine(s) recommended for my child, as indicated above, by checking the appropriate box under the column titled "Declined." I know that failure to follow the recommendations about vaccination may endanger the health or life of my child and others with whom my child might come into contact. I therefore agree to tell all health care professionals in all settings what vaccines my child has not received because he or she may need to be isolated or may require immediate medical evaluation and tests that might not be necessary if my child had been vaccinated.

I know that I may readdress this issue with my child's doctor or nurse at any time and that I may change my mind and accept vaccination for my child any time in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

I have been provided with and given the opportunity to read each Vaccine Information Statement from the Centers for Disease Control and Prevention explaining the vaccine(s) and the disease(s) it prevents for each of the vaccine(s) checked as recommended and which I have declined, as indicated above. I have had the opportunity to discuss the recommendation and my refusal with my child's doctor or nurse, who has answered all of my questions about the recommended vaccine(s). A list of reasons for vaccinating, possible health consequences of non-vaccination, and possible side effects of each vaccine is available at [www.cdc.gov/vaccines/pubs/vis/default.htm](http://www.cdc.gov/vaccines/pubs/vis/default.htm). I understand the following:

- The purpose of and the need for the recommended vaccine(s).
- The risks and benefits of the recommended vaccine(s).

Parent/Guardian Signature: _____	Date: _____
Witness: _____	Date: _____
I have had the opportunity to rediscuss my decision not to vaccinate my child and still decline the recommended immunizations.	
Parent's Initials: _____	Date: _____
Parent's Initials: _____	Date: _____



### Parental Refusal to Accept Vaccination: Resources for Pediatricians

The following are some of the resources available to help pediatricians develop a productive dialogue with vaccine-hesitant parents and answer questions about vaccine risks and benefits:

#### Web Sites

1. **AAP Childhood Immunization Support Program (CISP)**  
Information for providers and parents.  
[www.aap.org/immunization](http://www.aap.org/immunization)  
[www2.aap.org/immunization/pediatricians/refusaltovaccinate.html](http://www2.aap.org/immunization/pediatricians/refusaltovaccinate.html)
2. **Immunization Action Coalition (IAC)**  
The IAC works to increase immunization rates by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. The IAC "Unprotected People Reports" are case reports, personal testimonies, and newspaper and journal articles about people who have suffered or died from vaccine-preventable diseases.  
[www.immunize.org/reports](http://www.immunize.org/reports)
3. **Centers for Disease Control and Prevention (CDC) National Immunization Program**  
Information about vaccine safety.  
[www.cdc.gov/vaccines/hcp.htm](http://www.cdc.gov/vaccines/hcp.htm)
4. **National Network for Immunization Information (NNii)**  
Includes information to help answer patients' questions and provide the facts about immunizations.  
<http://www.immunizationinfo.org/professionals>
5. **Vaccine Education Center at Children's Hospital of Philadelphia**  
Information for parents includes "Vaccine Safety FAQs" and "A Look at Each Vaccine."  
[www.vaccine.chop.edu](http://www.vaccine.chop.edu)
6. **Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health**  
Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.  
[www.vaccinesafety.edu](http://www.vaccinesafety.edu)
7. **Immunize Canada**  
Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.  
[www.immunize.cpha.ca/en/default.aspx](http://www.immunize.cpha.ca/en/default.aspx)
8. **Sample office policy/letter to parents about refusal to vaccinate**

#### Journal Articles

1. Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003;112(6 Pt 1):1394-1397
2. Offit PA, Quarles J, Gerber MA, et al. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109(1):124-129
3. Diekema DS, American Academy of Pediatrics Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115(5):1428-1431

#### Books

1. American Academy of Pediatrics. *Red Book: 2012 Report of the Committee on Infectious Diseases*. Pickering LK, Baker CJ, Long SS, Kimberlin DW, eds. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012
2. Marshall GS. *The Vaccine Handbook: A Practical Guide for Clinicians*. 5th ed. West Islip, NY: Professional Communications, Inc; 2015

