



Vaccines for Children (VFC) Program Vaccine Management Plan

Practice Name: _____ Pin: _____

Vaccine Coordinator: _____

Back-Up Vaccine Coordinator: _____

Vaccine Management Personnel

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

Provider of Record (Enrollee)

- Complies with all federal vaccine management requirements, including key areas outlined in this plan.
- Designates one employee as the practice's Vaccine Coordinator, responsible for vaccine management.
- Designates one employee as the Back-up Vaccine Coordinator responsible for vaccine management when the primary Vaccine Coordinator is not available.
- Reports staffing changes regarding the Vaccine Coordinator, Back-up Vaccine Coordinator, and enrollee to the VFC Program.
- Meets and documents required orientation and annual training for the practice's vaccine management personnel.
- Ensures that vaccine management personnel are skilled and knowledgeable regarding VFC Program requirements for temperature monitoring and storage equipment.
- Ensures that the practice's vaccine inventory management is consistent with VFC Program requirements.
- Ensures that the practice's vaccine storage units meet VFC Program requirements.
- Updates and revises vaccine management plans at least annually and when necessary.
- Reviews VFC Program requirements and management plans with staff at least annually and when necessary.

Vaccine Coordinator

The Vaccine Coordinator's responsibilities vary depending on the amount of vaccine the practice gives and practice protocols. The Vaccine Coordinator is responsible for all vaccine management activities, completing required VFC Program trainings, including training other (especially new) staff. In other practices, a different person may have one or more vaccine management responsibilities, such as ordering vaccines. Below is a list of essential responsibilities.

Receiving vaccines

- Be present when vaccine is delivered and immediately process it into inventory.
- Ensures acceptable temperature ranges have been maintained.



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Storing vaccines

- Rotates the vaccine inventory so that vaccines with shorter expiration dates are used first.
- Ensures there are no expired vaccines in the refrigerator or freezer.
- Keep VFC Program vaccine separate from private vaccine stock.
- Perform routine cleaning on vaccine storage units.

Monitoring vaccine temperatures

- Use a certified calibrated continuous temperature monitoring device (data logger) to review refrigerator and freezer temperatures.
- Electronically upload temperature readings into Florida SHOTS at least once every seven days.
- Take immediate action if temperatures are outside acceptable ranges.
- Implement the Emergency Vaccine Management Plan, if necessary.
- Temperature logs must be maintained for three years. If you upload temperature data to Florida SHOTS, your data will be kept for three years.

Ordering vaccines

- Perform a physical inventory monthly of all vaccines in stock.
- Account for doses of returned or transferred vaccines since the last order.
- Complete and submit the VFC Program vaccine order in the Florida State Health Online Tracking System (SHOTS).

Back-Up Vaccine Coordinator

- Complete required VFC Program trainings.
- Meet responsibilities described above when the primary Vaccine Coordinator is not available.

Vaccine Storage and Handling

Vaccine storage and handling plans follow the “Vaccine Management Guidelines” found in the *VFC Program Manual* and the Centers for Disease Control and Prevention's (CDC) *Vaccine Storage and Handling Toolkit* found at <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>.

Vaccine Storage Units

Equipment

- The practice uses VFC Program compliant vaccine storage refrigerator(s) and freezer(s) and maintains recommended temperature ranges:
 - Refrigerator: between 36°F-46°F (2°C-8°C).
 - Freezer: below 5°F (-15°C).
- Storage units have adequate capacity to store vaccine supply at all times, including during peak back-to-school and flu season.
- Storage units are routinely cleaned inside, kept dust-free outside, and doors have proper seals.



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- Keep maintenance and repair records on file and make them available to review upon request.

Power Supply

- 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.
- Extension cords are never used to connect storage units to an outlet. “DO NOT UNPLUG” signs are posted at each outlet and circuit breakers.

Set-up

- Storage units are set up according to VFC Program requirements.
- Units are kept away from direct sunlight and away from walls to allow air circulation.
- Vaccine is never stored in the door, drawers, or bins. Unit drawers/deli crispers are removed.
- To stabilize temperatures, water bottles are kept in the refrigerator where vaccines cannot be stored. Frozen cold packs are kept in the freezer for similar purpose.
- VFC Program and private vaccine storage areas/shelves are marked “VFC” and “Private” to clearly identify vaccine supplies.
- Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine.
- The glycol-encased data logger probe is placed in the center of the unit, near the vaccines.
- The data logger’s display is securely attached to the outside of the storage unit.
- 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.
- Food, beverages, and laboratory specimens are not stored in the units at any time.
- When medications or biologic media (not inoculated) are stored in the unit, they are placed on the shelves below vaccines.

Temperature Monitoring

Data Loggers

- Each storage unit has a VFC Program compliant continuous temperature monitoring device or data logger accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$).
- Each data logger has a current and valid Certificate of Calibration (also known as a Report of Calibration).
- Each data logger has a biosafe glycol-encased probe placed in the center of the storage unit in close proximity to the vaccine.
- Each data logger has a digital display of current, minimum, and maximum temperatures.
- The practice has a minimum of one back-up data logger, meeting VFC Program requirements, for use when primary data loggers fail or are being recalibrated.
- Probes are NEVER placed in the unit’s doors, near or against unit’s walls, underneath air vents, or on the unit floor.
- Data logger batteries are replaced every six months.

