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Instructions for Completing the 2019 PA VFC Program Provider Agreement

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

PA Vaccines for Children Program Provider Agreement

TYPE OF AGREEMENT:

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

FACILITY INFORMATION:

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

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

FACILITY TYPE

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

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

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

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

MEDICAL DIRECTOR OR EQUIVALENT

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

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

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

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

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

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

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

SUBMISSION OF THE COMPLETE INFORMATION

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

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

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

Note:

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

2019 Pennsylvania Vaccines for Children Program Provider Agreement

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

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

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

Check one: <input type="radio"/> NEW <input type="radio"/> REACTIVATION <input type="radio"/> UPDATE			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? (<i>check one</i>)			<input type="radio"/> Yes <input type="radio"/> No	Office Email:
Type of facility: (<i>please only check one</i>):				
<input type="checkbox"/> Family Practice/General Practitioner; Internal Medicine; <input type="checkbox"/> OB/GYN; <input type="checkbox"/> Pediatrician; <input type="checkbox"/> Federally Qualified Health Center (FQHC); <input type="checkbox"/> Rural Health Clinic (RHC); <input type="checkbox"/> Other:				
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:				

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

VFC PIN#

ANNUAL TRAINING REQUIREMENT (please check box to indicate compliance)

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

VACCINES OFFERED (select only one box)

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

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

SELECT VACCINES OFFERED BY SPECIALTY PROVIDER:

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

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

VFC Pin#:

PROVIDERS PRACTICING AT THIS FACILITY

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

Provider Name	Title	License #	MA ID or NPI#

Please indicate any changes to practice staff below:

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

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

PROVIDER AGREEMENT

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

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

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

9.	<p>I will comply with the requirements for vaccine management including:</p> <ul style="list-style-type: none"> 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 healthcare. It also includes recipient practices that result in unnecessary cost to the Medicaid program.</p>
11.	<p>I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.</p>
12.	<p>For providers with a signed deputization Memorandum of Agreement between a FQHC or RHC and the Pennsylvania Department of Health to serve underinsured VFC-eligible children, I agree to:</p> <ul style="list-style-type: none"> 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 and Email:</p>	
<p>Title:</p>	<p>Specialty:</p>
<p>Physician License#:</p>	<p>Medicaid or NPI#</p>
<p><i>By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable for compliance with these requirements.</i></p> <p><input type="checkbox"/> Checking this box acknowledges my signature below.</p>	
<p>Medical Director (Physician) Signature:</p>	<p>Date:</p>

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

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



CHIP Patients are not eligible for VFC vaccines

Medicaid patients are eligible for VFC vaccines



Aetna Better Health

CHIP Card:

- "Kids"

Medicaid Card:

- Aetna Better Health



Blue Cross of NEPA

CHIP Card:

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



Medicaid not offered by this Carrier



Keystone Health Plan Central

CHIP Card:

- "Capital Cares 4 Kids" logo



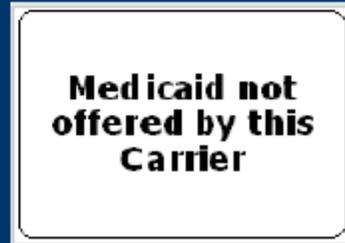
Medicaid not offered by this Carrier



HighMark Keystone Health Plan West

CHIP Card:

- "Y-18"



Medicaid not offered by this Carrier



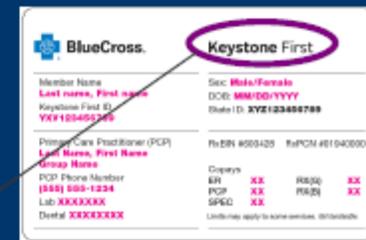
Keystone Health Plan East

CHIP Card:

- "PA Kids" logo

Medicaid Card:

- "Keystone First" logo



Continued: CHIP vs. Medicaid Insurance Cards



CHIP Patients are not eligible for VFC vaccines

Medicaid patients are eligible for VFC vaccines



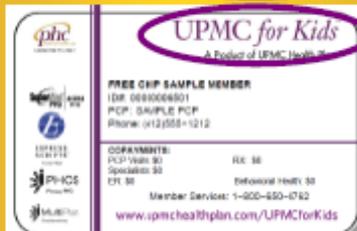
Geisinger Health Plan
CHIP Card:
 • "GHP Kids"
Medicaid Card:
 • Geisinger Health Plan



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



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



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



CHIP not offered by the following Medicaid carriers



Pa. VFC Eligibility/Insurance

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

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

Coverage Type	Eligible for PA VFC
Uninsured No insurance	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 even if they have any other type of primary health care coverage/insurance plan.

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

*PA Medical Assistance and Medical Assistance Managed Care Plans.

**CHIP Contractors 2019

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

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

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

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

1. Child's name: _____

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

Last name
First name
MI
4. Primary provider name: _____

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

	Eligible for VFC Vaccine				Not Eligible for VFC Vaccine		
	A	B	C	D	E	F	G
Date	Medicaid enrolled	No health insurance	American Indian or Alaska Native	*Underinsured served by FQHC, RHC or deputized provider	Has health insurance covering 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), Rural Health Clinic (RHC) or under an approved deputized provider. The deputized provider must have a written agreement with an FQHC/RHC and the state/local/territorial immunization program in order to vaccinate underinsured children.

