

Welcome to the Pennsylvania Vaccines for Children Program

<p style="text-align: center;">How to Contact Us:</p> <p>Pennsylvania Department of Health (PADOH) Division of Immunizations 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: paimmunizations@pa.gov Website link : http://www.health.state.pa.us/vfc</p>	<p style="text-align: center;">Provider Information</p> <p>Provider Identification Number (PIN)</p> <p>PIN</p> <p>(contact) (last name) (address) (address 2) (city) (state) (zip code)</p>
--	--

DISTRICT/COUNTY IMMUNIZATION NURSES

Northeast District # 1	Southeast District # 2	Northcentral District # 3
570-826-2062	610-378-4352	570-327-3400
Carbon, Lackawanna, Lehigh, Luzerne, Monroe, Northampton, Pike, Susquehanna, Wayne, Wyoming	Berks, Chester, Delaware, Lancaster, Schuylkill	Bradford, Centre, Clinton, Columbia, Lycoming, Montour, Northumberland, Potter, Snyder, Sullivan, Tioga, Union

Southcentral District # 4	Northwest District # 5	Southwest District # 6
717-787-8092	724-662-6068	724-830-2701
Adams, Bedford, Blair, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lebanon, Mifflin, Perry, York	Cameron, Clarion, Clearfield, Crawford, Elk, Forest, Jefferson, Lawrence, McKean, Mercer, Venango, Warren	Armstrong, Beaver, Butler, Cambria, Fayette, Greene, Indiana, Somerset, Washington, Westmoreland

ALLEGHENY COUNTY	412-578-7973
BUCKS COUNTY	215-345-3535
ERIE COUNTY	814-451-6788
MONTGOMERY COUNTY	610-278-5117

PHILADELPHIA IMMUNIZATION PROGRAM 215-685-6498

**PA STATEWIDE IMMUNIZATION INFORMATION SYSTEM (PA-SIIS)
877-774-4748**

VFC Provider Handbook 2016 Revisions

Table of Contents; updated to reflect changes

Welcome Letter; updated to reflect current phone numbers

Section 1

Page 1-2 Updated eligibility table

Added wording in charges and fees paragraph

Section 2

Page 2-3 Added wording “and may lead to disenrollment”

Page 2-5 Added wording under Notify PADOH regarding “Change in medical director/primary physician”

Page 2-5 Added wording under Twice-daily temperature documentation “on temperature log”

Section 3

Page 3-1 to 3-2 Added wording under Vaccines Available Through the Pa. VFC program “Meningococcal B”

Page 3-2 Changed number of vaccines to “10”

Page 3-3 Deleted Novartis and Added “GlaxoSmithKline”

Page 3-3 Added wording under Prior to placing a vaccine order “Accept previous shipments into PA-SIIS”

Page 3-4 Added wording under Returning Vaccines “When requesting a shipping label for the return of vaccines please allow one to five business days to receive notification.”

Section 4

Page 4-1 Deleted “Effective January 1, 2015, all” and “refrigerator portion of”

Page 4-2 Added last bullet under Pa. VFC requirements “Effective 2017”

Page 4-2 Added bullet under CDC requirements “Effective 2016 all vaccines stored in a dormitory style unit are considered non-viable”

Page 4-4 Updated wording under Certified Digital Thermometers

Page 4-5 Updated wording under Certified Digital Thermometers

Page 4-6 Added wording “Do not use multi-outlet power strips” and updated pictures

Page 4-7 Changed glycol to “buffered”

Page 4-7 Added wording “Or if you choose one of the following options below, it must be completed and faxed prior to October 1, 2016:”

Page 4-8 Updated CDC training links

Moved “View the video “Keys to Storing and Handling Your Vaccine Supply” information to Section 2

Page 4-8 Added wording under Clearly Written Procedures “twice daily documentation” and “the alternate site is still available and will adhere to Pa. VFC program requirements”

Page 4-11 Updated wording under Vaccine Ordering/Delivery/Receiving/Storing for Merck’s shipping times and added new pictures

Page 4-12 Added wording under Receiving the vaccine “Vaccine shipments must be accepted into PA-SIIS inventory.”

Page 4-13 Added two bullets under Vaccines must

Page 4-16 Added wording under Temperature log requirements “(current, minimum, and maximum)

Page 4-16 Added first bullet under Key points

Page 4-16 Added wording in fifth bullet “temperatures documents twice daily”

Page 4-18 Added wording under Transporting vaccine “(vials/syringes must remain in original packaging)”

Page 4-19 Updated wording under Expired and wasted vaccines and updated pictures

Page 4-20 Changed wording from 15-30 minutes to “within one to three hours”

Page 4-20 Updated wording under Sample of email message

Page 4-20 Added wording “Providers will be informed of saved/wasted vaccine doses and cost with every incident report.”

Section 6

6D – Added Meningococcal B to order form

6E – Updated Vaccine Emergency Handling Procedures and Disaster Recovery Plan

6F – Updated Vaccine Incident Report and Worksheet Forms

6H – Updated Temperature Logs

6J – Updated Digital Data Logger policy

6J – Updated contact information to NIST Certified Thermometer/Data Logger
Manufacturers

Table of Contents

Introduction

VFC Eligibility Section 1

Patient Eligibility Screening

Insured Children

Charges and Fees for Immunization of the VFC-Eligible Clients

Provider Enrollment/Requirements/Responsibilities Section 2

New Provider Enrollment

Provider Requirements

Provider Annual Enrollment Update

Pa. VFC site visits

 VFC compliance site visit

 AFIX site visit

 Follow-up site visit

 Annual provider training visit

 Unannounced storage and handling visit

Provider Responsibilities

 Notifying PADOH

 Staff training

 Developing and maintaining written procedures

 Twice-daily temperature documentation

 Vaccine storage and handling

Withdrawing from the VFC Program

Fraud Waste and Abuse

Vaccine Management, Ordering and Returning.....Section 3

Management

Vaccines Available Through the Pa. VFC Program

Vaccine Ordering

 Prior to placing a vaccine order

 Placing a vaccine order

 No internet access sites

Shipment of Order

Returning Vaccines

Vaccine Storage and Handling.....Section 4

Properly Functioning Equipment

- Vaccine storage units
- Certified digital thermometers
- Setting up your new equipment

Appropriately Trained Staff

- Designate primary and back-up contact persons
- Training your personnel

Clearly Written Procedures

Vaccine Ordering/Delivery/Receiving/Storing

- Ordering the vaccine
- Delivery of the vaccine shipment
- Receiving the vaccine
- Storing the vaccine

Documentation Requirements

- Temperature log requirements
- Maintaining your inventory
- Vaccine accountability
- Vaccine borrowing
- Transporting vaccine
- Expired and wasted vaccines

Vaccine Adverse Event Reporting System (VAERS)

Vaccine Cold Chain Failure

- Suspected vaccine cold chain failure – Required procedures for providers
- Confirmed vaccine cold chain failure – Required procedures for providers

PA-Statewide Immunization Information SystemSection 5

PA-SIIS

PA-SIIS User Log on Credentials

Log into PA-SIIS

Online Ordering

Training Manual

Initial PA-SIIS User Set-Up

Forms/Plans/ResourcesSection 6

Education Roster.....6-A

Enrollment in the Vaccines for Children Program6-B

- Instructions for completing the 2016 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
PADOH Supplied Vaccine Order, Inventory, and Accountability Form	
Pa. VFC Borrowing Report	
Pa. VFC Dose Tracking Form	
Required Plans	6-E
Vaccine Emergency handling procedures and disaster recovery plan	
Pa. VFC vaccine management plan	
Required Reporting	6-F
Vaccine Incident Report and Worksheet instructions	
Vaccine Incident Report and Worksheet	
Vaccine Return and Accountability Form	
Interim/Final Status Report (Revaccination form)	
Vaccine Adverse Event Reporting System (VAERS)	
Storage and Handling	6-G
Vaccine storage maintenance reminder	
Temperatures and Monitoring	6-H
Celsius and Fahrenheit Conversion Chart	
Recording freezer temperatures	
Freezer Fahrenheit and Celsius Temperature Log Form	
Recording refrigerator temperatures	
Refrigerator Fahrenheit and Celsius Temperature Log Form	
Transporting Vaccines	6-I
Transporting frozen vaccines	
Transporting refrigerated vaccines	
Vaccine Transport Hourly Monitoring Form and Inventory Sheet	
Best Practices and Resources	6-J
NIST certified thermometer/data logger manufacturers	
Pa. VFC digital data logger (DDL) policy	
Best practices in vaccine storage	
Cold storage unit manufacturers	
Lithium battery suppliers	
Resources and websites	
Acronyms	

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, 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 August 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 October 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 of Immunizations and Respiratory Disease (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 (PADOH), 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 the child is eligible for VFC vaccine and document findings (Section 6-C).

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

- Are enrolled in Medicaid; or
- Have no health insurance; or
- Are American Indian or Alaska Native; or
- Are underinsured. This includes a child who has health insurance, but the coverage does not include vaccines or 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 a state health center (SHC) under an approved deputization agreement.*

* The formal extension of VFC authority through a memorandum of understanding (MOU) 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/combo vaccines	Insured	No
Plan covers only a portion of the vaccine cost and does not have Medicaid as secondary insurance	Insured	No
Has Medicaid as secondary insurance	Medicaid eligible	Yes
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 (CPT) 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 (Pa. VFC PPA) by fax to 717-214-7223.
- Upon receipt of the completed Pa. VFC PPA, the provider identification number (PIN) will be assigned to your facility.
- A copy of the VFC Provider Handbook will be mailed to your facility. This 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.
- An immunization nurse from your district will contact you to schedule an enrollment/training site visit to review all aspects of the VFC program, assure the vaccine storage units and thermometers meet the requirements of the Centers for Disease Control and Prevention (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 PADOH 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 VFC coordinator a unique username and password referred to as “logon credentials.” This will allow staff to order vaccines online, update facility address and list vaccine shipping hours.
- View the video “Keys to Storing and Handling Your Vaccine Supply” and printing credentials from the CDC website. The video is found at the following sites:

<http://www2a.cdc.gov/vaccines/ed/shvideo/>
<http://www.youtube.com/watch?v=0atwOngjVQY>

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:

- 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 PADOH, 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
(<http://www2.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf>);
- Provide current vaccine information statements (VIS) and maintain records in accordance with the National Childhood Vaccine Injury Act. By federal law, all vaccine providers must give patients, or their parents or legal representatives, the appropriate VIS whenever a vaccination is given
(<http://www.cdc.gov/vaccines/hcp/vis/index.html>);
- Do not impose a charge for the cost of the vaccine to any eligible patient;
- Do not impose a charge for the administration of the vaccine in any amount higher than the maximum fee of **\$23.14**;
- Do not 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;
- Comply with VFC program procedures and requirements; and
- Adhere to all federal and state requirements.

Provider Annual Enrollment Update

In order to remain enrolled in the VFC Program and continue to receive VFC vaccines, it is mandatory to annually complete, sign and submit the Pa. VFC PPA. This document must be updated annually or whenever there is a significant change in enrollment or when the physician who signed the Pa. VFC PPA leaves the practice. Provider sites with internet access must complete the annual enrollment update electronically in Pennsylvania Statewide Immunization Information System (PA-SIIS) [Section 5].

The Pa. VFC PPA will be mailed to providers without internet access (Section 6-B). For those providers with no online capabilities, this document may be emailed, faxed or mailed to the PADOH.

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

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 PADOH for programmatic issues, including unannounced site visits. The model used to achieve Quality Assurance in the Pa. VFC program is the assessment, feedback, incentives and exchange (AFIX) model. AFIX is a quality improvement strategy to raise immunization coverage levels 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 in accordance with the laws and policies that govern 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 the 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 in accordance with 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 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.

Providers not scheduled to receive a VFC compliance visit during the calendar year **must** be scheduled to receive training on-line, by webinar or through an in-person classroom style presentation (Section 4-7).

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

- Assessing the provider's immunization coverage levels via an assessment 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 and adopt interventions for improvement. 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 in-service. 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 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 unannounced visits will serve as a spot check for proper storage and handling practices.

Provider Responsibilities

In addition to specific requirements to participate in the Pa. VFC program, there are also specific responsibilities that must be met. Those responsibilities consist of:

Notify PADOH regarding (Section 5):

- Change in facility name
- Change in facility address
- Change in facility telephone or fax number
- Change in primary VFC contact
- Change in back-Up VFC contact
- Change in medical director/primary physician

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.
- 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/PADOH requirements/recommendations
- Equipment (refrigerators/freezers)
- Thermometers/digital data loggers
- Maintenance of cold chain

Withdrawing from the VFC Program

In order to assure a smooth transition of services, the following steps must be taken should a facility choose to discontinue participating in the Pa. VFC Program.

- **Notify the Pa. VFC program 30 days in advance at (1-888-646-6864)** if the office plans to disenroll.
- 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 PADOH for help finding another VFC provider.