#### Handout

1. Immunization Action Coalition. Reliable sources of immunization information: where to go to find answers! <http://www.immunize.org/catg.d/p4012.pdf>. Accessed October 17, 2012

### Reliable Immunization Resources for Parents

#### Web Sites

1. **Centers for Disease Control and Prevention (CDC) Vaccine Information Statements**  
Provide possible health consequences of non-vaccination and possible side effects of each vaccine.  
[www.cdc.gov/vaccines/pubs/vis/default.htm](http://www.cdc.gov/vaccines/pubs/vis/default.htm)
2. **AAP Childhood Immunization Support Program (CISP)**  
Information for providers and parents.  
[www.aap.org/immunization](http://www.aap.org/immunization)
3. **Why Immunize?**  
A description of the individual diseases and the benefits expected from vaccination.  
[www2.aap.org/immunization/families/faq/whyimmunize.pdf](http://www2.aap.org/immunization/families/faq/whyimmunize.pdf)
4. **Pennsylvania Immunization Education Program of Pennsylvania Chapter, AAP**  
Includes answers to common vaccine questions and topics, such as addressing vaccine safety concerns; evaluating anti-vaccine claims; sources of accurate immunization information on the Web; and talking with parents about vaccine safety.  
[www.paiep.org](http://www.paiep.org)
5. **CDC For Parents: Vaccines for Your Children**  
Information about vaccine safety.  
[www.cdc.gov/vaccines/parents/index.html](http://www.cdc.gov/vaccines/parents/index.html)
6. **National Network for Immunization Information (NNii)**  
Includes information to help answer patients' questions and provide the facts about immunizations.  
[www.immunizationinfo.org/parents](http://www.immunizationinfo.org/parents)
7. **Vaccine Education Center at Children's Hospital of Philadelphia**  
Information for parents includes "Vaccine Safety FAQs" and "A Look at Each Vaccine."  
[www.vaccine.chop.edu](http://www.vaccine.chop.edu)
8. **Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health**  
Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.  
[www.vaccinesafety.edu](http://www.vaccinesafety.edu)
9. **Immunize Canada**  
Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.  
<http://immunize.cpha.ca/en/default.aspx>
10. **Vaccinate Your Baby**  
This Every Child By Two site serves as a central resource of vaccine information for parents. The site links to the latest research and studies about vaccines, an interactive timeline on the benefits of vaccines, information about vaccine safety and ingredients, and the importance of adhering to the recommended schedule.  
[www.vaccinateyourbaby.org](http://www.vaccinateyourbaby.org)

#### Books

1. American Academy of Pediatrics. *Immunizations and Infectious Diseases: An Informed Parent's Guide*. Fisher MC, ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006
2. Myers MG, Pineda D. *Do Vaccines Cause That?! A Guide for Evaluating Vaccine Safety Concerns*. Galveston, TX: Immunizations for Public Health; 2008
3. Offit PA. *Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure*. New York, NY: Columbia University Press; 2008
4. Offit PA. *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*. New York, NY: Basic Books; 2011
5. Mnookin S. *The Panic Virus: A True Story of Medicine, Science, and Fear*. New York, NY: Simon and Schuster; 2011
6. Offit PA, Moser CA. *Vaccines and Your Child: Separating Fact from Fiction*. New York, NY: Columbia University Press; 2011