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

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

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



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

Signature of person completing this form: _____

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

Facility name:

Pin #:

VACCINE BORROWING REPORT

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

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

COMPLETE THIS FORM WHEN:

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

HOW TO COMPLETE THIS FORM:

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

Reason for vaccine borrowing and replacement coding legend

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

WHAT TO DO WITH THIS FORM:

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

PA VFC DOSE TRACKING FORM



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

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

Vaccine Emergency Handling Procedures and Disaster Recovery Plan

Provider Site Name: _____

Address: _____

Telephone: _____

Date: _____ Person Completing Form: _____

VFC Coordinator: _____ Title: _____ Phone: _____

Cell #: _____ Email: _____

Back-up: _____ Title: _____ Phone: _____

Cell #: _____ Email: _____

Physician: _____ Title: _____ Phone: _____

Cell #: _____ Email: _____

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

Advanced Planning and Preparations Prior to Emergency

All Providers Must:

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

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

Vaccine Storage Unit Specifications

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

During Emergency Event:

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

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

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

In an emergency, call the following people immediately:

Primary Contact: _____ Phone: _____ Cell: _____

Backup Contact: _____ Phone: _____ Cell: _____

Physician Contact: _____ Phone: _____ Cell: _____

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

Original Emergency Handling Procedures Date: _____

Revision of Emergency Handling Procedures Date: _____

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

PA VFC Vaccine Management Plan and Designated Responsible Staff

VFC PIN#: _____ NAME: _____

Update Vaccine Management Plan and Designated Responsible Staff document annually.

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

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

Vaccine Storage Maintenance Reminder

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

Defrost Freezer Unit Monthly

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

Certificate of NIST digital data loggers

Date _____

Date _____

Model/Serial #

Date _____

Date _____

Annual/biannual recalibration of NIST digital data loggers

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

Yearly service of storage unit

(Recommended)

Vaccine Incident Report and Worksheet Instructions

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

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

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

Please Follow the Steps Below

1. If vaccine temperatures are out of recommended ranges for **less** than 30 minutes during temperature logging, you **must** take immediate action to correct the problem and document the action taken on the temperature log or attach an explanation of action taken.
 - Document corrective action taken on the temperature log and recheck temperatures every 30 minutes to ensure temperatures have returned to acceptable ranges. If there is not enough space on the temperature log to document corrective action taken, please write action taken on a separate sheet of paper and attach to temperature log. Retain for three years.

2. For temperatures that remain out of range for **more** than 30 minutes, **immediately** call the manufacturers and complete the Vaccine Incident Report and Worksheet forms (pages 1-4). Also complete a Vaccine Return and Accountability form (Section 6 – Forms) if vaccines are wasted and submit to Pa. VFC Program within five days of the incident.
 - List all details on the incident report.
 - Include a description of incident.
 - Describe incident resolution.
 - Include a corrective action plan.
 - Answer all questions on the report.
 - List all vaccines that were in the affected storage unit at the time of the incident (i.e., name, lot number, expiration, doses).
 - Write manufacturers recommendations, along with case number if available. (Record doses keeping, destroying and returning).
 - Attach copy of temperature log to incident report and fax to 717-214-7223.

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

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

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

Temperature log and calibration certificate

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

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

Temperature logs complete and copy included with the incident report

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

Vaccine waste

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

Details of contact with manufacturers are documented on vaccine worksheet.

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

Revaccination (Complete only if revaccination is necessary.)

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

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

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

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

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

Vaccine Incident Report and Worksheet Instructions

If temperatures are out of range less than 30 minutes:

Take immediate action to correct the problem.

Document corrective action on Step 3 of temperature log.

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

If temperatures are out of range more than 30 minutes:

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

VACCINE	MANUFACTURER	TELEPHONE #
DTaP (Daptacel), DTaP- IPV-Hib (Pentacel) IPOL (Polio), Flu, Hib (ActHib), Meningococcal (MCV4), Td, Tdap (Adacel)	Sanofi Pasteur https://www.sanofi.us/en	1-800-822-2463
Hep A (Vaqta), Hep B (Recombivax), Hib (PedvaxHib), HPV (Gardasil9), MMR, MMRV (Proquad), Pneumococcal PPV23 (Pneumovax), Rotavirus (RotaTeq), Varicella (Varivax)	Merck www.merck.com	1-800-672-6372
DTaP (Infanrix), DTaP-IPV-HepB (Pediarix), DTaP-IPV (Kinrix), Flu, Hep A (Havrix), Hep B PF (Engerix) Tdap (Boostrix), Shingrix, Twinrix, 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
FluMist	AstraZeneca www.astrazeneca.com/	1-877-633-4411
Flucelvax, Afluria, Fluvirin, Fluad	Seqirus www.seqirus.com	1-855-358-8966

Vaccine worksheet is completed to document manufacturer recommendation.

