

VFC & VFAAR

Vaccine Management Plan



Key Vaccine Management Information

INSTRUCTIONS: Fill in all information for your practice and keep near vaccine storage unit(s).

The Philadelphia Immunization Program requires each practice to develop and maintain a Routine Vaccine Management Plan and an Emergency Vaccine Management Plan. Plans should include practice-specific guidelines, protocols, and contact information. Plans must be updated whenever VFC/VFAAR program guidelines change and when staff with designated vaccine management responsibilities change.

Staff assigned vaccine management responsibilities are to review and sign the signature page at the end of this document annually and when the plan is updated. This Plan may be reviewed by VFC/VFAAR representatives during routine and unannounced site visits. Please ensure this Plan is accessible at all times.

Facility Name	VFC/VFAAR PIN	Today's Date
Address		Suite #
City	State	Zip Code

Role	Name	Title	Work Phone #	Cell Phone #
Site Medical Director				
Vaccine Coordinator				
Back-up Vaccine Coordinator				
Person Receiving Vaccine				
Person Storing Vaccine				
Person Checking Vaccine Temperatures				
Other				

Notes: _____

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Vaccine Storage Unit Locations and Maintenance

Maintenance/Repair Company				Phone Number	
Unit Type	Location	Funding Source (VFC, Private, etc.)	Brand	Model	Date of Last Maintenance
Refrigerator					
Freezer					

Certified Calibrated Thermometer and Maintenance

PDPH calibrates all PDPH-supplied thermometers. Each practice should have a copy of the certificate of calibration for PDPH thermometers.

Calibration Company/Laboratory		Phone Number	
Calibration Company/Laboratory		Phone Number	
Location of Calibration Certificates		Location of Back-up Thermometers	

Thermometer Model/Serial #	Primary or Back-up	Calibration Date	Date Battery Replaced	Alarm Setting Low	Alarm Setting High	Funding Source (VFC, Private, etc.)
	Primary					
	Back-up					

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Vaccine Management Personnel

This document highlights key duties of designated vaccine management staff. However, all personnel working with vaccines should be familiar with VFC/VFAAR requirements and guidelines.

Provider of Record

1. Complies with all federal vaccine management requirements, including key areas outlined in this plan.
2. Designates one employee as the practice's Vaccine Coordinator, responsible for vaccine management.
3. Designates one employee as the Back-up Vaccine Coordinator responsible for vaccine management when the primary Vaccine Coordinator is not available.
4. Reports staffing changes regarding the Vaccine Coordinator, Back-up Vaccine Coordinator, and Provider of Record to the VFC/VFAAR Program.
5. Meets and documents required orientation and annual training for the practice's vaccine management personnel.
6. Ensures that vaccine management personnel are skilled and knowledgeable regarding VFC/VFAAR requirements for temperature monitoring and storage equipment.
7. Ensures that the practice's vaccine inventory management is consistent with VFC/VFAAR Program requirements.
8. Ensures that the practice's vaccine storage units meet VFC/VFAAR requirements.
9. Updates and revises vaccine management plans at least annually and when necessary.
10. Reviews VFC/VFAAR requirements and management plans with staff at least annually and when necessary.
11. Ensures monthly vaccine reporting to KIDS Plus IIS (Immunization Information System).

Vaccine Coordinator

1. Completes required VFC/VFAAR Program trainings.
2. Meets responsibilities described in the Vaccine Coordinator job aid.
3. Oversees the practice's vaccine management for routine and emergency situations.
4. Monitors vaccine storage units.
5. Maintains VFC/VFAAR-related documentation in an accessible location.
6. Notifies PDPH if your address changes or your site closes permanently.

Back-up Vaccine Coordinator

1. Completes required VFC/VFAAR Program trainings.
2. Meets responsibilities described in the Vaccine Coordinator job aid when the primary Vaccine Coordinator is not available.