# ACRONYMS

<b>AAFP</b>	American Academy of Family Physicians
<b>AAP</b>	American Academy of Pediatrics
<b>ACIP</b>	Advisory Committee on Immunization Practices <a href="https://www.cdc.gov/vaccines/acip/index.html">https://www.cdc.gov/vaccines/acip/index.html</a>
<b>AFIX</b>	Assessment, Feedback, Incentives, & Exchange
<b>AIM</b>	<a href="#">Association of Immunization Managers</a>
<b>AMA</b>	American Medical Association
<b>AOA</b>	American Osteopathic Association
<b>ASTHO</b>	Association of State and Territorial Health Officials
<b>BPHC</b>	Bureau of Primary Health Care
<b>CoCASA</b>	Comprehensive Clinic Assessment Software Application <a href="https://www.cdc.gov/vaccines/programs/cocasa/index.html">https://www.cdc.gov/vaccines/programs/cocasa/index.html</a>
<b>CCF</b>	Cold Chain Failure
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CHIP</b>	Children's Health Insurance Program
<b>CII</b>	(The President's) Childhood Immunization Initiative
<b>CMS</b>	Centers for Medicare and Medicaid Services
<b>CPT</b>	Current Procedural Terminology
<b>DDL</b>	Digital Data Logger
<b>DOI</b>	Division of Immunizations
<b>DT</b>	Diphtheria and Tetanus Toxoids
<b>DTaP</b>	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine
<b>DTP</b>	Diphtheria, Tetanus and Pertussis Vaccine
<b>DTP/Hib</b>	Diphtheria, Tetanus, Pertussis, and Haemophilus influenzae type B
<b>E-IPV</b>	Enhanced-Inactivated Polio Vaccine
<b>EPSDT</b>	Early and Periodic Screening Diagnostic, and Treatment
<b>FDA</b>	Food and Drug Administration
<b>Fed-Ex</b>	Federal Express
<b>FFS</b>	Fee-for-Service

<b>FMO</b>	Financial Management Office
<b>FQHC</b>	Federally Qualified Health Center <a href="https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html#fqhc">https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html#fqhc</a>
<b>HEDIS</b>	Healthcare Effectiveness Data Information Set
<b>Hep B</b>	Hepatitis B Vaccine
<b>Hib</b>	<i>Haemophilus influenzae</i> type B vaccine
<b>HMO</b>	Health Maintenance Organization
<b>HPV</b>	Human Papillomavirus
<b>HRSA</b>	Health Resources and Services Administration
<b>IHS</b>	Indian Health Services
<b>IIS</b>	Immunization Information Systems
<b>ILAC</b>	International Laboratory Accreditation Cooperation
<b>IQIP</b>	Immunization Quality Improvement for Providers
<b>IR</b>	Incident report
<b>LQA</b>	Lot Quality Assurance
<b>MA</b>	Medical Assistance
<b>MCH</b>	Maternal and Child Health programs
<b>MCV4</b>	Meningococcal Conjugate Vaccines
<b>MMR</b>	Measles, Mumps, and Rubella Vaccine
<b>MOA</b>	Memorandum of agreement
<b>NDC</b>	National Drug Code
<b>NIST</b>	National Institute of Standards and Technology
<b>NVPO</b>	<a href="#">National Vaccine Program Office</a>
<b>OBRA</b>	Omnibus Budget Reconciliation Act
<b>OOR</b>	Out-of-range
<b>PA DHS</b>	Pennsylvania Department of Human Services
<b>PA DOH</b>	Pennsylvania Department of Health
<b>PA-SIIS</b>	Pennsylvania Statewide Immunization Information System
<b>PA VFC</b>	<a href="#">Pennsylvania Vaccines for Children</a>
<b>PA VFC PPA</b>	Pennsylvania Vaccines for Children Participating Provider Agreement
<b>PCV-13</b>	Pneumococcal Conjugate Vaccine (13 valent)
<b>PHS</b>	Public Health Service

<b>PIN</b>	Provider Identification Number
<b>PPO</b>	Preferred Provider Organizations
<b>PPV-23</b>	Pneumococcal Polysaccharide Vaccine (23 valent)
<b>RHC</b>	Rural Health Clinic <a href="https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html#rhc">https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html#rhc</a>
<b>Td</b>	Tetanus and Diphtheria Toxoids
<b>Tdap</b>	Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis
<b>UPS</b>	United Parcel Service
<b>VACMAN</b>	Vaccine Management software
<b>VAERS</b>	Vaccine Adverse Event Reporting System
<b>VICP</b>	National Vaccine Injury Compensation Program
<b>VTrckS</b>	Vaccine Tracking System <a href="https://www.cdc.gov/vaccines/programs/vtrcks/index.html">https://www.cdc.gov/vaccines/programs/vtrcks/index.html</a>
<b>WIC</b>	Women, Infants and Children program