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

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

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

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

VACCINE RETURN AND ACCOUNTABILITY

PENNSYLVANIA DEPARTMENT OF HEALTH

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

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

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

UNOPENED: Is a box of 10 single dose vials with three doses administered – the remaining seven doses are considered “unopened”;

Is a five-pack of syringes with only two doses administered, the remaining three syringes are considered “unopened”; and

Includes situations in which the original packaging (box) of any vaccine is missing, but the vial/syringe still has the plastic cap/safety cap on and has not been punctured.

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

WASTED: Is any vaccine that has been drawn up but not administered;

Is a vial or syringe that is accidentally broken;

Includes open/partial vials exposed to out-of-range temperatures, power outages, unit failures or expired vaccines.

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

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

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

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

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

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

Sample of the email

The email reads:

[UPS Label Delivery, 1Z2R43839097612737](#)

UPS Returns Label Delivery

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

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

[View UPS Returns Documentation Instructions](#)

[Retrieve Your Shipment Label.](#)

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

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

WASTED / DESTROYED

NON-VIABLE, NON- RETURNABLE VACCINE FORM

VTckS Waste ID: _____

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

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

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

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

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

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

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

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

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

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

NON-VIABLE RETURNABLE VACCINE FORM

VTrckS Return ID: _____

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

Date: _____ Person reporting _____ VFC PIN #: _____
 Site name: _____ Phone #: _____

Was an incident report submitted for these vaccines? Yes No

Will an incident report be submitted for these vaccines? Yes No

Does this facility have routine UPS service? Yes No

If yes, do you prefer UPS shipping label sent via email? Yes No

If facility does not have UPS service, would you prefer UPS shipping label sent via email? Yes/No

Email address: _____ # of shipping labels needed _____

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

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

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

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

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

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

Non-Viable returnable vaccines Reason Code includes:

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

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

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

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

Interim/Final Status Report Following Cold Chain Failure

Pin # _____ Date cold chain failure discovered _____

Name and address of provider site:

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

Method used to contact clients: Phone Letter Other

(Attach a copy of the letter if applicable.)

Number of clients revaccinated _____ Number of clients not revaccinated _____

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

Why were clients not revaccinated? Client refusal Physician refusal Other

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

Number of doses of each vaccine administered to date:

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

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

Overall progress toward completion of revaccination per physician: _____

Any further action needed? _____

Signature of Physician: _____

Date: _____

VFC Frequently Asked Questions

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

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

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

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

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

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

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

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

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

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

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

Question: Where do I get my patient population numbers?

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

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

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

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

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

Enrollment and VFC Eligibility

1. What are the requirements for enrolling with VFC?

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

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

2. Is there a fee to enroll with VFC?

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

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

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

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

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

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

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

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

5. Which patients are eligible to receive VFC vaccines?

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

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

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

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

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

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

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

7. Where do I get my patient population numbers?

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

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

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

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

10. Does VFC provide vaccines to adults?

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

Storage and Handling

11. What are the VFC requirements for vaccine storage?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20. Does VFC supply free data loggers to providers?

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

Statewide Immunization Information System - SIIS

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

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

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

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

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

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

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

Requesting for VFC Vaccines

25. How often should I request for vaccines?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recording Vaccine Temperatures

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

Keep temperature logs for **3 years**.

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

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

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



Refrigerator units: Temperatures 35.9°F or lower are out of range and require incident report to PA VFC program.
Temperatures 46.1°F or higher are out of range and require incident report to PA VFC program.

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



Step 1

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

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

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

Initial on correct line for am or pm.

Month/Year _____ VFC Pin # _____

Facility Name _____

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

Step 2

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

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

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

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

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

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

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

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

(Continued on next page)

Recording Vaccine Temperatures (cont'd)

Step 3

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

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

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

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

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

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

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

Step 4

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

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

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



Step 5

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

PA VFC Fahrenheit Refrigerator Temperature Log

Facility Name _____

Month/Year _____

VFC Pin # _____

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

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

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

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

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

Attach additional _____
pages as needed.

PA VFC Fahrenheit Freezer Temperature Log

Facility Name _____

Month/Year _____

VFC Pin # _____

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

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

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

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

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

Attach additional _____
pages as needed.

PA VFC Celsius Refrigerator Temperature Log

Facility Name _____

Month/Year _____

VFC Pin # _____

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

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

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

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

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

Attach additional _____
pages as needed.

PA VFC Celsius Freezer Temperature Log

Facility Name _____

Month/Year _____

VFC Pin # _____

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

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

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

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

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

Attach additional _____
pages as needed.

TRANSPORTING FROZEN VACCINES BY NECESSITY

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

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

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

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

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

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

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

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

TRANSPORTING REFRIGERATED VACCINES

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

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

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

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

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

Materials for transport must be readily available at all times.

