



I, on behalf of myself and any and all practitioners associated with this medical office, group practice, Health Maintenance Organization (HMO), health department, community/migrant/rural clinic, hospital, or other entity of which I am the physician-in-chief, medical director or equivalent, agree to comply with all VFC Program requirements listed below.

### 1. Vaccine Management Plan

- A. Maintain a current and completed [vaccine management plan](#) (for routine and emergency situations) that includes practice-specific vaccine management guidelines and protocols, names of staff with temperature monitoring responsibilities, and completion dates of required EZIZ lessons for key practice staff.
- B. Review and update the plan at least once a year, when VFC Program requirements change, and when staff with designated vaccine management responsibilities change.
- C. Ensure all staff with assigned vaccine management responsibilities review, sign, and date the plan annually and whenever the management plan is updated.

### 2. Staffing & Training

- A. Designate an on-site Provider of Record Designee authorized to sign VFC Program documents and assume responsibility for VFC-related matters in the absence of the Provider of Record.
- B. Designate fully trained on-site Vaccine Coordinator and Backup Vaccine Coordinator as outlined in "[Vaccine Coordinator Roles & Responsibilities](#)".
- C. Maintain compliance with annual training requirements for the Provider of Record and Designee, Vaccine Coordinator and Backup, and other key practice staff authorized to store and handle vaccines.
- D. Ensure all staff with temperature monitoring responsibilities are properly trained on temperature monitoring, use of the practice's temperature monitoring devices, and the required actions for out-of-range temperatures.
- E. Ensure that staff authorized to accept packages are trained to notify the Vaccine Coordinator immediately upon delivery of vaccine shipments.
- F. [Report changes in key practice staff](#) to the VFC Call Center immediately.

### 3. Vaccine Storage Units

- A. Use or purchase refrigerators or freezers that comply with [VFC vaccine storage unit requirements](#). Very high volume providers must use pharmacy- or biologic-grade stand-alone or combination refrigerators. Other providers may use pharmacy- or biologic-grade, commercial-grade stand-alone, and household-grade stand-alone refrigerators and freezers.
- B. Never use any of the following for vaccine storage: household-grade combination refrigerator-freezers, compact household-grade stand-alone refrigerators (with capacity 11 cubic feet or less), dormitory-style or bar-style combined refrigerator/freezers, manual defrost refrigerators, convertible units, or cryogenic (ultra-low) freezers.
- C. Dedicate vaccine refrigerators and freezers to the storage of vaccines only.
- D. Purchase new vaccine refrigerators or freezers if existing storage units do not meet VFC Program requirements, or in the event of storage unit malfunctioning that resulted in spoiled vaccines.

### 4. Digital Data Loggers (Continuous Temperature Monitoring Devices)

- A. Use or purchase data loggers that comply with [VFC temperature monitoring device requirements](#) for each vaccine storage unit and at least one backup device; ensure each device has a [valid certificate of calibration](#).



- B. Never use these devices for vaccine temperature monitoring: thermometers (e.g., round dial thermometers, fluid-filled and/or min-max bar thermometers, household-use and kitchen thermometers, infrared temperature guns, alcohol or mercury thermometers, and bi-metal stem thermometers); chart recorders; or data loggers with probes that aren't immersed in a vial filled with liquid, loose media, or a solid block of material.
- C. Purchase and use digital data loggers to monitor vaccine storage unit temperatures upon expiration of the certificate of calibration of the current device (primary and backups) but no later than December 1, 2017.
- D. Ensure all data loggers include the following minimum features: a digital display of current, minimum, and maximum temperatures; minimum accuracy of  $\pm 1.0^{\circ}\text{F}$  ( $0.5^{\circ}\text{C}$ ); a buffered temperature probe (the one that comes with the device) immersed in a vial filled with up to 60mL liquid (e.g., glycol, ethanol, glycerin), loose media (e.g., sand, glass beads), or a solid block of material (e.g., Teflon<sup>®</sup>, aluminum); an out-of-range temperature alarm; logging interval of at least 30 minutes; and memory storage of 4,000 readings or more.
- E. Replace with digital data loggers any primary or backup thermometers deemed no longer accurate within  $\pm 1.0^{\circ}\text{F}$  ( $\pm 0.5^{\circ}\text{C}$ ).
- F. Store the backup device's buffered probe in the vaccine storage unit; store the digital display in a cabinet and document its location on the practice's vaccine management plan.
- G. [Calibrate primary and backup devices](#) annually, or every other year when manufacturers recommend a period longer than two years—ideally by a laboratory with accreditation from an ILAC MRA signatory body.
- H. Ensure certificates of calibration issued by non-accredited laboratories include a [valid certificate of calibration](#).
- I. Keep certificates of calibration on file and make them available to VFC Field Representatives upon request.