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Vaccine Storage and Temperature Monitoring Equipment

Equipment

1. The practice uses VFC/VFAAR-compliant vaccine storage refrigerator(s) and freezer(s) and maintains recommended temperature ranges:
 - Refrigerator: between 35°F - 46°F (2°C - 8°C)
 - Freezer: below 5°F (-15°C)
2. Storage units have adequate capacity to store vaccine supply at all times, including during peak back-to-school and flu season.
3. Storage units are routinely cleaned inside, kept dust-free outside, and doors have proper seals.
4. Keeps maintenance and repair records on file and makes them available to review upon request.

Power Supply

1. Each unit is plugged directly into a wall outlet and is not controlled by a light switch, power strips, or surge protectors with an on/off switch.
2. Extension cords are never used to connect storage units to an outlet.
3. Plug guards are used to prevent power interruption.
4. “DO NOT UNPLUG” signs are posted at each outlet and circuit breakers.

Set-up

1. Storage units are set up according to VFC/VFAAR Program requirements.
2. Units are kept away from direct sunlight and away from walls to allow air circulation.
3. Vaccine is never stored in the door, drawers, or bins. Unit drawers/deli crispers are removed.
4. Store water bottles in fridge and cold packs in freezer to help maintain the interior temperature in the event of a power loss.
5. VFC/VFAAR and private vaccine storage areas/shelves are marked “VFC” or “VFAAR” and “Private” to clearly identify vaccine supplies.
6. Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine. Vaccines are grouped by pediatric, adolescent, and adult types.
7. The glycol-encased thermometer probe is placed in the center of the unit, near the vaccines.
8. The thermometer’s display is securely attached to the outside of the storage unit.
9. Vaccines are stored in their original packaging until administered; vaccine supply is 2-3 inches away from walls, air vents, and floor to allow space for air circulation.
10. Food, beverages, and laboratory specimens are not stored in the units at any time.
11. When medications or biologic media (not inoculated) are stored in the unit, they are placed on the shelves below vaccines.

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Vaccine Storage and Temperature Monitoring Equipment

Thermometers

1. Each storage unit has a VFC/VFAAR-compliant thermometer accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$).
2. Each thermometer has a current and valid Certificate of Calibration (also known as a Report of Calibration).
3. Each thermometer has a biosafe glycol-encased probe placed in the center of the storage unit in close proximity to the vaccine.
4. Each thermometer has a digital display of current, minimum, and maximum temperatures.
5. The practice has a minimum of one back-up thermometer, meeting VFC requirements, for use when primary thermometers fail or are being recalibrated.
6. Probes are NEVER placed in the unit's doors, near or against unit's walls, underneath air vents, or on the unit floor.
7. Thermometer batteries are replaced every six months.

Annual Thermometer Calibration

1. Primary and back-up thermometers are calibrated annually (or every other year if the manufacturer's recommendation is for a longer period).
2. Thermometer calibration is done by a laboratory with accreditation from an ILAC/MRA signatory body.
3. Valid certificates not issued by an accredited lab must include: date of testing, thermometer model/serial number, measurement results, uncertainties, pass/fail statements, and statement that testing meets ISO 17025 Standard.
4. Certificates of Calibration are filed in a readily accessible area, kept for three years, and are presented to PDPH staff for review upon request.
5. Thermometers are replaced when no longer accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) based on calibration results.

Safeguarding Vaccines, Handling, and Reporting Out-of-range Temperatures

1. When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage.
2. The VFC/VFAAR Program is contacted to report the incident.
3. Vaccine considered spoiled is marked "DO NOT USE."
4. The practice has an Emergency Vaccine Management Plan to follow in the case of power outage, appliance malfunction, weather conditions, or human error that may affect vaccine viability.
5. When necessary to transport vaccine to another storage unit or to a predetermined site, the practice always follows VFC/VFAAR Program guidelines.
6. Actions are documented on the VFC/VFAAR temperature log and other VFC/VFAAR forms, as appropriate.