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

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

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

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



HOW TO PACK VACCINE

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

Vaccine Transport Inventory Sheet

VFC Provider Site Name: _____ Pin #: _____

Vaccine packed by: _____ Date: _____ Time prepared: _____

Type of vaccine (Circle one) Frozen / Refrigerated

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

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

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

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

Facility accepting vaccine: _____

Date received: _____ Time received: _____

Type of vaccine (Circle one) Frozen / Refrigerated

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

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

Signature of person storing vaccine: _____

Signature of person accepting vaccine: _____

Vaccine Transport Monitoring Sheet

VFC provider site name: _____ PIN #: _____

Vaccine packed by: _____ Date: _____ Time prepared: _____

Type of vaccine (Circle one.) Frozen/refrigerated

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

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

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

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

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

Facility accepting vaccine: _____

Date received: _____ Time received: _____

Type of vaccine (Circle one.) Frozen/refrigerated

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

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

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

Signature of person storing vaccine: _____

Signature of person accepting vaccine: _____

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

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

NIST-CERTIFIED DIGITAL DATA LOGGER MANUFACTURERS

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

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



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

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

Continuous Monitoring Devices:

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

Temperature Monitoring:

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

Data Logger Settings:

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

Data Storage and Download Requirements:

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

Digital Data Logger Minimum Requirements:

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

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

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

Maintaining Temperatures and the Cold Chain:

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

Pre-Purchase Worksheet for Digital Data Logger

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

Instructions for using this worksheet:

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

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

BEST PRACTICES IN VACCINE STORAGE

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

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

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

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

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

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

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

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

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

The cold storage unit selected must be:

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

Large enough to accommodate the year's largest inventory;

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

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

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

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

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

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

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

Cleaned/defrosted monthly;

Able to rotate inventory on a weekly basis;

Identified in the circuit breaker box; Labelled with do NOT unplug stickers; and

The provider should have maintenance/service contacts established.

Vaccine Manufacturer/Distributor Contact List

Manufacturer/Distributor Websites	Telephone/E-mail	Products
ACAM2000 Sanofi Pasteur https://www.sanofi.us/en/products-and-resources/vaccines	800-822-2463 www.sanofi.us/en/products-and-resources/vaccines	Smallpox
bioCSL https://www.seqirus-us.com/	855-358-8966 cs.flu@seqirus.com	IIV cclIV4, aIIIVE
Centers for Disease Control and Prevention https://www.cdc.gov/ncezid/dsr/index.html https://www.cdc.gov/laboratory/drugservice/index.html	404-639-3670 drugservice@cdc.gov	Distributor for anthrax vaccine adsorbed (AVA), diphtheria antitoxin, smallpox vaccine
CSL Limited (Merck distributor) www.merckvaccines.com/	800-637-2590	IIV
Emergent BioDefense Operations Lansing, Inc. http://www.biothrax.com/	877-246-8472 productsafety@ebsi.com	Anthrax vaccine adsorbed (AVA)
GlaxoSmithKline (GSK) www.gskvaccines.com/	866-475-8222 vaccine.service-center@gsk.com	DTaP, DTaP-HepB-IPV, DTaP-IPV, HepA, HepB, HepA-HepB, Hib, IIV, JE, MenB-4C, MenACWY-CRM, Rabies, RV1, RZV, Tdap
Massachusetts Biological Labs https://www.umassmed.edu/massbiologics/	800-457-4626	Td
AstraZeneca https://www.astrazeneca.com/	800-236-9933	LAIV, RSV

Manufacturer/Distributor Websites	Telephone/E-mail	Products
Merck & Co., Inc. www.Merckvaccines.com	877-829-6372	HepA, HepB, Hib, 9vHPV, ZVL, MMR, MMRV, PPSV23, RV5, VAR
Novartis https://www.novartis.com/	862-778-2100	IIV
PaxVax https://www.paxvaxconnect.com/vivotif	888-483-9053	Cholera (oral) Typhoid (oral)
Pfizer http://www.pfizer.com/products	800-438-1985	MenB-FHbp, PCV13
Sanofi Pasteur https://www.sanofi.us/en/products-and-resources/vaccines	800-822-2463	DT, DTaP, DTaP-IPV/Hib, DTaP-IPV, Hib, IIV, IPV, MenACWY-D, Rabies, Td, Tdap, Typhoid, YF
Seqirus www.seqirus-us.com/	855-358-8966 Customerservice.us@seqirus.com	IIV, ccIIV4, aIIV3
Valneva (Intercell distributor) https://www.valneva.com/en/	301-556-4500	Japanese Encephalitis, Cholera

Vaccine Coordinator roles and responsibilities

Designate a person to be the primary vaccine coordinator for your facility. This person will be responsible for ensuring all vaccines are stored and handled correctly. Appoint a second staff member to serve as an alternate in the absence of the primary coordinator (this is particularly important in case of after-hours emergencies). Both coordinators should be fully trained in routine and emergency policies and procedures.

Coordinator responsibilities:

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

Staff Training

All staff members who receive deliveries and/or handle or administer vaccines should be familiar with storage and handling policies and procedures at your facility. Keep standard operating procedures for storage and handling near storage units and make sure staff knows where to find them.