Fraud Waste and Abuse

The Pa. VFC Program recognizes that a vast majority of VFC providers abide 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 inquiry into potential violations of federal and state criminal, civil and administrative laws, rules and regulations; and
- A process to refer potential violations of applicable federal and state criminal, civil and administrative laws, 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.

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 shorter-dated vaccines first.
- Notify immunization nurses to assist in relocating vaccines expiring in 90 to 120 days to avoid waste.
- Deplete current single antigen vaccine inventory prior to 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 PADOH:

- 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 PADOH provides 10 vaccines for which there is more than one manufacturer's brand. PADOH staff will contact the provider if the brand ordered is not available, requesting a second choice.

The 10 vaccines are:

- 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
Sanofi Pasteur (ActHIB)
Merck (PevaxHIB)
- HPV Human papillomavirus
Merck (Gardasil)
GlaxoSmithKline (Cervarix)
- Influenza Flu
GlaxoSmithKline (Fluarix)
Medimmune (FluMist)
Sanofi Pasteur (Fluzone)

- 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)

Vaccine Ordering

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

Prior to placing a vaccine order

- Confirm your practice information in PA-SIIS (i.e., shipping address, shipping hours) [Section 5].
- Accept previous shipments into PA-SIIS.
- Reconcile inventory in PA-SIIS (Section 5).

Placing a vaccine order

- Order monthly: first thru 15th.
- Order only one month's supply of vaccine.
- Order by number of doses, **not packages**.
- Order according to type of facility (private provider – order only pediatric vaccines; public providers – pediatric and adult).
- Indicate in PA-SIIS "NOTES" field if needed by a specific date or any other special instructions.
- Contact the PADOH toll free line 1-888-646-6864 or email questions to 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.

No internet access sites

- Include current inventory on the Pa. Department of Health Supplied Vaccine Order, Inventory and Accountability Form (Section 6-D).

- Review the order; include PIN #, date and sign before faxing to the PADOH for processing. Fax to 717-441-3800.

Shipment of order

- Vaccines should arrive five to 10 business days after ordering. Shipments are delivered Tuesday through Friday via 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.

Returning Vaccines

All vaccines, including flu, deemed “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. The vaccine return and accountability form must be completed for returning all vaccines (Section 6-F).

Vaccines may be returned when:

- They are expired;
- They are stored or handled improperly (must complete incident report);
- A storage unit failure occurs (must complete incident report); or
- A power outage occurs (must complete incident report).

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 thermometers

Vaccine Storage Units (Section 6-J)

Pa. VFC requirements

PADOH supplied vaccine must be stored in one of the following:

- Stand-alone storage unit;
- Household combination unit (**must** have separate stand-alone freezer); or
- Medical grade combination unit.

Providers with PADOH approved household combination units will be given 90 days to acquire a stand-alone freezer.

- During the 90 days, the provider will not be allowed to order additional frozen VFC vaccine.
- Providers making no accommodation to acquire a stand-alone freezer within 90 days will be suspended from ordering all VFC vaccines.
- Providers will remain suspended until a stand-alone freezer is acquired.
- After one year of suspension, the provider will be disenrolled from the VFC program.

- **Effective 2017**, 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. After one year of suspension, the provider will be disenrolled from the VFC program.

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 strongly recommended to use medical grade stand-alone freezers and stand-alone 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.

- **Effective 2016**, 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 any time.

STANDALONE STORAGE UNITS

Commercial/Household Type

Freezerless



Refrigerator only



Medical grade

Under-the-counter



Full-sized



Vaccine storage units must be:

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

Refrigerator: 35°F to 46°F /2°C to 8°C

Freezer: -58°F to 5°F/-50°C to -15°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 sufficient space (at least four inches) around the sides and top for air circulation.

Certified Digital Thermometers (Section 6-J)

Pa. VFC requirements

- A digital data logger/continuous temperature monitoring device or a digital min/max thermometer must have an active digital 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 thermometer 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 PADOH will accept a manufacturer's suggestion not to exceed two years.
- Thermometer probes must be placed/secured in the center of each storage unit.
- VFC providers are **required** to have at least one back-up thermometer, at the provider site, with a valid and current certificate of calibration readily available to ensure twice a day temperature assessment and recordings.
- **Effective 2018**, CDC will require all VFC providers to purchase a digital data logger with an active temperature display, continuous monitoring and recording capabilities, and a detachable biosafe glycol-encased/buffered material probe in all VFC storage units. Please refer to the digital data logger policy in Section 6-J.

- Providers are responsible for the maintenance and NIST recalibration of all temperature monitoring devices/thermometers. Newly purchased units and recalibrations are at the expense of the provider site.

CDC recommendations

Based on studies of temperature monitoring devices conducted by NIST in 2009, CDC recommends continuous digital data loggers with detachable probes for continuous temperature monitoring with the following characteristics:

- Digital display on outside of storage unit to allow reading temperatures without opening unit door;
- Detachable probe in a bottle filled with a glycol/buffered material, which more closely reflects vaccine temperatures, which have been found to be more thermostable than air temperature (which fluctuates with defrost cycles and opening and closing the storage unit door);
- Alarm to alert out-of-range temperatures;
- Accuracy within $\pm 1^{\circ}\text{F}$ ($\pm .5^{\circ}\text{C}$);
- Low battery indicator;
- Continuous monitoring and recording capabilities to track and record temperatures over time; and
- 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.

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 one to two weeks 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.
- Have a safety-lock plug or “DO NOT UNPLUG” sign at the unit.
- Have a “DO NOT DISCONNECT” sign at the breaker box.

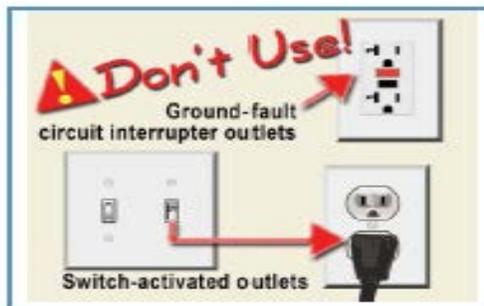


Safety-lock plug



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.



Appropriately Trained Staff

Designate primary and back-up contact persons 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 persons;
- 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 PADOH regarding any short-dated vaccines and removing expired vaccines from the viable vaccines storage units;
- Ensuring thermometers used inside both refrigerators and freezers are NIST certified thermometers with glycol/buffered probes;
- Ensuring appropriate monitoring and documentation of temperature logs;
- Notifying the PADOH immediately regarding any vaccine storage and handling problems to include IR 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 PA DOH provided vaccines; and
- Only transporting vaccine to other locations using procedures pre-approved by PADOH, 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 PADOH.

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 the educational roster to your immunization nurse as completed annually.

The CDC required provider annual education may be met by completing one of the below options:

- Having a VFC compliance visit with the immunization nurse; or
- Requesting an annual provider training with the immunization nurse.

Or if you choose one of the following options below, it must be completed and faxed prior to Oct.1, 2016:

- Two CDC “You Call the Shots” programs (print credentials from CDC website and fax/email copies to your immunization nurse)

- [Vaccines For Children \(VFC\) JAN 2016](#)
Scroll to bottom of page and click "continue" to start program
- [Vaccine Storage and Handling JAN 2016](#)
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>
- Completion of VFC Annual Provider Training and Survey from PA VFC program
 - http://www.health.pa.gov/My%20Health/Immunizations/Vaccines-for-Children/Pages/vfc_training.aspx#.Vug9pvLD-Un

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 an **emergency handling plan**. For this plan:

- Identify an alternative vaccine storage facility that has proper refrigerator and freezer units, temperature-monitoring capabilities (twice daily documentation) and backup power where vaccine can be stored in an emergency. An alternate site available 24/7 is preferred.
- Call annually to make sure the alternate site is still available and will meet Pa. VFC program requirements.
- Designate staff who will be responsible for packing and moving the vaccine to a safe location.
- Have the appropriate packing material on hand at all times, including insulated containers and cold/ice packs, bubble wrap, etc.
- Have a list of emergency phone numbers for local utility companies.
- Make written descriptions of floor plans and vaccine locations available.

Develop and maintain a current written **vaccine disaster recovery plan**, providing guidelines to ensure the vaccine cold chain is maintained. The plan should include:

- Identification of an alternative storage facility, such as a hospital, packing plant or local pharmacy, with back-up power (generator) where the vaccine can be stored and monitored during an emergency;
- Identification and training of staff responsible to pack, monitor and move vaccine during an emergency;
- Location of a supply of appropriate packing materials (insulated containers, ice packs, temperature monitoring device, temperature logs, etc.);
- Identification of available transportation and location to move vaccine (secure storage facility during an emergency); and
- Annual review with date and signature of reviewer for documentation.

Vaccine Ordering/Delivery/Receiving/Storing

Ordering the vaccine (Section 3)

- A provider must meet all recommendations and requirements to order VFC vaccine and to ultimately decrease vaccine wastage. If a noncompliant provider submits an order, the order will be deleted after five 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.
- 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 . Please include your VFC pin number with any communications.

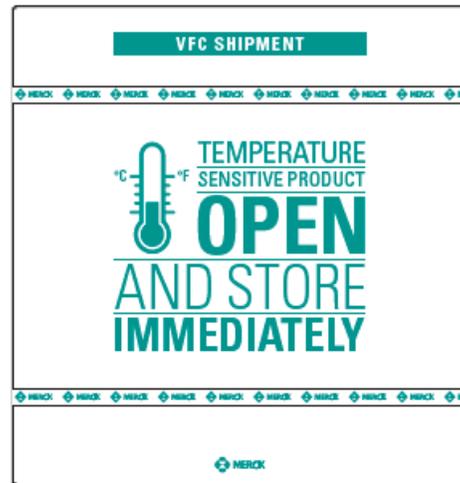
Delivery of the vaccine shipment

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

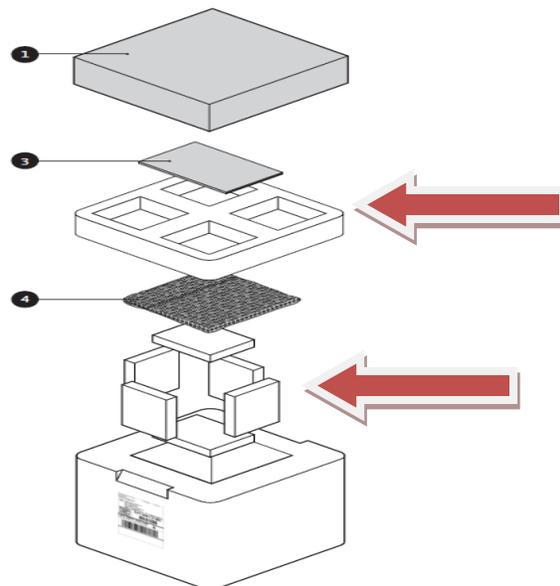
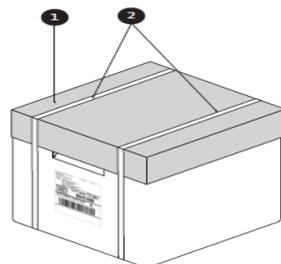
Providers are not required to return the empty shipping cartons to McKesson Specialty Distribution or Merck. Providers may choose to keep some for “emergency transport” or dispose of the boxes.

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.”

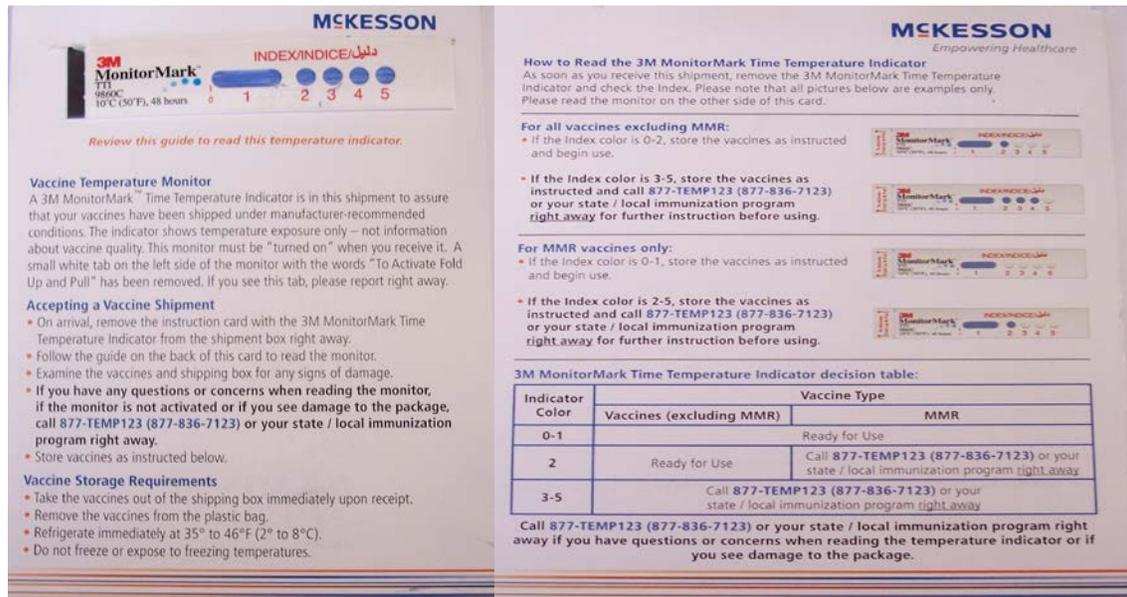
If received after the specified date, contact the MERCK Order Management Center immediately for replacement instructions at **1-800-MERCK-RX** (1-800-637-2579).