## 5. Vaccine Refrigerator & Freezer Configuration

- A. [Prepare vaccine refrigerators](#) and [vaccine freezers](#) in compliance with VFC Program requirements.
- B. Place water bottles in vaccine refrigerators and ice packs in vaccine freezers to stabilize temperatures.
- C. Place buffered probes in the center of the refrigerator and freezer near vaccines.
- D. Place the data logger's digital display outside of the storage unit to allow temperature monitoring without opening the vaccine storage unit door.
- E. Plug the vaccine refrigerator and freezer directly into a nearby, dedicated wall outlet that does not have built-in circuit switches and is not controlled by a light switch; never plug vaccine storage units into extension cords, or power strips or surge protectors with an on/off switch.
- F. Post "Do Not Unplug" signs on the electrical outlets and circuit breakers to prevent interruption of power.
- G. [Set up vaccine refrigerators](#) and [vaccine freezers](#) in compliance with VFC Program requirements.
- H. Designate separate shelf space or breathable mesh baskets for VFC-supplied and privately purchased vaccines.
- I. Clearly label shelves or baskets to group vaccines by pediatric, adolescent, and adult types.
- J. Allocate enough space to position vaccines or baskets 2-3 inches away from walls, floor, and other baskets to allow space for air circulation.
- K. Post [VFC temperature logs](#) on vaccine storage unit doors or in an easily accessible location.

## 6. Vaccine Orders & Accountability

- A. Account for every dose of VFC-supplied vaccine ordered and received by the provider's practice.
- B. Order routine ACIP-recommended vaccines according to the provider population, category, order frequency, vaccine usage, and on-hand inventory.
- C. Order all vaccines for each order period in accordance with the practice's patient estimates and in sufficient quantities to last until the next order period; individual vaccine orders are not permitted.
- D. Stock one brand and formulation for each vaccine to avoid administration errors.



## Provider Agreement Addendum

- E. Keep track of VFC vaccine doses administered since the previous order (including influenza) using the VFC ["Daily Usage Log"](#), ["Flu Usage Log"](#), an immunization registry, or equivalent electronic or paper form.
- F. Conduct a physical vaccine inventory before ordering routine vaccines to determine current doses on hand.
- G. Report on each vaccine order the VFC vaccine doses administered since the previous order and the current doses on hand.
- H. Maintain accurate and separate stock records (e.g., purchase invoices) for privately purchased vaccines and make them available upon request.

### 7. Receiving Vaccine Deliveries

- A. Never reject vaccine shipments.
- B. Receive and unpack vaccines immediately upon delivery.
- C. Inspect vaccines for out-of-range temperatures and shipping times during transport.
- D. Check package contents to ensure brands and quantities match the packing slip and approved VFC order.
- E. Report immediately all shipment issues (e.g., damaged boxes, out-of-range temperatures and shipping times, and incorrect brands and quantities) using the VFC ["Vaccine Receiving Log and Checklist"](#).

### 8. Vaccine Storage

- A. Always store vaccines within manufacturer recommended ranges.
- B. Store frozen vaccines (MMR, MMRV, and VAR) between -58.0°F and 5.0°F (-50.0°C and -15.0°C).
- C. Store all other vaccines between 35.0°F and 46.0°F (2.0°C and 8.0°C).
- D. Store vaccines in original packaging and within closed boxes to protect from light and allow for air circulation.
- E. Store VFC-supplied and privately purchased vaccines separately and grouped by vaccine type.
- F. Do not store vaccines in the doors, drawers, or bins.
- G. Place vaccines with the earliest expiration dates toward the front of the vaccine storage unit and use first.