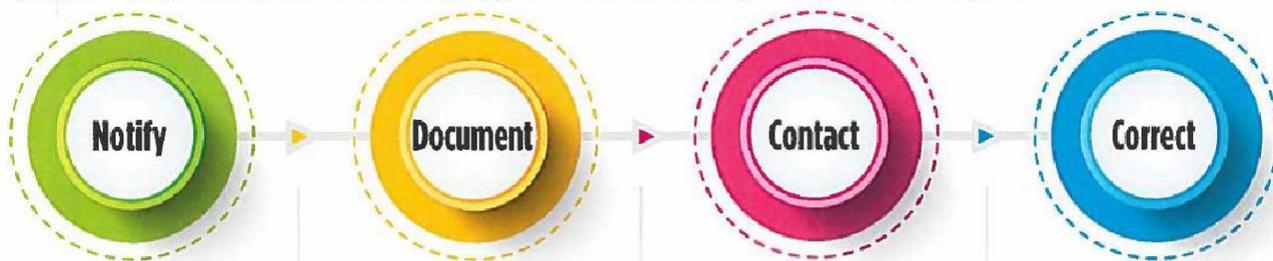
CDC recommends that storage and handling training should be done:

- As part of new employee orientation;
- Annually as a refresher for all staff involved in immunization activities;
- Whenever new vaccines are added to inventory; and
- Whenever recommendations are updated.

The coordinator will also maintain the Vaccines for Children email (RA-PAVFC@pa.gov) on your safe senders list to ensure you receive the important communications from the VFC program.

Handling a Temperature Excursion in Your Vaccine Storage Unit

Any temperature reading outside ranges recommended in the manufacturers' package inserts is considered a temperature excursion. Identify temperature excursions quickly and take immediate action to correct them. This can prevent vaccine waste and the potential need to revaccinate patients.



- » Notify the primary or alternate vaccine coordinator immediately or report the problem to a supervisor.
- » Notify staff by labeling exposed vaccines, "DO NOT USE," and placing them in a separate container apart from other vaccines in the storage unit. Do not discard these vaccines.

- » Document details of the temperature excursion:
 - Date and time
 - Storage unit temperature (including minimum/maximum temperatures during the time of the event, if available)
 - Room temperature, if available
 - Name of the person completing the report
 - General description of the event (i.e., what happened)
 - If using a digital data logger (DDL), determine the length of time vaccine may have been affected
 - Inventory of affected vaccines
 - List of items in the unit other than vaccines (including water bottles)
 - Any problems with the storage unit and/or affected vaccines before the event
 - Other relevant information

- » Contact your immunization program and/or vaccine manufacturer(s) for guidance per your standard operating procedures (SOPs).
- » Be prepared to provide the manufacturer or immunization program with documentation and DDL data so they can offer you the best guidance.

Contact manufacturer for excursions:

Merck	1-800-672-6372
Sanofi Pasteur	1-800-822-2463
GlaxoSmithKline	1-888-825-5249
Pfizer	1-800-438-1985
Seqirus	1-855-358-8966

- » If the temperature alarm goes off repeatedly, do not disconnect the alarm until you have determined and addressed the cause.
- » Check the basics, including:
 - Power supply
 - Unit door(s)
 - Thermostat settings
- » If the excursion was the result of a temperature fluctuation, refer to the chapter, "Vaccine Storage and Temperature Monitoring Equipment," in CDC's *Vaccine Storage and Handling Toolkit* for detailed guidance on adjusting storage unit temperature to the appropriate range.
- » If you believe the storage unit has failed, implement your emergency vaccine SOPs. Never allow vaccines to remain in a nonfunctioning unit.



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

CS248275-BG

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	https://www.americanbiotechsupply.com/	1-800-648-4041
Fisher Scientific	www.fishersci.com	1-800-640-0640
Follett	www.follettice.com	1-800-523-9361
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
Minibar RX	http://minibarrx.com/	1-215-583-3022
Panasonic purchased Sanyo	https://www.phchd.com/us/biomedical/	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	https://us.gsk.com/en-us/products/our-vaccines/
Merck & Co., Inc.	1-877-829-6372		WWW.MERCKVACCINES.COM
Pfizer	1-800-438-1985		http://www.pfizer.com/products
Sanofi Pasteur	1-800-822-2463		https://www.sanofi.us/en/products-and-resources/vaccines
Seqirus	1-855-358-8966		https://www.seqirus-us.com/
Advisory Committee on Immunization Practices			https://www.cdc.gov/vaccines/acip/index.html
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			https://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html
VFC Provider Handbook			https://www.health.pa.gov/topics/programs/immunizations/Pages/VFC.aspx



Documenting Parental Refusal to Have Their Children Vaccinated

345 Park Blvd
Itasca, IL 60143
Phone: 630/626-6000
Fax: 847/434-8000
E-mail: kidsdocs@aap.org
www.aap.org

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All parents and patients should be informed about the risks and benefits of preventive and therapeutic procedures, including vaccination. In the case of vaccination, the American Academy of Pediatrics (AAP) strongly recommends and federal law mandates that this discussion include the provision of the Vaccine Information Statements (VISs). Despite our best efforts to educate parents about the effectiveness of vaccines and the realistic chances of vaccine-associated adverse events, some will decline to have their children vaccinated. This often results from families misinterpreting or misunderstanding information presented by the media and on unmonitored and biased Web sites, causing substantial and often unrealistic fears.