- 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.



WHAT'S IN THE MCKESSON SHIPMENTS



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

Receiving the vaccine

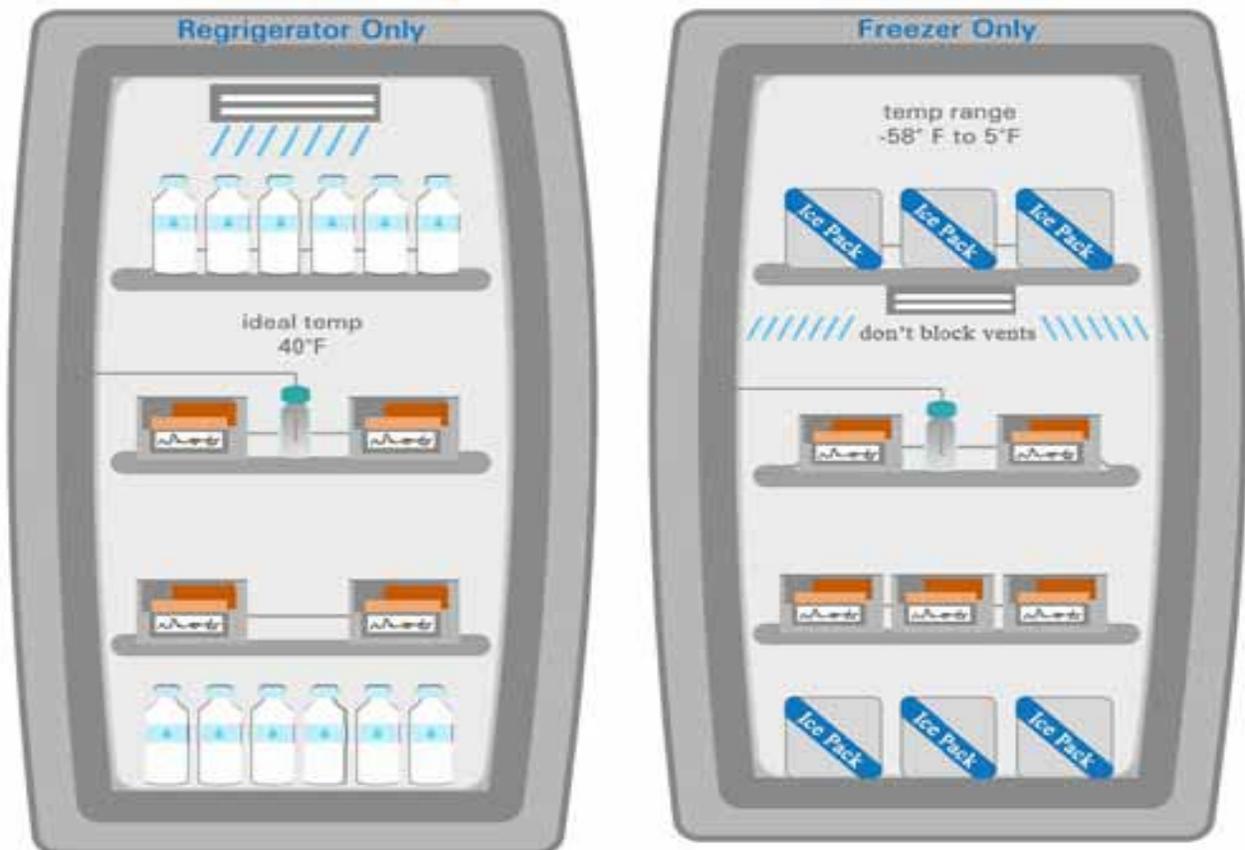
- Check the temperature indicator enclosed in the shipment to determine if the vaccines were exposed to temperatures outside of the proper range for storage and handling, and immediately notify McKesson Specialty Customer Care directly at 877-TEMP123 (877-836-7123).
- Evaluate the condition of the vaccines 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 PADOH at 717-214-7223.
- Compare quantities, lot numbers and expiration dates carefully; immediately advise the PADOH the same day or next business day regarding any discrepancies between the contents 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 have been removed from the carton.

Storing the vaccines

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

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; and
- Be stored with water bottles/coolant packs in freezer.



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.)

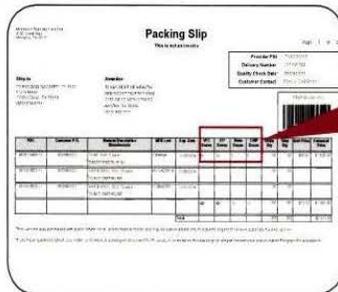


Separating and Storing Your Vaccine Stock

1 How to identify vaccine by public funding type

There are 2 types of public funding:

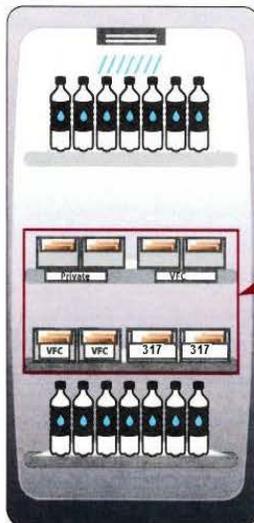
- VFC
- 317



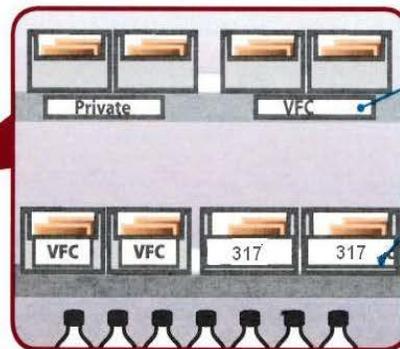
VFC Doses	317 Doses
25	20

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:



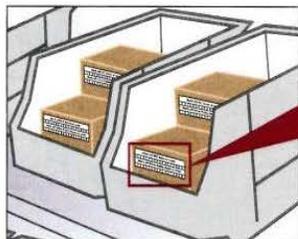
Label the storage unit shelf.

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 PADOH supplied temperature log with your PIN preprinted 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 PADOH staff.

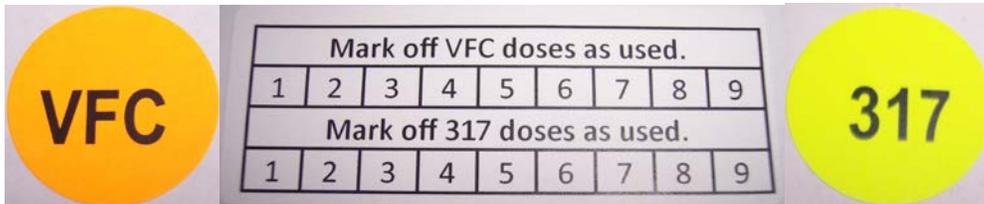
Key points to remember when completing your monthly temperature log:

- 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.
- If vaccine temperatures have not been documented for more than 72 hours, contact the manufacturers to ascertain the vaccine viability.
- 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 PADOH.
- 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.
- 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. Complete and submit the Vaccine Incident Report and Worksheet (Section 6-F) to PADOH 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.

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

PADOH 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;
- Reporting expired/wasted vaccines (Section 6-F); and
- Limiting thermostat adjustments to the primary and back-up vaccine contact persons.



A warning sign must be posted on the storage unit.

Vaccine borrowing

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. 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.

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.

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 Hourly Monitoring Report"

Providers can receive the UPS return label several ways:

- By email from uoltsupport@ups.com to a single email address, within one to three hours after return data is received at McKesson;
- By routine U.S. mail – seven to 10 business days; or
- By UPS driver at scheduled pick-up time.

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 to include in your outbound shipment or send it to the consignee. The label will be available for only 30 days. If label is not received within 30 days, the process must be repeated.

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.](#)

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 and forwarded to the PADOH 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

(Section 6-F). Reporting an adverse advent to VAERS does not initiate a claim for compensations; a petition must be filed with VICP to start a claim for compensation.

Vaccine Cold Chain Failure

Suspected vaccine cold chain failure – Providers Shall:

- 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. 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 temperature.
- Complete and submit the Vaccine Incident Report and Worksheet Form (Section 6-F) and fax to the PADOH at 717-214-7223 within five days of a suspected cold chain failure.

Confirmed vaccine cold chain failure – Providers Shall:

- 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 other periods of cold chain failure; submit copies with the incident report to DOI.
- Complete a Vaccine Return and Accountability Form (Section 6-F).
- Return unopened vials of all expired/wasted vaccines, including influenza vaccine, within six months to McKesson Specialty Distribution in a prepaid McKesson shipping container. Complete the Vaccine Return Form found in section 6 of the VFC Provider Handbook and fax to 717-214-7223; 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 the 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.
- Within fourteen workdays of confirmation of vaccine cold chain failure, review office databases, registries, patient charts to identify those persons receiving

- vaccines during the identified cold chain failure period(s) and determine who needs to be revaccinated.
- Within twenty-one workdays of confirmed cold chain failure, prepare and submit a Corrective Action Plan to the Division of Immunizations Quality Assurance staff outlining the steps to identify, recall and revaccinate patients who had received potentially compromised vaccine.
 - Within six weeks of confirmation of cold chain failure, contact identified patients and/or guardian of children by telephone or written correspondence with the following information:
 - Purpose of recall;
 - Explanation of need for revaccination;
 - Information about available clinics and times for revaccination; and
 - Scheduled appointments to revaccinate persons who were vaccinated during the cold chain failure timeframe.
 - 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 childcare facility.
 - Keep an ongoing log of the number of persons revaccinated and the number of doses of each vaccine administered.
 - Submit interim status report and/or final report (Section 6-F) as directed by PADOH.

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.

During 2013, all PADOH vaccine ordering was transitioned from paper to online through PA-SIIS. PADOH providers are strongly encouraged to enroll in PA-SIIS to ensure a smooth transition of placing PADOH supplied vaccine orders electronically.

PA-SIIS User Log on Credentials

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

Log into PA-SIIS

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

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

PA-SIIS support site: www.health.state.pa.us/pasiis

Phone number: 877-774-4748

Online Ordering

Orders for all PADOH supplied vaccine must be placed electronically through the PA-SIIS. Provider orders will still be reviewed by the PADOH staff and then electronically uploaded to the ordering system through the PA-SIIS. The only exceptions are those providers who do not have internet (online) capabilities. PADOH will accept faxed, mailed or online orders from providers with no internet connection.

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

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, 6th 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.

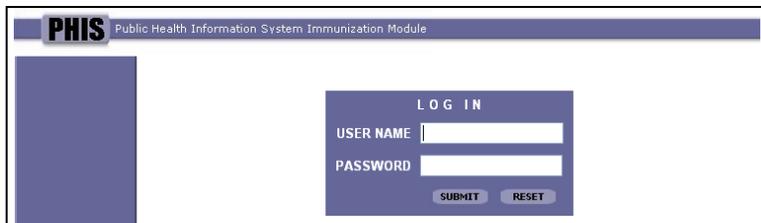
As an additional security measure, the PA-SIIS will time out after a period of inactivity. This is to prevent someone else from using your computer and connection if you step away without logging out. If the system times out, you must re-log in to resume using the system.