### 9. Temperature Monitoring

- A. Ensure vaccine storage unit temperatures are recorded on [VFC temperature logs](#).
- B. Monitor and record current, minimum and maximum temperatures in vaccine refrigerators and freezers twice each day, at the beginning and end of each business day—even if using digital data loggers.
- C. Download and analyze temperature data files (if using digital data loggers) at the end of every two-week period—or sooner if an excursion is identified. Look for temperature trends that might indicate performance issues with vaccine storage units.
- D. Acknowledge that if temperatures are not monitored and documented, if temperature logs are missing, or if temperature logs are falsified, all affected vaccines will be automatically deemed non-viable and considered a negligent vaccine loss.
- E. Ensure VFC temperature logs are legible and completed accurately.
- F. Immediately cross out, correct, and initial neatly any inadvertent documentation error.
- G. Ensure the supervisor certifies and signs that temperatures were recorded twice daily, staff printed names and initials, and corrective actions were taken when the VFC temperature log is complete for each 15-day period.
- H. Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted.
- I. Retain paper logs and electronic files related to temperature monitoring for three years.



## 10. Reporting Storage & Handling Incidents

- A. Take immediate action to prevent vaccine spoilage and to correct any improper storage condition if a vaccine storage unit temperature is identified as out of range.
- B. Mark as “Do Not Use” any vaccines exposed to out-of-range temperatures; do not administer vaccines until vaccine viability has been determined by the vaccine manufacturers.
- C. Download and review temperature data files for every temperature excursion if using digital data loggers.
- D. Report and document all out-of-range temperatures on MyVFCvaccines.org.
- E. Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper [refrigerated vaccine transport](#) and [frozen vaccine transport](#).

## 11. Vaccine Inventory Management

- A. Conduct a physical vaccine inventory at least monthly and before ordering routine vaccines using the VFC ["Vaccine Physical Inventory Form"](#) or equivalent electronic or paper form.
- B. Never borrow VFC-supplied vaccines to supplement private stock, or vice versa.
- C. For vaccines that will expire within 6 months and cannot be used, notify the VFC Call Center prior to transferring to another VFC provider.
- D. Remove spoiled, expired, and wasted vaccines from storage units immediately to prevent inadvertent use.
- E. Report all VFC-supplied spoiled, expired, or wasted vaccines prior to submitting a new vaccine order.
- F. Monitor vaccine storage units regularly and purchase additional units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements.

## 12. Vaccine Transport

- A. Contact the VFC Call Center prior to transferring vaccines and only transfer to an alternate location that has vaccine storage units and temperature monitoring devices that meet VFC Program requirements.
- B. Never routinely transfer VFC-supplied vaccines to other VFC providers.
- C. Never transfer VFC-supplied vaccines to non-VFC providers.
- D. Store VFC-supplied vaccines only at facilities designated in the provider profile; never store VFC vaccines in personal residences.
- E. Transport vaccines only when absolutely necessary and follow the guidelines for proper [refrigerated vaccine transport](#) and [frozen vaccine transport](#).
- F. Use digital data loggers to monitor temperatures during vaccine transport and at mass vaccination clinics.
- G. Complete the VFC ["Refrigerated Vaccine Transport Log"](#) or ["Frozen Vaccine Transport Log"](#) each time vaccines are transported.
- H. Acknowledge that vaccines transported without proper documentation of temperature monitoring may be deemed non-viable.

## 13. Vaccine Administration

- A. For non-Medi-Cal VFC-eligible children, waive the administration fee if the parent/guardian is unable to pay.
- B. For Medi-Cal children, never bill the difference between Medi-Cal’s administration fee and the administration fee cap to the parent/guardian.
- C. Acknowledge that revaccination is recommended if non-viable vaccines have been administered to patients.



#### **14. Program Integrity**

- A. Ensure that I and my staff conduct ourselves in an ethical, professional, and respectful manner in all interactions with VFC Program staff.
- B. Never destroy, alter, or falsify immunization or VFC Program-related records.

To receive VFC-supplied vaccines, confirm acknowledgement of this agreement.

***Failure to comply with any of the above could be grounds for suspension of vaccine ordering privileges and/or termination from the VFC Program.***