Within a 12-month period, 74% of pediatricians report encountering a parent who refused or delayed one or more vaccines. A 2011 survey of children six months to six years of age reported that 13% of parents followed an alternative vaccination schedule. Of these, 53% refused certain vaccines and 55% delayed some vaccines until the child was older. Seventeen percent reported refusing all vaccines. In a 2009 survey, 11.5% of parents of children 17 years and younger reported refusing at least one vaccine. The use of this or a similar form in concert with direct and non-condescending discussion can demonstrate the importance you place on appropriate immunizations, focuses parents' attention on the unnecessary risk for which they are accepting responsibility, and may in some instances induce a wavering parent to accept your recommendations.

Providing parents (or guardians) with an opportunity to ask questions about their concerns regarding recommended childhood immunizations, attempting to understand parents' reasons for refusing one or more vaccines, and maintaining a supportive relationship with the family are all part of a good risk management strategy. The AAP encourages documentation of the health care provider's discussion with parents about the serious risks of what could happen to an unimmunized or under-immunized child. Provide parents with the appropriate VIS for each vaccine at each immunization visit and answer their questions. For parents who refuse one or more recommended immunizations, document your conversation and the provision of the VIS(s), have a parent sign the Refusal to Vaccinate form, and keep the form in the patient's medical record. The AAP also recommends that you revisit the immunization discussion at each subsequent appointment and carefully document the discussion, including the benefits to each immunization and the risk of not being age-appropriately immunized. For unimmunized or partially immunized children, some physicians may want to flag the chart to be reminded to revisit the immunization discussion, as well as to alert the provider about missed immunizations when considering the evaluation of future illness, especially young children with fevers of unknown origin.

This form may be used as a template to document that the health care provider had a discussion with the parent signing the form about the risks of failing to immunize the child. It is not intended as a substitute for legal advice from a qualified attorney as differing state laws and factual circumstances will impact the outcome. While it may be modified to reflect the particular circumstances of a patient, family, or medical practice, practices may want to consider obtaining advice from a qualified attorney. If a parent refuses to sign the refusal form such refusal along with the name of a witness to the refusal should be documented in the medical record.

The AAP Section on Infectious Diseases and other contributing sections and committees hope this form will be helpful to you as you deal with parents who refuse immunizations. It is available on the AAP Web site on the Section on Infectious Diseases Web site (<http://www2.aap.org/sections/infectdis/resources.cfm>), and the Web site for the AAP Childhood Immunization Support Program (<http://www2.aap.org/immunization/pediatricians/refusaltovaccinate.html>).

Sincerely,

/s/

Tina Tan, MD, FAAP

Chairperson

AAP Section on Infectious Diseases

/s/

Ed Rothstein, MD, FAAP

AAP Section on Infectious Diseases

Refusal to Vaccinate

Child's Name _____ Child's ID# _____

Parent's/Guardian's Name _____

My child's doctor/nurse, _____ has advised me that my child (named above) should receive the following vaccines:

Recommended	Declined
<input type="checkbox"/> Hepatitis B vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria tetanus (DT or Td) vaccine	<input type="checkbox"/>
<input type="checkbox"/> <i>Haemophilus influenzae</i> type b (Hib) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Pneumococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Inactivated poliovirus (IPV) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Measles-mumps-rubella (MMR) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Varicella (chickenpox) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Influenza (flu) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Meningococcal conjugate or polysaccharide vaccine	<input type="checkbox"/>
<input type="checkbox"/> Hepatitis A vaccine	<input type="checkbox"/>
<input type="checkbox"/> Rotavirus vaccine	<input type="checkbox"/>
<input type="checkbox"/> Human papillomavirus (HPV) vaccine	<input type="checkbox"/>
<input type="checkbox"/> Other _____	<input type="checkbox"/>

- That some vaccine-preventable diseases are common in other countries and that my unvaccinated child could easily get one of these diseases while traveling or from a traveler.
- If my child does not receive the vaccine(s) according to the medically accepted schedule, the consequences may include
 - Contracting the illness the vaccine is designed to prevent (the outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness requiring hospitalization, death, brain damage, paralysis, meningitis, seizures, and deafness; other severe and permanent effects from these vaccine-preventable diseases are possible as well).
 - Transmitting the disease to others (including those too young to be vaccinated or those with immune problems), possibly requiring my child to stay out of child care or school and requiring someone to miss work to stay home with my child during disease outbreaks.
- My child's doctor and the American Academy of Pediatrics, the American Academy of Family Physicians, and the Centers for Disease Control and Prevention all strongly recommend that the vaccine(s) be given according to recommendations.