To log into PA-SIIS:

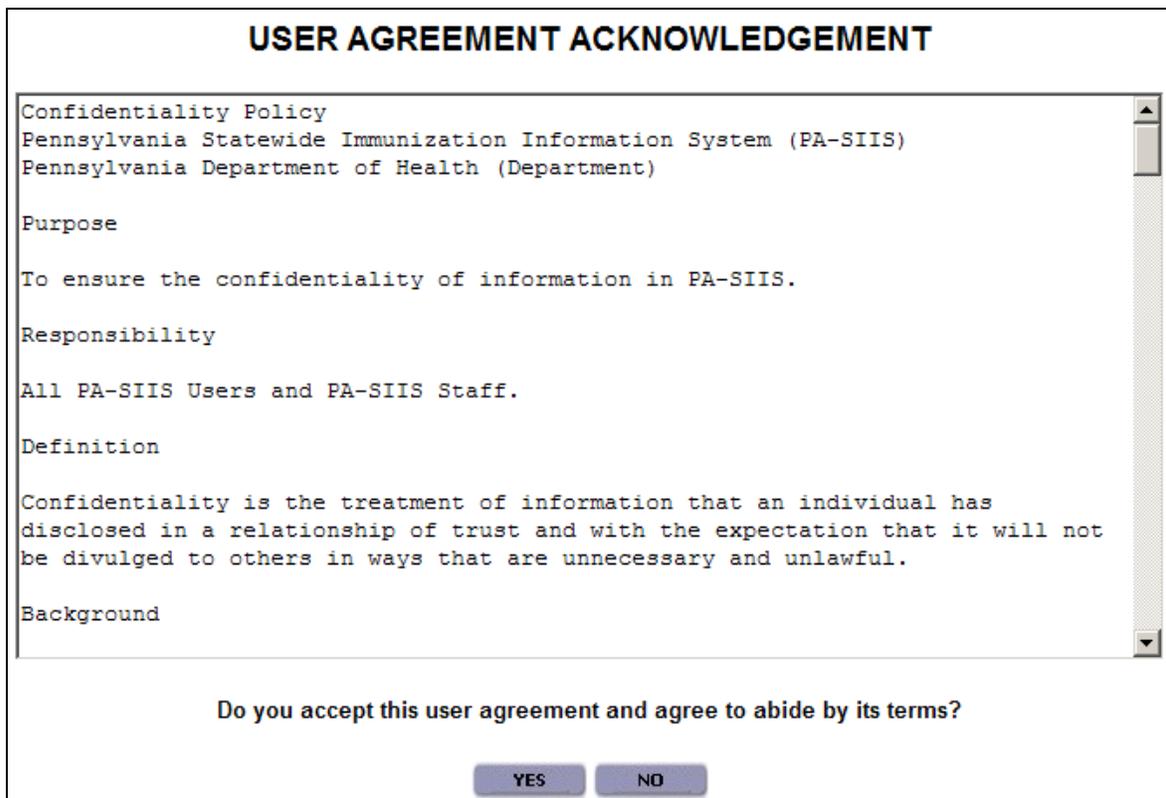
1. Using your Web browser, navigate to the PA-SIIS Web site:

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

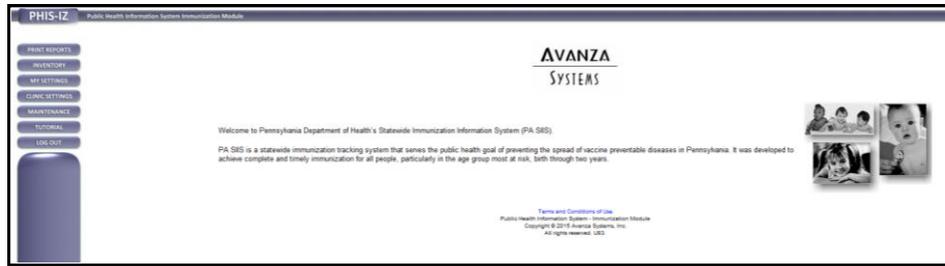
2. When the login screen appears, enter your user name and password into the appropriate fields. The password will display as a series of asterisks (****) for security purposes.



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 :

pennsylvania
DEPARTMENT OF HEALTH

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

CLINIC NAME * Sample Clinic	CLINIC TYPE Private	VFC PIN 123854	
CLINIC PHONE * 7177832548	EXTENSION 	CLINIC FAX 7177723258	
PRIMARY VFC CONTACT			
LAST NAME * Duck	FIRST NAME * Shirley	MIDDLE NAME 	EMAIL ADDRESS
BACKUP VFC CONTACT			
LAST NAME * Duck	FIRST NAME * Shirley	MIDDLE NAME 	EMAIL ADDRESS
Clinic Address * EDIT 555 Walnut Street Floor 6 Harrisburg, Pennsylvania 17101		Shipping Address EDIT 	
Associated Providers EDIT 		Delivery Times EDIT Mon Tue Wed Thu Fri	
Patient Population EDIT Total (0) Enrolled in MA (0) Uninsured (0) American Indian (0) Underinsured (0)		VFC Acknowledgement EDIT Physician Name: License #: MA ID: VFC Enrollment Signature Date:	

UPDATE CANCEL

* 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		

* 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 type="text"/>		
<input checked="" type="checkbox"/> RECOMMEND			
LOT INFORMATION			
LOT NUMBER 58794	EXPIRATION DATE 6/30/2010	MANUFACTURER 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 NAME	TRADE SOURCE	FUNDING VOLUME ORDERED

- Your clinic name will automatically default in the Clinic field. Select the **Add Orders** button at the bottom of the *Edit Orders* screen. The *Add New Order* screen will appear. At the top of the Add New Order Screen you will see a notes field: This field should be used to explain rush orders in order to prevent approval and shipment delays. You will also notice two radial buttons requesting you to attest your temperature log is current and maintained, and that you completed your inventory reconciliation (section C) prior to submitting your current vaccine order.

All Childhood Vaccines (Ages 0-18) are listed first on the new ordering screen.

ADD NEW ORDER

ORDER ID 48223	CLINIC Cumberland County SHC	VFC PIN S42101	ORDER DATE 6/16/2015	STATUS * Pending Approval ▼
PRIORITY ORDER No ▼	REASON Select ▼			
NOTES 				
VACCINE DOSE QUANTITY ORDERED BY FUNDING SOURCE				
VACCINE	TRADE NAME	VFC		
Childhood Vaccines				
DTaP	49281-0286-10 Daptacel	0		
DTaP	58160-0810-11 Infanrix VIAL	0		
DTaP	58160-0810-52 Infanrix SYR	0		

All Adult vaccines (Ages 19 and over) are listed for our providers that are permitted to order Adult (317) vaccines.

Adult Vaccines (Ages 19 and over)				
Hep A - Adult	58160-0826-52 Havrix ADU SYR	0		
Hep A - Adult	00006-4096-09 Vaqta ADU SYR	0		
Hep B - Adult	58160-0821-52 Engerix ADU SYR	0		
Hep B - Adult	00006-4094-09 Recomb ADU SYR	0		
HPV4	00006-4045-41 Gardasil 4 ADU	0		
MCV4	46028-0208-01 Menveo ADU	0		
MMR	00006-4681-00 MMR ADU	0		
PNU - 13	00005-1971-02 Prevnar 13 ADU	0		
PNU - 23	00006-4943-00 PPV 23 ADU	0		
Td	49281-0215-15 Tenivac ADU SYR	0		
Tdap	58160-0842-52 Boostrix ADU SYR	0		
Tdap	49281-0400-15 Adacel ADU SYR	0		
Varicella	00006-4827-00 Varicella ADU	0		

By checking this box I take full responsibility for this information and attest that there is a current temperature log at this practice site with documentation in compliance with the Vaccines for Children vaccine temperature log documentation requirements.

By checking this box I take full responsibility for this information and attest that the Department-supplied vaccine inventory listed is an accurate reflection of the inventory on hand at this practice site.

UPDATE

CANCEL

- 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.
- 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	11763	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:

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 :
500	Influenza	Non-VFC	58794	6/30/2010	500

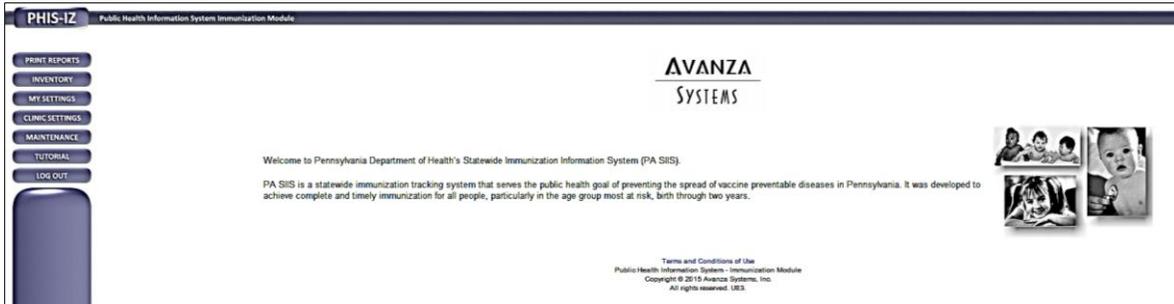
Is this shipment complete ?

Yes

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.

The screenshot shows the "EDIT MY SETTINGS" form. It contains the following fields and controls:

- FIRST NAME:** Text input field containing "Donald".
- MIDDLE NAME:** Empty text input field.
- LAST NAME:** Text input field containing "Duck".
- LOGIN ID:** Text input field containing "fcaniglia2".
- PASSWORD:** Password input field with masked characters (dots).
- CONFIRM PASSWORD:** Password input field with masked characters (dots).
- IMMN. PROVIDER:** A dropdown menu currently showing "SELECT".
- USER NOTES:** A large empty text area.
- SIGNATURE BLOCK:** A large empty text area with scroll arrows on the right side.

At the bottom of the form are two buttons: "UPDATE" and "CLOSE MY SETTINGS".

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

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

UPDATE CANCEL

* 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 | 2016 | 6-A |
| • Enrollment in the Vaccines for Children Program | | 6-B |
| Instructions for Completing the 2016 Pa. VFC Program Provider Agreement | 2016 | |
| Pa. VFC Program Provider Agreement | 2016 | |
| • Insurance and VFC Eligibility | | 6-C |
| CHIP MA Card Comparison | 2016 | |
| Eligibility vs. healthcare coverage | 2016 | |
| Pa. VFC Eligibility Screening Record | 2016 | |
| • Ordering and Accountability | | 6-D |
| PADOH Supplied Vaccine Order, Inventory and Accountability Form | 2016 | |
| Pa. VFC Borrowing Report | 2016 | |
| Pa. VFC Dose Tracking Form | 2016 | |
| • Required Plans | | 6-E |
| Emergency Handling Procedures and Vaccine Disaster Recovery Plan | 2016 | |
| Pa. VFC Vaccine Management Plan | 2016 | |
| • Required Reporting | | 6-F |
| Vaccine Incident Report and Worksheet Instructions | 2016 | |
| Vaccine Incident Report and Worksheet | 2016 | |
| Vaccine Return and Accountability Forms | 2016 | |

Interim/Final Status Report (Revaccination Form)	2016	
Vaccine Adverse Event Reporting System (VAERS)	2016	
● Storage and Handling Maintenance		6-G
Vaccine Storage Maintenance Reminder	2016	
● Temperatures and Monitoring		6-H
Celsius and Fahrenheit Conversion Chart	2016	
Recording Freezer Temperatures	2016	
Freezer Fahrenheit and Celsius Temperature Log Form	2016	
Recording Refrigerator Temperatures	2016	
Refrigerator Fahrenheit and Celsius Temperature Log Form	2016	
● Transporting Vaccines		6-I
Transporting Frozen Vaccines	2016	
Transporting Refrigerated Vaccines	2016	
Vaccine Transport Hourly Monitoring Form and Inventory Sheet	2016	
● Best Practices and Resources		6-J
NIST Certified Thermometer/Data logger Manufacturers	2016	
Pa. VFC Digital Data Logger (DDL) Policy	2016	
Best Practices in Vaccine Storage	2016	
Cold Storage Unit Manufacturers	2016	
Lithium Battery Suppliers	2016	
Resources and Websites	2016	
Acronyms	2016	

Instructions for Completing the 2016 PA VFC Program Provider Agreement

The 2016 procedures and forms have been revised to meet Centers for Disease Control (CDC) requirements for new enrollment, reactivation and annual updates to participate in the VFC Program. Prior to completing the forms ensure that you have the “2016 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, Annual Renewal, 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.
6. **Back-up Vaccine Coordinator Name** – *(see above)*
7. **Back-up Vaccine Coordinator Email** – please indicate the work email account.
8. **Facility Address** – Provide the street name and street number, suite number, etc., 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 of the person who will be able to answer questions regarding vaccine ordering. 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.

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, circle 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 doses administered during past 12 months.
 - 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)** – For re-enrollment only 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. If “Offers Select Vaccines” is checked, please indicate which vaccines are offered by checking each type from the list. (This option is only available for facilities designated as Specialty Providers by the VFC Program).
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 # and Medicaid or NPI #, 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 – The name of the official VFC registered Physician provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who 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 via 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 this 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 “2016 PA VFC Program Provider Agreement”.

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

SUBMISSION OF THE COMPLETE INFORMATION

If you manually completed the enrollment form you must fax or mailed 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, as well as 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).