Data logger Calibration

- Primary and back-up data loggers are calibrated annually (or according to the manufacturer’s recommendation).



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- Data logger calibration is done by a laboratory with accreditation from an ILAC/MRA signatory body.
- Valid certificates not issued by an accredited lab must include: date of testing, data logger model/serial number, measurement results, uncertainties, pass/fail statements, and statement that testing meets ISO 17025 Standard.
- Certificates of Calibration are filed in a readily accessible area, kept for three years, and are presented to VFC Program and Immunization Section staff for review upon request.
- Data loggers 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

- When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage.
- The VFC Program is contacted to report the incident and to file a storage and handling incident report.
- Label vaccine "DO NOT USE." Keep vaccine stored in the recommended temperature range, if possible.
- 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.
- When necessary to transport vaccine to another storage unit or to a predetermined site, the practice always follows VFC Program guidelines.
- Actions are documented on the VFC Program temperature log and other VFC Program forms, as appropriate.

Temperature Monitoring and Documentation

- Read and record refrigerator and freezer temperatures twice a day, when the clinic opens and before it closes.
 - Record current temperatures on a VFC Program supplied temperature log twice a day. If available, record minimum and maximum temperatures once a day, preferably in the morning.
 - Record a.m. temperatures before opening storage units.
 - Record p.m. temperatures at the end of the day.
 - Reset MIN and MAX after each reading by pressing the memory clear button (in most data loggers).
- The person documenting the storage unit temperature initials the temperature log.
- Document temperatures on VFC Program temperature log even if the practice uses a continuously recording/graphing data logger, data logger, or remote monitoring system.
- Temperature logs are posted on the storage unit door or nearby in an accessible location.
- The practice maintains completed temperature logs for three years and makes them available for review upon request to VFC Program representatives.

Inventory Management

Vaccine Stock

- The practice conducts a physical vaccine inventory at least once a month and before ordering vaccine.



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- The practice has enough vaccine supply to meet the needs of its VFC Program eligible patients.
- The practice must keep up to four weeks' additional supply to mitigate shortages in the event of shipment delays.
- The practice uses an inventory control system, i.e., usage log, which documents each patient, vaccine type, lot number, and date of administration.
- The practice maintains accurate records, including purchase invoices, for privately purchased vaccines and makes them available upon request to VFC Program representatives.
- Vaccine drawn up and not used is disposed of and accounted for properly in the Florida SHOTS.
- 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, Returns, and Transfers

- The practice organizes vaccines so those with the shortest expiration dates are used first.
- The practice returns expired and/or spoiled vaccine to McKesson for excise tax credit within six months of expiration/spoilage.
- If the practice has vaccine due to expire within three months and it will not be used:
 - Notify the VFC Program about the vaccine.
 - Request a transfer approval from the VFC Program.
 - Identify VFC Program providers in the area to contact and inquire if they may be able to use the soon-to-expire vaccines.
- If a practice transfers or transports vaccine, it follows VFC Program guidelines, and completes the appropriate transaction in Florida SHOTS.
- If vaccine becomes spoiled or expires, staff removes it immediately from the storage unit, reports it to the VFC Program, and adjusts it out of their inventory in Florida SHOTS.
- The practice may return unused vials/prefilled 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.
- Vaccine that is spoiled or expired must be reported to the VFC Program before a new order can be submitted.

Vaccine Ordering

- Orders are submitted in Florida SHOTS and placed according to assigned order frequency, vaccine usage, and take into account the inventory in stock. Orders are placed with sufficient inventory on hand to allow time for order processing and vaccine delivery
- The practice does a physical inventory before placing a vaccine order.
- Providers must document inventory and doses administered since the previous order for each order.



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- Every VFC Program vaccine dose is accounted; vaccine doses not accounted for or lost due to negligence will be replaced at the expense of the provider of record for the facility.
- The practice verifies its hours of operation in the Florida SHOTS before submitting each order.
- Any changes to the practice’s hours are reported to the VFC Program to avoid receiving vaccine shipments when the clinic is closed or the staff is not available. The VFC Program is not responsible for wasted vaccine due to incorrect delivery address or provider hours.

Receiving and Inspecting Vaccine Shipments

- The practice assumes responsibility for all VFC Program vaccine shipped to its site.
- Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, length of time the vaccine was in transit, and that the vaccines being delivered match those listed on the packing slip and order confirmation.
- The practice never rejects vaccine shipments.
- The practice reports shipment discrepancies and vaccine exposed to out-of-range temperatures immediately to the VFC Program.
- Vaccines are immediately stored according to VFC Program requirements.
- The practice accepts the pending receipt in Florida SHOTS to add the vaccine to their inventory.

Staff Training on Vaccine Management and VFC Program Requirements

All office staff that handle or administer vaccines should receive annual training to ensure they are familiar with the **Vaccine Management Plan** and the VFC Program requirements.

Signature Log

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 Program representatives during routine and drop-in site visits. By signing, I acknowledge I have reviewed and am familiar with the information in this document.

Review Date:	
Provider of Record Name:	Signature:
Vaccine Coordinator Name:	Signature:
Back-Up Coordinator Name:	Signature:

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