Nevertheless, I have decided at this time to decline or defer the vaccine(s) recommended for my child, as indicated above, by checking the appropriate box under the column titled "Declined." I know that failure to follow the recommendations about vaccination may endanger the health or life of my child and others with whom my child might come into contact. I therefore agree to tell all health care professionals in all settings what vaccines my child has not received because he or she may need to be isolated or may require immediate medical evaluation and tests that might not be necessary if my child had been vaccinated.

I know that I may readdress this issue with my child's doctor or nurse at any time and that I may change my mind and accept vaccination for my child any time in the future.

I acknowledge that I have read this document in its entirety and fully understand it.

I have been provided with and given the opportunity to read each Vaccine Information Statement from the Centers for Disease Control and Prevention explaining the vaccine(s) and the disease(s) it prevents for each of the vaccine(s) checked as recommended and which I have declined, as indicated above. I have had the opportunity to discuss the recommendation and my refusal with my child's doctor or nurse, who has answered all of my questions about the recommended vaccine(s). A list of reasons for vaccinating, possible health consequences of non-vaccination, and possible side effects of each vaccine is available at www.cdc.gov/vaccines/pubs/vis/default.htm. I understand the following:

- The purpose of and the need for the recommended vaccine(s).
- The risks and benefits of the recommended vaccine(s).

Parent/Guardian Signature: _____	Date: _____
Witness: _____	Date: _____
I have had the opportunity to rediscuss my decision not to vaccinate my child and still decline the recommended immunizations.	
Parent's Initials: _____	Date: _____
Parent's Initials: _____	Date: _____



Parental Refusal to Accept Vaccination: Resources for Pediatricians

The following are some of the resources available to help pediatricians develop a productive dialogue with vaccine-hesitant parents and answer questions about vaccine risks and benefits:

Web Sites

1. **AAP Childhood Immunization Support Program (CISP)**
Information for providers and parents.
www.aap.org/immunization
www2.aap.org/immunization/pediatricians/refusaltovaccinate.html
2. **Immunization Action Coalition (IAC)**
The IAC works to increase immunization rates by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. The IAC "Unprotected People Reports" are case reports, personal testimonies, and newspaper and journal articles about people who have suffered or died from vaccine-preventable diseases.
www.immunize.org/reports
3. **Centers for Disease Control and Prevention (CDC) National Immunization Program**
Information about vaccine safety.
www.cdc.gov/vaccines/hcp.htm
4. **National Network for Immunization Information (NNii)**
Includes information to help answer patients' questions and provide the facts about immunizations.
<http://www.immunizationinfo.org/professionals>
5. **Vaccine Education Center at Children's Hospital of Philadelphia**
Information for parents includes "Vaccine Safety FAQs" and "A Look at Each Vaccine."
www.vaccine.chop.edu
6. **Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health**
Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.
www.vaccinesafety.edu
7. **Immunize Canada**
Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.
www.immunize.cpha.ca/en/default.aspx
8. **Sample office policy/letter to parents about refusal to vaccinate**

Journal Articles

1. Offit PA, Jew RK. Addressing parents' concerns: do vaccines contain harmful preservatives, adjuvants, additives, or residuals? *Pediatrics*. 2003;112(6 Pt 1):1394-1397
2. Offit PA, Quarles J, Gerber MA, et al. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109(1):124-129
3. Diekema DS, American Academy of Pediatrics Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115(5):1428-1431

Books

1. American Academy of Pediatrics. *Red Book: 2012 Report of the Committee on Infectious Diseases*. Pickering LK, Baker CJ, Long SS, Kimberlin DW, eds. 29th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2012
2. Marshall GS. *The Vaccine Handbook: A Practical Guide for Clinicians*. 5th ed. West Islip, NY: Professional Communications, Inc; 2015

Handout

1. Immunization Action Coalition. Reliable sources of immunization information: where to go to find answers! <http://www.immunize.org/catg.d/p4012.pdf>. Accessed October 17, 2012

Reliable Immunization Resources for Parents

Web Sites

1. **Centers for Disease Control and Prevention (CDC) Vaccine Information Statements**
Provide possible health consequences of non-vaccination and possible side effects of each vaccine.
www.cdc.gov/vaccines/pubs/vis/default.htm
2. **AAP Childhood Immunization Support Program (CISP)**
Information for providers and parents.
www.aap.org/immunization
3. **Why Immunize?**
A description of the individual diseases and the benefits expected from vaccination.
www2.aap.org/immunization/families/faq/whyimmunize.pdf
4. **Pennsylvania Immunization Education Program of Pennsylvania Chapter, AAP**
Includes answers to common vaccine questions and topics, such as addressing vaccine safety concerns; evaluating anti-vaccine claims; sources of accurate immunization information on the Web; and talking with parents about vaccine safety.
www.paiep.org
5. **CDC For Parents: Vaccines for Your Children**
Information about vaccine safety.
www.cdc.gov/vaccines/parents/index.html
6. **National Network for Immunization Information (NNii)**
Includes information to help answer patients' questions and provide the facts about immunizations.
www.immunizationinfo.org/parents
7. **Vaccine Education Center at Children's Hospital of Philadelphia**
Information for parents includes "Vaccine Safety FAQs" and "A Look at Each Vaccine."
www.vaccine.chop.edu
8. **Institute for Vaccine Safety, Johns Hopkins Bloomberg School of Public Health**
Provides an independent assessment of vaccines and vaccine safety to help guide decision-makers and educate physicians, the public, and the media about key issues surrounding the safety of vaccines.
www.vaccinesafety.edu
9. **Immunize Canada**
Immunize Canada aims to meet the goal of eliminating vaccine-preventable disease through education, promotion, advocacy, and media relations. It includes resources for parents and providers.
<http://immunize.cpha.ca/en/default.aspx>
10. **Vaccinate Your Baby**
This Every Child By Two site serves as a central resource of vaccine information for parents. The site links to the latest research and studies about vaccines, an interactive timeline on the benefits of vaccines, information about vaccine safety and ingredients, and the importance of adhering to the recommended schedule.
www.vaccinateyourbaby.org