2016 Pennsylvania Vaccines for Children Program Provider Agreement

All pages of this form must be completed annually in order for providers to be able to participate in the Vaccines for Children (VFC) Program; a form must be completed for each site to which 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"/> ANNUAL RENEWAL <input type="radio"/> UPDATE		VFC Pin#:		
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? (check one)		<input type="radio"/> Yes <input type="radio"/> No	Office Email:	
Type of facility: (please only check one):				
<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:				
Annual Patient Population 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				
PROVIDER VACCINE DELIVERY HOURS, NOT OFFICE HOURS: INCLUDE LUNCH / TIME STAFF IS NOT AVAILABLE				
Monday:				
Tuesday:				
Wednesday:				
Thursday:				
Friday:				

**2016 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 October 1, 2016 or have a VFC compliance site visit within the current year. For more information concerning CDC's requirement for annual training please refer to section 4 of the VFC provider handbook or visit our website at <http://www.health.state.pa.us/vfc>.

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 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; 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 | |

**2016 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"> a) Ordering vaccine and maintaining appropriate vaccine inventories; b) Not storing vaccine in dormitory-style units at any time; 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; d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.
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>Fraud: 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>Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.</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"> a) Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit; b) Vaccinate "walk-in" VFC-eligible underinsured children; and c) Report required usage data. <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:</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>

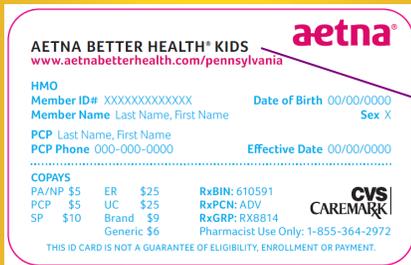
After completing the "2016 VFC Program Provider Agreement Form" mail to the Division of Immunizations Room 1026 H&W Building 625 Forster Street, Harrisburg, PA 17120-0701 or fax to 717-214-7223.

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:

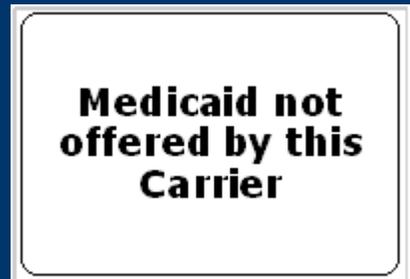
- Aetna Better Health



Blue Cross of NEPA

CHIP Card:

- "First Priority Health for Kids"



Medicaid not offered by this Carrier



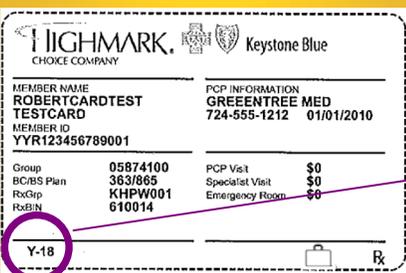
Keystone Health Plan Central

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



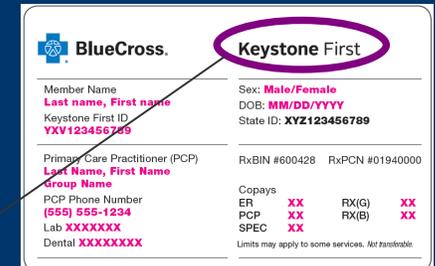
Keystone Health Plan East

CHIP Card:

- "PA Kids" logo

Medicaid Card:

- "Keystone First" logo



Continued: CHIP vs. Medicaid Insurance Cards



CHIP Patients are not eligible for

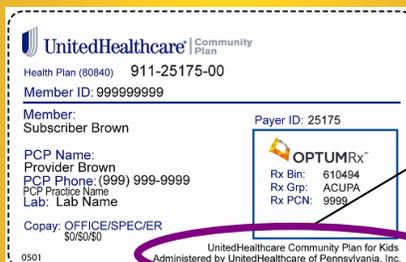
Medicaid patients are eligible for VFC vaccines



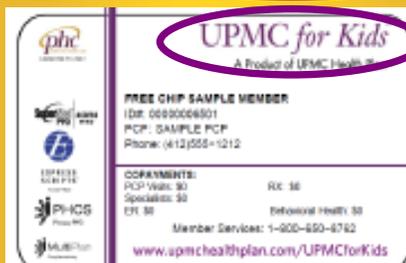
Geisinger Health Plan
CHIP Card:
 • "GHP Kids"
Medicaid Card:
 • Geisinger Health Plan



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



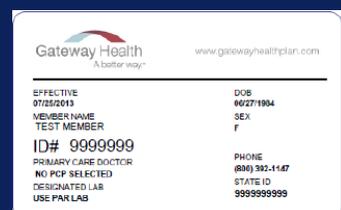
United Healthcare
 • Community Plan for Kids
 • United Healthcare Community Plan for Families



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 between 0 through 18 years of age presents at a VFC provider site, please refer to the below chart to determine if he/ she is eligible for the PA VFC Program.

Coverage Type	Eligible for PA VFC
Uninsured No Insurance	YES
Medicaid/ MA +	YES * see chart with specific plans
Alaskan Native	YES regardless of insurance coverage
American Indian	YES regardless of insurance coverage
Underinsured Limited Health Coverage/Insurance Immunizations Not covered	YES Must receive vaccines at; Federally Qualified Health Center (FQHC) Rural Health Center (RHC) or deputized State Health Center (SHC)
CHIP	NO ** considered private insurance see listing of specific plans
Private Insurance	NO

+A Medicaid eligible child is eligible for PA VFC vaccines regardless 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
AmeiHealth 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 2016

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/ UnitedHealthcare: UnitedHealthcare 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 and 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 3 years or longer depending on state law. The record may be completed by the parent, guardian, individual of record, or by 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
Date	Medicaid Enrolled	No Health Insurance	American Indian or Alaska Native	*Underinsured served by FQHC, RHC or deputized provider	Has health insurance that covers vaccines	**Other underinsured	***Enrolled in CHIP

**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) or 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). These children 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 & 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 e-mail to: paimmunizations@pa.gov			

VACCINE	CURRENT INVENTORY			NEW VACCINE ORDER				
	DOSES ON HAND	LOT#	EXPIRATION DATE	MANUF	BRAND	NDC	PKG DESCRIPTION	DOSES ORDERED
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	
EIPV				Sanofi	IPOL	49281-0860-10	(1 pk) multi-dose vials	
HEP A - Peds				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 - Peds				Merck	Recombivax	00006-4981-00	(10 pk) 1-dose vials	
				Merck		00006-4093-02	(10 pk) 1-dose syringes	
				GSK	Engerix	58160-0820-11	(10 pk) 1-dose vials	
				GSK		58160-0820-52	(10 pk) 1-dose syringes	
Hib				Merck	PedvaxHIB	00006-4897-00	(10 pk) 1-dose vials	
				Sanofi	ActHIB	49281-0545-05	(5 pk) 1-dose vials	
HPV - Peds				Merck	Gardasil 9	00006-4119-03	(10 pk) 1-dose vials	
Meningococcal Conjugate-Peds				Sanofi	Menactra	49281-0589-05	(5 pk) 1-dose vials	
				GSK	Menveo	46028-0208-01	(5 pk) 1-dose vials	
Meningococcal B - Peds				Pfizer	Trumenba	00005-0100-10	(10 pk) 1-dose syringes	
				GSK	Bexsero	46028-0114-01	(10 pk) 1-dose syringes	
MMR - Peds				Merck	MMR-II	00006-4171-00	(10 pk) 1-dose vials	
MMR-V - Peds				Merck	ProQuad	00006-4999-00	(10 pk) 1-dose vials	
Pneumococcal Polysaccharide				Merck	Pneumovax (PPV23)	00006-4943-00	(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 - Peds				Sanofi	Tenivac	49281-0215-10	(10 pk) 1-dose vials	
				Sanofi		49281-0215-15	(10 pk) 1-dose syringes	
Tdap - Peds				Sanofi	Adacel	49281-0400-10	(10 pk) 1-dose vials	
				Sanofi		49281-0400-15	(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 - Peds				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
- 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 (7Other or 13Other) 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 placed on time/delay in shipping)	1	VFC vaccine shipment delay (order placed 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 was exchanged with VFC dose	4	Short-dated VFC dose was 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:	13Other
Other – Describe:	7Other		

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
- ▼ 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 available 24/7 is preferred; an example would be a hospital. Call annually 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.

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 and understood by:

Date:

Original Emergency Handling Procedures Date: _____

Revision of Emergency Handling Procedures Date: _____

Company	Name	Telephone
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		
	http://www.nws.noaa.gov	
	http://www.nhc.noaa.gov	
	http://www.goes.noaa.gov	
FEMA		
	http://www.fema.gov/index.shtm	

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, Hep B, Hib, HPV, Influenza, Meningococcal, MMR, Pneumococcal, Polio and Rotavirus vaccines are stored in the refrigerator with temperatures maintained at 35° to 46°F/2 to 8°C.
5. Frozen vaccines (Varicella, and MMRV) must be stored in the freezer with temperatures maintained at 5°F to negative 58°F/negative 15°C to negative 50°C. MMR may be stored in the freezer. Diluents are stored at refrigerator 35°F to 46°F/2 to 8°C or room temperatures 68°F to 77°F/20°C to 25°C.
6. Stand-alone/Medical grade storage units are recommended. Household combination units are required to be accompanied by a stand-alone freezer to avoid suspension of ordering privileges. A 90- day grace period will be given during a site visit to providers to obtain a stand-alone freezer. 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 identify vaccine storage unit switches to prevent turning off the power supply without prior notification given to _____ [designated person].
8. Calibrated thermometers with current Certificate of NIST/ILAC Traceability and Calibration, probes are located in the central compartment of each VFC vaccine refrigerator and freezer storage unit. Thermometers are due for recalibration _____. Certificates are kept and maintained by _____ [designated person].
9. Temperature logs are maintained on site for 3 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, if your thermometer has this capability.
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 & submitted to the VFC Program within 5 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 multidose 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 3 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 Incident Report and Worksheet Instructions

**Refrigerator: 35° to 46° Fahrenheit / 2° to 8° Celsius
Aim for 40° Fahrenheit (5° Celsius)**

**Freezer: - 58° to 5° Fahrenheit /-50° to -15° Celsius
Aim for below 0° Fahrenheit (-20°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, **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). A Vaccine Return and Accountability form (Section 6 – Forms) is also necessary for completion if vaccines are to be wasted and submit to DOI within five days of the incident.
 - List all details on the incident report
 - Description of incident
 - Incident resolution
 - Corrective action plan
 - Answer all questions on 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 for keep, destroy and return)
 - Attach copy of temperature log to incident report and fax to 717-214-7223

Call the Pa. VFC Program at 888-646-6864 for questions or assistance.

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

Date	Pin #
Demographics	
Practice Name	
Address	Phone #
	County District
Incident Criteria	
Date /Time of Incident	
Type of Incident (Power failure, refrigerator/freezer failure, improperly stored, thermometer malfunction, shipping/transporting error etc.)	
Reported by	Reported to
Temperature Data	
Refrigerator- circle appropriately below	Freezer- circle appropriately below
Pharmaceutical Commercial Standalone Combo	Pharmaceutical Commercial Standalone Combo
Make/Model	Make/Model
Date/Time Temperature	Date/Time Temperature
Min Max	Min Max
Temperatures are reviewed and documented twice daily during operating hours? YES NO	
Water bottles are stored in both refrigerator and freezer? YES NO	
Description of Incident (Write a narrative giving details of incident; attach additional sheet of paper if needed.)	
Incident Resolution (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, Thermometer repaired replaced Date _____	
Notified your VFC Immunization nurse of storage repairs/replacements Date _____	
Manufacturers contacted immediately and completed incident report faxed within 5 days YES NO	
Other/Additional information:	
Must complete all four pages of worksheet and fax within 5 days to 717-214-7223	

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 #
DT, DTaP (Tripedia), DTaP (Daptacel), DTaP-IPV-Hib (Pentacel) EIPV (Polio), Flu (Fluzone), Hib (ActHib), Meningococcal (MCV4), Td (Decavac), Tdap (Adacel))	sanofi pasteur www.us.aventipasteur.com	1-800-822-2463
Flu (Afluria), Hep A (Vaqta), Hep B (Recombivax), HepB-Hib (Comvax), Hib (PedvaxHib), HPV (Gardasil), MMR, MMRV (Proquad), Pneumococcal PPV23 (Pneumovax), Rotavirus (RotaTeq), Varicella (Varivax)	Merck www.merck.com	1-800-672-6372
DTaP (Infanrix), DTaPHBIP (Pediarix), DTaP-IPV (Kinrix), Flu (Fluarix), Hep A (Havrix), Hep B PF (Engerix), Hep AB (Twinrix), HPV (Cervarix), Tdap (Boostrix), Rotavirus (Rotarix), Meningococcal (Menveo) Meningococcal B (Bexsero)	GlaxoSmithKline www.gsk.com	1-888-825-5249
PNU13 (Prevnar PCV 13), Meningococcal B (Trumenba)	Pfizer www.pfizer.com	1-800-572-8221
Flu Mist (LAIV)	MedImmune www.medimmune.com	1-877-358-6478

Vaccine Worksheet is completed to document manufacturer recommendation.