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Temperature Monitoring Documentation

1. Reads and records refrigerator and freezer temperatures twice a day, when the clinic opens and before it closes:
 - Reads and records current refrigerator and freezer temperatures twice each day.
 - Records AM temperatures before opening storage units.
 - Records PM temperatures at the end of the day.
 - Resets MIN and MAX after each reading by pressing the memory clear button (in most thermometers).
2. The person documenting the storage unit temperature initials the temperature log.
3. Temperatures are documented on VFC/VFAAR Program temperature logs even if the practice uses a continuously recording/graphing thermometer, data logger, or remote monitoring system.
4. Temperature logs are posted on the storage unit door or nearby in an accessible location.
5. The practice maintains completed temperature logs for three years and makes them available for review upon request to VFC/VFAAR Representatives.

Inventory Management

1. A physical vaccine inventory is conducted at least once a month and before ordering vaccine.
2. The practice has enough vaccine supply to meet the needs of its VFC/VFAAR-eligible patients.
3. The practice may keep up to two-weeks additional supply to mitigate shortages in the event of shipment delays.
4. The practice uses an inventory control system, i.e., usage log, which documents each patient, vaccine type, lot number, and date of administration.
5. The practice maintains accurate records, including purchase invoices, for privately purchased vaccines and makes them available upon request to VFC/VFAAR Representatives.
6. Vaccine that is drawn up and not used is disposed of properly.
7. When diluent is packaged with vaccine, the practice stores them together. When diluent is not packaged with its vaccine, the diluent is clearly labeled and stored where it can be easily identified.

Stock Rotation and Returns

1. The practice organizes vaccines so those with the shortest expiration dates are used first.
2. The practice returns expired and/or spoiled vaccine to McKesson within 30 days of expiration/spoilage.
3. If vaccine becomes spoiled or expires, staff remove it immediately from the storage unit, report it to the VFC Program, and complete the appropriate documentation.
4. The practice may return unused vials/pre-filled syringes to McKesson if unopened and in original packaging. The following vaccine supplies should not be returned:
 - Used syringes with or without needles
 - Syringes with vaccine drawn up and not used
 - Broken or damaged vaccine vials
 - Multi-dose vials that have already been withdrawn
5. Before a new order can be submitted, vaccine that is spoiled or expired must be reported to the VFC/VFAAR Program by submitting a returned vaccine form.

Philadelphia Department of Public Health - Division of Disease Control - Immunization Program

<http://kids.phila.gov/> - 500 South Broad Street - Philadelphia, PA 19146

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Vaccine Ordering

1. When a vaccine is offered by two or more manufacturers, the practice must choose one brand.
2. The practice does a physical inventory before placing a vaccine order.
3. The practice orders all the vaccines it needs before the next assigned order.
4. A summary of on-hand inventory and temperature logs (since the last order) are included with each order.
5. Orders are placed with sufficient inventory on hand to allow time for order processing and vaccine delivery.
6. Every VFC/VFAAR vaccine dose is accounted for. Vaccine doses not accounted for or lost due to negligence will be replaced at the expense of the Provider of Record for the site.
7. The practice verifies its operation hours before submitting each order. Any changes to the practice's hours are reported to PDPH to avoid receiving vaccine shipments when the clinic is closed or the staff is not available.

Receiving and Inspecting Vaccine Shipments

1. The practice is familiar with procedures for accepting vaccine shipments.
2. The practice assumes responsibility for all VFC vaccine shipped to its site.
3. Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, and that the vaccines being delivered match those listed on the packing slip and order confirmation.
4. The practice never rejects vaccine shipments.
5. The practice reports shipment discrepancies and vaccine exposed to out-of-range temperatures immediately to the VFC Program.
6. Vaccines are immediately stored according to VFC requirements.

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Signature Log

By signing, I acknowledge I have reviewed and am familiar with the information in this document.

Date	
Updates and Comments	
Provider of Record Name	Signature
Vaccine Coordinator Name	Signature
Back-up Vaccine Coordinator Name	Signature
Additional Staff	Signature

Date	
Updates and Comments	
Provider of Record Name	Signature
Vaccine Coordinator Name	Signature
Back-up Vaccine Coordinator Name	Signature
Additional Staff	Signature