Books

1. American Academy of Pediatrics. *Immunizations and Infectious Diseases: An Informed Parent's Guide*. Fisher MC, ed. Elk Grove Village, IL: American Academy of Pediatrics; 2006
2. Myers MG, Pineda D. *Do Vaccines Cause That?! A Guide for Evaluating Vaccine Safety Concerns*. Galveston, TX: Immunizations for Public Health; 2008
3. Offit PA. *Autism's False Prophets: Bad Science, Risky Medicine, and the Search for a Cure*. New York, NY: Columbia University Press; 2008
4. Offit PA. *Deadly Choices: How the Anti-Vaccine Movement Threatens Us All*. New York, NY: Basic Books; 2011
5. Mnookin S. *The Panic Virus: A True Story of Medicine, Science, and Fear*. New York, NY: Simon and Schuster; 2011
6. Offit PA, Moser CA. *Vaccines and Your Child: Separating Fact from Fiction*. New York, NY: Columbia University Press; 2011

ACRONYMS

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices https://www.cdc.gov/vaccines/acip/index.html
AFIX	Assessment, Feedback, Incentives, & Exchange
AIM	Association of Immunization Managers
AMA	American Medical Association
AOA	American Osteopathic Association
ASTHO	Association of State and Territorial Health Officials
BPHC	Bureau of Primary Health Care
CoCASA	Comprehensive Clinic Assessment Software Application https://www.cdc.gov/vaccines/programs/cocasa/index.html
CCF	Cold Chain Failure
CDC	Centers for Disease Control and Prevention
CHIP	Children's Health Insurance Program
CII	(The President's) Childhood Immunization Initiative
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
DDL	Digital Data Logger
DOI	Division of Immunizations
DT	Diphtheria and Tetanus Toxoids
DTaP	Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine
DTP	Diphtheria, Tetanus and Pertussis Vaccine
DTP/Hib	Diphtheria, Tetanus, Pertussis, and Haemophilus influenzae type B
E-IPV	Enhanced-Inactivated Polio Vaccine
EPSDT	Early and Periodic Screening Diagnostic, and Treatment
FDA	Food and Drug Administration
Fed-Ex	Federal Express
FFS	Fee-for-Service

FMO	Financial Management Office
FQHC	Federally Qualified Health Center https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html#fqhc
HEDIS	Healthcare Effectiveness Data Information Set
Hep B	Hepatitis B Vaccine
Hib	<i>Haemophilus influenzae</i> type B vaccine
HMO	Health Maintenance Organization
HPV	Human Papillomavirus
HRSA	Health Resources and Services Administration
IHS	Indian Health Services
IIS	Immunization Information Systems
ILAC	International Laboratory Accreditation Cooperation
IQIP	Immunization Quality Improvement for Providers
IR	Incident report
LQA	Lot Quality Assurance
MA	Medical Assistance
MCH	Maternal and Child Health programs
MCV4	Meningococcal Conjugate Vaccines
MMR	Measles, Mumps, and Rubella Vaccine
MOA	Memorandum of agreement
NDC	National Drug Code
NIST	National Institute of Standards and Technology
NVPO	National Vaccine Program Office
OBRA	Omnibus Budget Reconciliation Act
OOR	Out-of-range
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
PA VFC PPA	Pennsylvania Vaccines for Children Participating Provider Agreement
PCV-13	Pneumococcal Conjugate Vaccine (13 valent)
PHS	Public Health Service

PIN	Provider Identification Number
PPO	Preferred Provider Organizations
PPV-23	Pneumococcal Polysaccharide Vaccine (23 valent)
RHC	Rural Health Clinic https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html#rhc
Td	Tetanus and Diphtheria Toxoids
Tdap	Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis
UPS	United Parcel Service
VACMAN	Vaccine Management software
VAERS	Vaccine Adverse Event Reporting System
VICP	National Vaccine Injury Compensation Program
VTrckS	Vaccine Tracking System https://www.cdc.gov/vaccines/programs/vtrcks/index.html
WIC	Women, Infants and Children program