Vaccine Return and Accountability Forms documents 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 ten 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 6 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 5 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
3. McKesson will be forwarding UPS return labels in one of three ways:
 - By E-Mail to the primary VFC Contact indicated in PA-SIIS from uoltsupport@ups.com with a subject line – UPS Shipping API. Providers should receive UPS return label within 1 to 3 hours after Division of Immunizations staff enters the return in to 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 indicate three boxes will be used to return vaccines, the provider will receive three separate e-mails with one label per e-mail – the labels are not specific to any of the 3 boxes
 - Unused labels **must be discarded** and cannot be used on future returns
 - By routine US Mail addressed to the primary VFC Contact indicated in PA-SIIS – approximately 7 to 10 business days
 - By the UPS driver at the time of scheduled pick-up for those without routine UPS service

Sample of the e-mail

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 e-mail 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 to your UPS driver the next time they are 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 pick-up. The label will be created at the time of pick-up 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**

RETURNABLE – NON-VIABLE VACCINE

Date: _____	** VTrckS Return ID _____	VFC PIN #: _____
Site Name: _____		
Person Reporting: _____	Phone: _____	# of Shipping Labels needed _____
Does this facility have routine UPS service – please check the appropriate box: YES <input type="checkbox"/> NO <input type="checkbox"/>		
If yes, do you prefer to have UPS shipping label sent via e-mail? YES <input type="checkbox"/> NO <input type="checkbox"/>		
E-Mail Address: _____		

**** VTrckS Return ID number will be provided to the VFC Contact by fax or e-mail**

NON-VIABLE VACCINES TO RETURN TO MCKESSON

COMPLETION OF ALL COLUMNS IS REQUIRED

NDC #**	Vaccine	Manufacturer	Lot #	Expiration 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. Vaccine spoiled in transit

If it is a partial vial it is considered wasted and non-viable – non-returnable and should be documented on the non-returnable section

Please fax completed Vaccine Return and Accountability Form to (717) 214-7223

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

WASTED- NON-VIABLE- NON-RETURNABLE

Date: _____	VFC PIN #: _____
Site Name: _____	
Person Reporting: _____	Phone: _____

ACCOUNTABILITY OF WASTED, NON-VIABLE – NON-RETURNABLE VACCINES

COMPLETION OF ALL COLUMNS IS REQUIRED

NDC #**	Vaccine	Manufacturer	Lot #	Expiration 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 this vaccine.

Properly dispose of all wasted non-viable/non-returnable vaccine.

Wasted – Non-Viable- Non-Returnable Vaccine 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 passed the expiration date
- F. All vaccines deemed **non-viable/non-returnable** must be properly disposed of according to the policy in place at your facility.

Please fax completed Vaccine Return and Accountability Form to (717) 214-7223

Pennsylvania Department of Health
Division of Immunizations
Room 1026 Health & Welfare Building
625 Forster Street
Harrisburg, PA 17120-0701

Interim/Final Status Report of Corrective Actions Following Cold Chain Failure

Pin # _____ Date Cold Chain Failure Discovered _____

Name & Address of Provider Site:

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

Method used to contact clients: Phone Letter Other

(Attach copy of 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 & 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

Date Cold Chain Failure Resolved _____ (To be completed by Division of Immunization)



VACCINE ADVERSE EVENT REPORTING SYSTEM

24 Hour Toll-Free Information 1-800-822-7967

P.O. Box 1100, Rockville, MD 20849-1100

PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only

VAERS Number _____

Date Received _____

Patient Name:

Last _____ First _____ M.I. _____

Address

City _____ State _____ Zip _____

Telephone no. (____) _____

Vaccine administered by (Name):

Responsible Physician _____

Facility Name/Address

City _____ State _____ Zip _____

Telephone no. (____) _____

Form completed by (Name):

Relation Vaccine Provider Patient/Parent

to Patient Manufacturer Other

Address (if different from patient or provider)

City _____ State _____ Zip _____

Telephone no. (____) _____

1. State

2. County where administered

3. Date of birth
mm / dd / yy

4. Patient age

5. Sex
 M F

6. Date form completed
mm / dd / yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
 Patient died (date mm / dd / yy)
 Life threatening illness
 Required emergency room/doctor visit
 Required hospitalization (____ days)
 Resulted in prolongation of hospitalization
 Resulted in permanent disability
 None of the above

9. Patient recovered YES NO UNKNOWN

10. Date of vaccination
mm / dd / yy AM
Time _____ PM

11. Adverse event onset
mm / dd / yy AM
Time _____ PM

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a. _____	_____	_____	_____	_____
b. _____	_____	_____	_____	_____
c. _____	_____	_____	_____	_____
d. _____	_____	_____	_____	_____

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a. _____	_____	_____	_____	_____	_____
b. _____	_____	_____	_____	_____	_____

15. Vaccinated at:

Private doctor's office/hospital Military clinic/hospital
 Public health clinic/hospital Other/unknown

16. Vaccine purchased with:

Private funds Military funds
 Public funds Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions (specify)

20. Have you reported this adverse event previously?
 No To health department
 To doctor To manufacturer

Only for children 5 and under

22. Birth weight
_____ lb. _____ oz.

23. No. of brothers and sisters

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
<input type="checkbox"/>	In patient	_____	_____	_____
<input type="checkbox"/>	In brother or sister	_____	_____	_____

Only for reports submitted by manufacturer/immunization project

24. Mfr./imm. proj. report no.

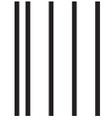
25. Date received by mfr./imm.proj.

26. 15 day report?
 Yes No

27. Report type
 Initial Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

"Fold in thirds, tape & mail — DO NOT STAPLE FORM"



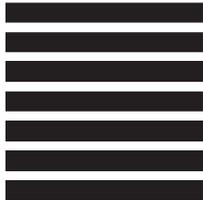
NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES
OR APO/FPO

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD

POSTAGE WILL BE PAID BY ADDRESSEE



VAERS
P.O. Box 1100
Rockville MD 20849-1100



DIRECTIONS FOR COMPLETING FORM

(Additional pages may be attached if more space is needed.)

GENERAL

- Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.)
- Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.
- Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA's legal responsibility.
- These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems". Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.
- Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

SPECIFIC INSTRUCTIONS

Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

- Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.
- Item 9: Check "YES" if the patient's health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient's condition is not known.
- Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please
- and 11: indicate "AM" or "PM" when possible if this information is known. If more than one adverse event, give the onset date and time for the most serious event.
- Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.
- Item 13: List ONLY those vaccines given on the day listed in Item 10.
- Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in Item 10.
- Item 16: This section refers to how the person who gave the vaccine purchased it, not to the patient's insurance.
- Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine(s) was given.
- Item 18: List any short term illnesses the patient had on the date the vaccine(s) was given (i.e., cold, flu, ear infection).
- Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.
- Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.
- Item 26: This space is for manufacturers' use only.

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 Thermometer

Date _____

Date _____

Model/Serial #

Date _____

Date _____

Annual/Biannual Recalibration of NIST thermometers

Due Date

Completed Date

Refrigerator:

Freezer:

Yearly Service of Storage unit

(Recommended)

Fahrenheit to Celsius and Celsius to Fahrenheit Conversion

°F	°C	°F	°C	°F	°C	°C	°F	°C	°F
-22	-30.0	30	-1.1	82	27.8	-30	-22.0	22	71.6
-21	-29.4	31	-0.6	83	28.3	-29	-20.2	23	73.4
-20	-28.9	32	0.0	84	28.9	-28	-18.4	24	75.2
-19	-28.3	33	0.6	85	29.4	-27	-16.6	25	77.0
-18	-27.8	34	1.1	86	30.0	-26	-14.8	26	78.8
-17	-27.2	35	1.7	87	30.6	-25	-13.0	27	80.6
-16	-26.7	36	2.2	88	31.1	-24	-11.2	28	82.4
-15	-26.1	37	2.8	89	31.7	-23	-9.4	29	84.2
-14	-25.6	38	3.3	90	32.2	-22	-7.6	30	86.0
-13	-25.0	39	3.9	91	32.8	-21	-5.8	31	87.8
-12	-24.4	40	4.4	92	33.3	-20	-4.0	32	89.6
-11	-23.9	41	5.0	93	33.9	-19	-2.2	33	91.4
-10	-23.3	42	5.6	94	34.4	-18	-0.4	34	93.2
-9	-22.8	43	6.1	95	35.0	-17	1.4	35	95.0
-8	-22.2	44	6.7	96	35.6	-16	3.2	36	96.8
-7	-21.7	45	7.2	97	36.1	-15	5.0	37	98.6
-6	-21.1	46	7.8	98	36.7	-14	6.8	38	100.4
-5	-20.6	47	8.3	99	37.2	-13	8.6	39	102.2
-4	-20.0	48	8.9	100	37.8	-12	10.4	40	104.0
-3	-19.4	49	9.4	101	38.3	-11	12.2		
-2	-18.9	50	10.0	102	38.9	-10	14.0		
-1	-18.3	51	10.6	103	39.4	-9	15.8		
0	-17.8	52	11.1	104	40.0	-8	17.6		
1	-17.2	53	11.7			-7	19.4		
2	-16.7	54	12.2			-6	21.2		
3	-16.1	55	12.8			-5	23.0		
4	-15.6	56	13.3			-4	24.8		
5	-15.0	57	13.9			-3	26.6		
6	-14.4	58	14.4			-2	28.4		
7	-13.9	59	15.0			-1	30.2		
8	-13.3	60	15.6			0	32.0		
9	-12.8	61	16.1			1	33.8		
10	-12.2	62	16.7			2	35.6		
11	-11.7	63	17.2			3	37.4		
12	-11.1	64	17.8			4	39.2		
13	-10.6	65	18.3			5	41.0		
14	-10.0	66	18.9			6	42.8		
15	-9.4	67	19.4			7	44.6		
16	-8.9	68	20.0			8	46.4		
17	-8.3	69	20.6			9	48.2		
18	-7.8	70	21.1			10	50.0		
19	-7.2	71	21.7			11	51.8		
20	-6.7	72	22.2			12	53.6		
21	-6.1	73	22.8			13	55.4		
22	-5.6	74	23.3			14	57.2		
23	-5.0	75	23.9			15	59.0		
24	-4.4	76	24.4			16	60.8		
25	-3.9	77	25.0			17	62.6		
26	-3.3	78	25.6			18	64.4		
27	-2.8	79	26.1			19	66.2		
28	-2.2	80	26.7			20	68.0		
29	-1.7	81	27.2			21	69.8		

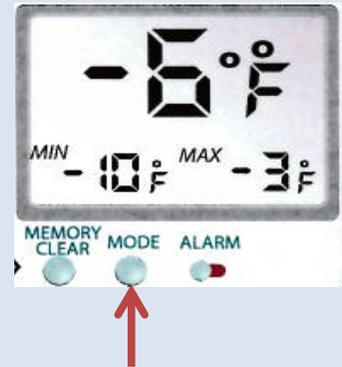
Recording Freezer Temperatures

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

Keep temperature logs for 3 years.

Set Mode Display to **-58°F Lo and 5°F Hi (-50°C Lo and -15°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 freezer since the memory was cleared or data was downloaded. The **MAX** shows the **warmest** temperature in the freezer 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)



Temperatures **5°F and below** are OK. Temperatures **above 5°F** are in **DANGER**.

The step numbers below correspond to the steps on the temperature log.

Step 1

- A.** Start a new log at the beginning of every month. Write the **month** and **year** and **location** of freezer if you have more than one.
- B.** Write your **initials**. Then write the a.m. or p.m. **time**.

Month/Year	September 2016
(Days 1-15)	
Freezer location:	Injection Room

Staff initials	LH	
Day of Month	1	
Time	8:00	
	a.m.	p.m.

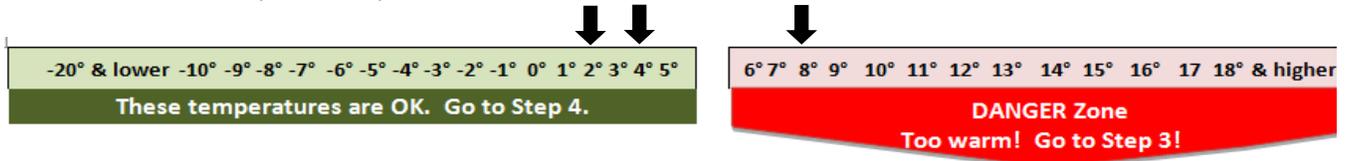
Step 2

- A.** Read the **CURRENT, MIN, and MAX** temperatures on the thermometer display. Write the temperatures in the space provided.

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

CURRENT	4
MIN	2
MAX	8

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

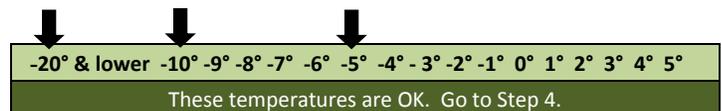


- C.** Circle all the temperatures that are in DANGER Zone (even if they are due to temporary causes, such as taking inventory). Then go to Step 3.

CURRENT	4
MIN	2
MAX	8

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

CURRENT	-10
MIN	-21
MAX	-5



Recording Freezer Temperatures (cont'd)

Step 3

- A. If temperatures are in a DANGER Zone, immediately take these actions, which are listed on the log.

DANGER Zone
Too warm! Go to Step 3!

If you ever see temps in Danger Zone (above 5°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 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!

- B. Document actions. Attach an extra sheet of paper to the log if you need more room.

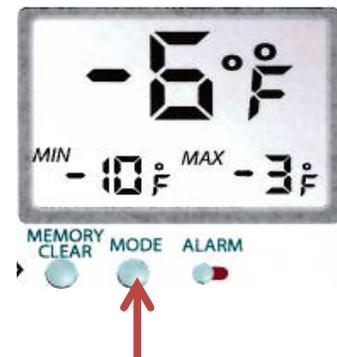
Document the date and actions you take: 9/6/13, 5pm warm temps due to taking inventory. Called VFC. Vaccines OK. Temps ok in 1 hour.

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 thermometer press the MEMORY CLEAR button on the thermometer **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.



Step 5

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

Freezer Temperature Log - Fahrenheit

Month/Year _____
Facility Name _____

(Days 1 - 15) VFC PIN: _____

Record **CURRENT, MIN, and MAX TEMPERATURES TWICE A DAY. COMPLETE Steps 1 – 4.**

**MAINTAIN FREEZER TEMPERATURES:
-58°F to 5°F**

Step 1 Write your initials and the time of day.

Step 2 Read the thermometer display. (See example at bottom right.) Write the temperatures below. Circle all temperatures that are in DANGER. (See zones below.) Then go to Step 3. If ALL temperatures are OK, go to Step 4.

Staff Initials	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Day of Month	AM	PM																												
Time																														
CURRENT																														
MIN																														
MAX																														

-20° & lower -10° -9° -8° -7° -6° -5° -4° -3° -2° -1° 0° 1° 2° 3° 4° 5°
These temperatures are OK. Go to Step 4.



6° 7° 8° 9° 10° 11° 12° 13° 14° 15° 16° 17° 18° & higher
DANGER Zone
Too warm! Go to Step 3!

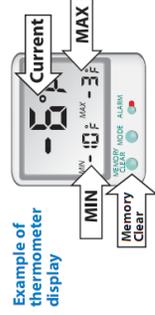
Step 3 If temps are in Danger Zone (above 5°F), even for a short time:

- Put a "Do Not use Vaccine" sign on the vaccines.
 - Alert your supervisor immediately.
 - If temps are in Danger Zone over 30 minutes – Call the manufacturers immediately, then complete the Incident Report.
- MUST document the Date and Actions taken:**
-
-

Step 4 For a Digital Min/Max thermometer: Press the MEMORY CLEAR button on the thermometer every time you finish logging temperatures.
For a Digital Data Logger or Continuous Monitoring Device: Weekly/monthly (recommended weekly) downloads from the data logger to a computer file are required to be completed.
(For further information, refer to your PA VFC Provider Handbook, Section 6)

Supervisor review of temperature logs recommended.

At the end of the month, file this log and keep it for 3 years.



1-888-646-6864



Freezer Temperature Log - Celsius

Month/Year _____

(Days 1 - 15)

VFC PIN: _____

Facility Name _____

Record CURRENT, MIN, and MAX TEMPERATURES TWICE A DAY. COMPLETE Steps 1 – 4.

Step 1 Write your initials and the time of day.

Step 2 Read the thermometer display. (See example at bottom right.) Write the temperatures below.

Circle all temperatures that are in DANGER. (See zones below.) Then go to **Step 3**.

If ALL temperatures are OK, go to **Step 4**.

MAINTAIN FREEZER TEMPERATURES:

-50°C to -15°C

Staff Initials	1		2		3		4		5		6		7		8		9		10		11		12		13		14		15	
Day of Month	AM	PM																												
Time																														

CURRENT

MIN

MAX

-27° & lower -26° -25° -24° -23° -22° -21° -20° -19° -18° -17° -16° -15°

These temperatures are OK. Go to Step 4.



-14° -13° -12° -11° -10° -9° -8° -7° -6° -5° -4° & higher

DANGER Zone

Too warm! Go to Step 3!

Step 3

If temps are in Danger Zone (above -15°C), even for a short time:

- Put a "Do Not use Vaccine" sign on the vaccines.
- Alert your supervisor immediately.
- If temps are in Danger Zone over 30 minutes – Call the manufacturers immediately, then complete the Incident Report.

MUST document the Date and Actions taken:

Step 4

For a Digital Min/Max thermometer: Press the MEMORY CLEAR button on the thermometer every time you finish logging temperatures.

For a Digital Data Logger or Continuous Monitoring Device: Weekly/monthly (recommended weekly) downloads from the data logger to a computer file are required to be completed.

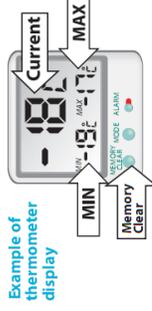
(For further information, refer to your PA VFC Provider Handbook, Section 6)

Supervisor review of temperature logs recommended.

At the end of the month, file this log and keep it for 3 years.

Revised Mar 2016 www.health.pa.gov

Page 1 of 2



Example of thermometer display



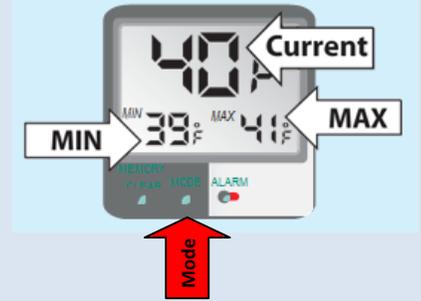
1-888-646-6864

Recording Refrigerator Temperatures

Record **CURRENT, MIN, AND MAX** temperatures in vaccine refrigerators twice a day. Keep temperature logs for 3 years.

Set Mode Display to 35°F Lo and 46°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 refrigerator since the memory was cleared or data was downloaded. The **MAX** shows the **warmest** temperature in the refrigerator since the memory was cleared or data was downloaded. MIN/MAX numbers tell you if temperatures were ever in a DANGER Zone since you last checked them. (See Step 2 for example.)



Temperatures between 35°F to 46°F are OK. Temperatures below 35°F and above 46°F are in DANGER.

The step numbers below correspond to the steps on the temperature log.

Step 1

- A.** Start a new log at the beginning of every month. Write the **month** and **year** and **location** of refrigerator if you have more than one.
- B.** Write your **initials**. Then write the a.m. or p.m. time.

Month/Year	September 2016
(Days 1-15)	
Refrigeration location:	Injection Room

Staff initials	LH	
Day of Month	1	
Time	8:00	
	a.m.	p.m.

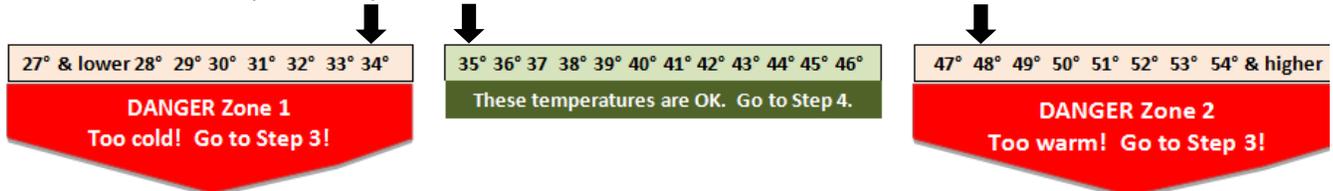
Step 2

- A.** Read the **CURRENT, MIN, and MAX** temperatures on the thermometer display. Write the temperatures in the space provided.

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

CURRENT	35
MIN	34
MAX	48

- B.** Check if the temperatures you recorded are OK or in DANGER Zones.



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

CURRENT	35
MIN	34
MAX	48

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

CURRENT	41
MIN	40
MAX	43

35° 36° 37° 38° 39° 40° 41° 42° 43° 44° 45° 46°
These temperatures are OK. Go to Step 4.

Step 3

- A. If temperatures are in a DANGER Zone, immediately take these actions, which are listed on the log.

DANGER Zone 1
Too cold! Go to Step 3!

If you ever see temps in Danger Zone 1 (below 35°F), even for a short time:

- Put a "Do Not Use Vaccine" sign on the vaccines.
- Alert your supervisor immediately.
- If temps are in Danger Zone over 30 minutes – **Call manufacturers immediately**, then complete the Incident Report.

The most damage to refrigerated vaccine happens when the vaccine gets too cold. You must take the action steps above if temperatures are ever below 35°F!

DANGER Zone 2
Too warm! Go to Step 3!

If temperatures are in Danger Zone 2 (above 46°F):

- Put a "Do Not Use Vaccine" sign on the vaccines.
- Alert your supervisor immediately .
- If temps are in Danger Zone over 30 minutes – **Call manufacturers immediately**, then complete the Incident Report.

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

- B. Document actions. Attach an extra sheet of paper to the log if you need more room.

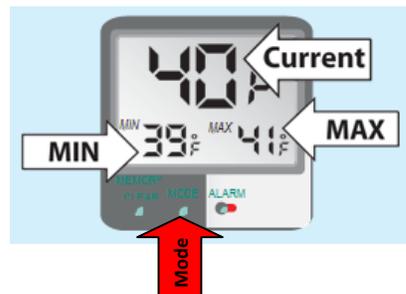
Document the date and actions you take: *9/6/13, 5pm warm temps due to taking inventory. OK in 1 hour.*

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

Step 4

For a Digital Min/Max thermometer press the MEMORY CLEAR button on the thermometer **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.



Step 5

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

Refrigerator Temperature Log - Fahrenheit

(Days 16 - 31) VFC PIN: _____

Month/Year _____
Facility Name _____

Record CURRENT, MIN, and MAX TEMPERATURES TWICE A DAY. COMPLETE Steps 1 – 4.

Step 1 Write your initials and the time of day.

Step 2 Read the thermometer display. (See example at bottom right.) Write the temperatures below.

Circle all temperatures that are in DANGER. (See zones below.) Then go to Step 3.

If ALL temperatures are OK, go to Step 4.

**MAINTAIN REFRIGERATOR TEMPERATURES:
35°F to 46°F**

Staff Initials	16		17		18		19		20		21		22		23		24		25		26		27		28		29		30		31	
Day of Month	AM	PM																														
Time																																

CURRENT																														
MIN																														
MAX																														

27° & lower 28° 29° 30° 31° 32° 33° 34°

DANGER Zone 1
Too cold! Go to Step 3!

35° 36° 37° 38° 39° 40° 41° 42° 43° 44° 45° 46°

These temperatures are OK. Go to Step 4.

AIM FOR 40°

47° 48° 49° 50° 51° 52° 53° 54° & higher

DANGER Zone 2
Too warm! Go to Step 3!

Step 3 If temps are in Danger Zone 1 (below 35°F), even for a short time:

- Put a "Do Not use Vaccine" sign on the vaccines.
- Alert your supervisor immediately.
- If temps are in Danger Zone over 30 minutes – Call the manufacturers immediately, then complete the Incident Report.

MUST document the Date and Actions taken:

Step 3 If temps are in Danger Zone 2 (above 46°F), even for a short time:

- Put a "Do Not use Vaccine" sign on the vaccines.
- Alert your supervisor immediately.
- If temps are in Danger Zone over 30 minutes – Call the manufacturers immediately, then complete the Incident Report.

Step 4

For a Digital Min/Max thermometer: Press the MEMORY CLEAR button on the thermometer every time you finish logging temperatures.

For a Digital Data Logger or Continuous Monitoring Device: Weekly/monthly (recommended weekly) downloads from the data logger to a computer file are required to be completed.

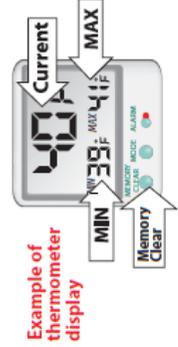
(For further information, refer to your PA VFC Provider Handbook, Section 6)

Supervisor review of temperature logs recommended.

At the end of the month, file this log and keep it for 3 years.

Revised Mar 2016 www.health.pa.gov

Page 2 of 2



1-888-646-6864

TRANSPORTING FROZEN VACCINES BY NECESSITY

CDC and Merck do NOT recommend transporting varicella-containing vaccines

Varicella containing vaccine to be transported in the original box in a portable freezer
(preferred by CDC and Merck)
or in a cooler with frozen packs for *less 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.

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

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

If temperatures are maintained at the recommended range
-58°F to +5°F (-50°C to -15°C), it is recommended Merck be contacted with details.

If the temperature is outside of the recommended range of
-58°F to +5°F (-50°C to -15°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°F to +5°F (-50°C to -15°C).
2. Label "DO NOT USE", 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°F to +5°F (-50°C to -15°C).
4. Merck National Service Center phone number is 1-800-672-6372. This number is open 7:00 AM to 8:00 PM. 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. An Incident Report will need completed and faxed to the PA VFC program at 717214-7223 within 5 days.

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 hourly during transport and through-out the duration of the clinic.

Diluent should travel with its corresponding vaccine and 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 outside of cooler should state "keep refrigerated", vaccine type, quantity, date, time, and originating facility.

Temperature monitoring: The CDC recommends digital data loggers for all temperature monitoring. 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 when using a digital data logger. When using a thermometer, hourly documentation is necessary.

Coolant: The CDC recommends use of conditioned frozen water bottles. Frozen water bottles and cold packs 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. Frozen cold packs must be conditioned at room temperature for two hours.

Insulating Materials: Premeasure: (2) pieces of corrugated cardboard and (2) one inch layers of bubble wrap or packing foam for each cooler. When using cold packs two inch layers of insulating materials are necessary.



HOW TO PACK VACCINE

1. Conditioned frozen water bottles or cold packs should be spread over the bottom of the cooler.
2. Completely cover conditioned frozen water bottles or cold packs 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 and two inches of insulating material if using cold packs.
4. Vaccine is placed on top of insulating materials with the refrigerated buffered probe of the monitoring device nestled between the layers of vaccine and 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 or cold packs are 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 35° F and 46° 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 35° F and 46° F for at least 5 days.

Vaccine Transport Hourly Monitoring

Date _____ Time prepared _____

Vaccine Packed by _____

Frozen Refrigerated (circle one) Vaccine Type _____

Lot Numbers _____

Total Doses _____ Inventory Sheet Attached

Diluents enclosed Yes No N/A (circle one)

VFC Provider & Pin Number _____

Person Transporting _____

TIME	TEMPERATURE		
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F
	am or pm	C	F

Facility Accepting Vaccine _____

Date Received _____ Time Received _____

Frozen Refrigerated (circle one) Vaccine Type _____

Lot Numbers _____

Total Doses _____ Inventory Sheet Attached

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

Signature of person transporting vaccine

Signatures on Inventory Sheet

Signature of person accepting vaccine

All vaccine transport forms must be kept on file for three years and be available on request.

Vaccine Transport Inventory Sheet

Date _____ Time prepared _____

VFC Provider & Pin Number _____

Vaccine Packed by _____

Frozen Refrigerated (circle one)

Diluents enclosed Yes No N/A (circle one)

VACCINE	BRAND NAME & NUMBER OF DOSES						LOT NUMBERS
DTaP	Daptacel		Tripedia		Infanrix		
DTaP-HepB-IPV	Pediarix						
Dtap-IPV-Hib	Pentacel						
Dtap-IPV	Kinrix						
Hep A-Peds	Havrix		Vaqta				
HepB	Engerix		Recombivax				
Hep B-Hib	Comvax						
Hib	ActHIB		PedvaxHIB		Hiberix		
HPV	Gardasil						
IPV polio	IPV						
MCV4 Mening	Menactra		Menveo		Bexsero		Trumenba
MMR	MMR						
MMRV	ProQuad						
PCV 13	Pevnar						
Pneumovax 23	PPV 23						
Rotavirus	Rotateq		Rotarix				
Td	Tenivac		Decavac				
Tdap	Adacel		Boostrix				
Varicella	Varivax						
OTHER							

Facility Accepting Vaccine _____

Date Received _____ Time Received _____

Frozen Refrigerated (circle one)

Diluents enclosed Yes No N/A (circle one)

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 _____

NIST CERTIFIED THERMOMETER/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 #
Lascar Electronics	www.lascarelectronics.com	814-835-0621
Control Solutions	www.vfcdataloggers.com	888-311-0636
LabRepCo	www.labrepco.com	800-521-0754
Fisher Healthcare	www.fishersci.com	800-766-7000
Traceable Products	www.traceable.com	281-482-1714
Weber Scientific	www.weberscientific.com	800-328-8378
Sper Scientific	www.sperdirect.com	480-948-4448
Delta Trak	www.deltatrak.com	800-962-6776
Grainger	www.grainger.com	800-472-4643
Dickson	www.dicksondata.com	800-757-3747
Berlinger USA LLC	http://www.berlinger.com	508-366-0084
VWR	www.vwrsp.com	800-932-5000
Madgetech	www.madgetech.com	603-456-2011
ThermCo Products, Inc.	www.thermcoproducts.com	973-300-9100

PA Vaccines for Children (VFC) 2016 DIGITAL DATA LOGGER (DDL) POLICY

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

Continuous Monitoring Devices:

CDC recommends using 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 (am and pm)
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 35°F/Max 46°F (Min 2°C/Max 8°C)
 - **Freezer** Min -58°F /Max 5°F (Min -50°C /Max -15°C)
2. Set recording duration intervals (every 15 minutes is recommended; but will accept up to every 30 minutes)

Data Storage and Download Requirements:

1. Weekly/monthly (recommended weekly) downloads from the data logger to a computer file are required to be completed. This downloaded data should be kept for at least 3 years and be accessible by staff members.
2. Keep temperature logs for at least 3 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 a digital display
3. Must have an alarm for OOR temperatures (recommend both visual and audible)
4. Low battery indicator
5. Accuracy of +/- 1°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 will accept up to every 30 minutes)
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)
 - Measure results indicate passing with uncertainty = +/- 1° F (0.5° C)
 - Statement that calibration testing conforms to ISO 17025
12. Detachable probe must be encased in a biosafe buffered material
 - VFC highly recommends a biosafe glycol buffer; but will accept the following 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 and complete incident report
4. Call the Division of Immunizations directly
 - Report the incident for further instructions
 - Phone 1-888-646-6864 ask for the VFC QA nurse

Maintaining Temperatures and the Cold Chain:

1. Maintain proper temperature for vaccine storage
 - Refrigerator: 35° to 46° Fahrenheit / 2° to 8° Celsius
 - Average 40° Fahrenheit (5° Celsius)
 - Freezer: - 58° to 5° Fahrenheit /-50° to -15° Celsius
 - Average 0° Fahrenheit (-18° Celsius)
2. Ensure working thermometers are used inside both refrigerators and freezers. NIST certified thermometers, calibrated per manufacturer's recommendations are required for vaccine storage. Thermometer 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 5 days of incident. Instruction and Forms are available in Section 6F Provider Handbook.
6. Providers are responsible for the maintenance and NIST recalibration of all temperature monitoring devices/thermometers. Newly purchased units and recalibrations are at the expense of the provider site.

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:

Standalone storage units, medical grade preferred.

Household combination unit, using refrigerator portion only, must have separate stand alone freezer.

Medical grade combination units must have a separate compressor for each function

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

New providers are strongly recommended to use Medical grade stand-alone freezers & stand-alone freezerless refrigerators for vaccine storage. Absolutely No DORMITORY or BAR style units will be allowed.

Providers with a DOH approved household combination units will be given 90 days to acquire a stand-alone freezer.

During the 90 days, the provider will NOT be allowed to order additional frozen VFC vaccine.

Providers making no accommodation to acquire a stand –alone freezer within 90 days will be suspended from ordering all VFC vaccines.

Providers will remain suspended until a stand-alone freezer is acquired.

After one year of suspension, the provider will be disenrolled from the VFC program.

Effective 2017, 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.

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 to 8 degrees C or 35 to 46 degrees

Capable of maintaining freezer temperature of -50 to 15 degrees C or -58 to +5 degrees F

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

Enough space to store frozen water bottles or coolant packets in the freezer to hold temperature

Capable of housing a calibrated thermometer accurate to +/- 0.5 degrees C or +/- 1 degree F

Calibrated digital display thermometer/data logger with probe centrally located in the storage unit

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

Cleaned/ Defrosted on a monthly basis

Able to rotate inventory on a weekly basis

Identified in the circuit breaker box

Labelled with do NOT unplug stickers

The provider should have maintenance/service contacts established

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	www.aegisfridge.com	1-800-796-2344
American BioTech Supply	www.americanbiotechsupply.com	1-800-648-4041
Fisher Scientific	www.fishersci.com	1-800-640-0640
Follett	www.follettice.com	1-800-523-9361, 610-252-7301
Geneva Scientific	www.Geneva-Scientific.com	1-877-436-3827
Haier (not all models acceptable)	www.haier.com	1-877-337-3639
Helmar	www.helmerinc.com	1-800-743-5637
LAB RepCo	www.labrepco.com	1-800-521-0754
Migali Scientific	www.migaliscientific.com	1-855-464-4254
Panasonic purchased Sanyo	www.us.panasonic-healthcare.com www.sanyobiomedical.com	1-800-858-8442
Sears (not all models acceptable)	www.sears.com	1-800-349-4358
Summit	www.summitmedicalrefrigerators.com	1-718-893-3900
Sun Frost	www.sunfrost.com	1-707-822-9095
Thermo Scientific	www.thermoscientific.com	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	www.amazon.com	1-888-280-4331
AtBatt	www.atbatt.com	1-877-528-2288
Control Solutions	www.vfcdataloggers.com	1-503-410-5996
Supply Link, Inc.	supply-link@hotmail.com	1-614-565-2084
Lascar Electronics	www.lascarelectronics.com	1-814-835-0621
RadioShack	www.radioshack.com	1-800-843-7422
Walmart	www.walmart.com	1-800-925-6278

Examples of common batteries:



RESOURCES AND WEBSITES

RESOURCE	TELEPHONE #	FAX #	WEBSITE
Division of Immunizations (DOI)	717-787-5681 <u>Toll Free</u> 1-888-646-6864	DOI office 717-214-7223 vaccine orders 717-441-3800	General E-Mail Account: PAIMMUNIZATIONS@PA.GOV
PA Department of Health	1-877-PAHEALTH		WWW.HEALTH.PA.GOV
Centers for Disease Control and Prevention (CDC)	1-800-232-2522		http://www.cdc.gov/vaccines/
Vaccine Adverse Event Reporting System (VAERS)	1-800-822-7967		http://vaers.hhs.gov/index
Statewide Immunization Information System	1-717-783-2548		www.health.pa.gov
PA Department of Human Services			WWW.DHS.PA.GOV

RESOURCE	TELEPHONE #	FAX #	WEBSITE
GlaxoSmithKline (Novartis)	1-866-475-8222	215-599-9179	http://us.gsk.com/en-us/vaccines
MedImmune	1-301-398-0000		WWW.MEDIMMUNE.COM
Merck & Co., Inc.	1-877-829-6372		WWW.MERCKVACCINES.COM
Pfizer	1-800-572-8221		http://www.pfizer.com/products
Sanofi Pasteur	1-800-822-2463		http://www.sanofi.us//us/
Advisory Committee on Immunization Practices			<a href="http://WWW.CDC.GOV/VACCINES/RECS/ACIP/D
EFAULT.HTM">HTTP://WWW.CDC.GOV/VACCINES/RECS/ACIP/D EFAULT.HTM
American Academy of Pediatrics			WWW.AAP.ORG
Immunization Action Coalition			WWW.IMMUNIZE.ORG

RESOURCE	TELEPHONE #	FAX #	WEBSITE
American Academy of Family Physicians			WWW.AAFP.ORG
General Recommendations on Immunizations			http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf
Guide to Contraindications to Vaccinations			http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm
VFC-ACIP Vaccine Resolutions			http://www.cdc.gov/vaccines/programs/vfc/providers-resolutions.htm
VFC Provider Handbook			http://www.health.pa.gov/My%20Health/Immunizations/Vaccines-for-Children/Pages/VFC-Provider-Handbook.aspx#.VPcWNXco5D8

ACRONYMS

ACIP	Advisory Committee on Immunization Practices
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare & Medicaid Services
CPT	Current Procedural Terminology
DDL	Digital Data Logger
DOI	Division of Immunizations
FDA	Food and Drug Administration
FED-EX	Federal Express
FQHC	Federally Qualified Health Center
HEDIS	Healthcare Effectiveness Data Information Set
ILAC	International Laboratory Accreditation Cooperation
IR	Incident Report
MA	Medical Assistance
MOU	Memorandum of Understanding
NDC	National Drug Code
NIST	National Institute of Standards & Technology
OBRA	Omnibus Budget Reconciliation Act
PA DHS	Pennsylvania Department of Human Services
PA DOH	Pennsylvania Department of Health
PA-SIIS	Pennsylvania Statewide Immunization Information System
PA VFC	Pennsylvania Vaccines for Children Program
PA VFC PPA	Pennsylvania Vaccines for Children Participating Provider Agreement

PIN	Provider Identification Number
RHC	Rural Health Clinic
UPS	United Parcel Service
VAERS	Vaccine Adverse Event Reporting System
VICP	National Vaccine Injury Compensation Program
VIS	Vaccine Information Statement
VFC	Vaccines for Children Program