**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. Provider Profile

A. Designate the on-site Provider of Record Designee, who is authorized to sign VFC Program documents and assume responsibility for VFC-related matters in the absence of the Provider of Record.
B. Designate the on-site Vaccine Coordinator and Backup Vaccine Coordinator (IMM-968), who are responsible for implementing the practice's vaccine management plan (IMM-1122).
C. Immediately report in myCAvax any changes to key practice staff roles (Vaccine Coordinator or Backup, Provider of Record or Designee); any changes to the Provider of Record or Designee require an electronic signature by the Provider of Record.
D. Immediately report to the VFC Program changes to the practice address or account ownership, which may require additional follow-up.

## 2. Vaccine Management Plan

A. Maintain a current and complete vaccine management plan (IMM-1122) for routine and emergency situations that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and required EZIZ lesson completion dates for all key practice staff.
B. Review and update the plan at least annually, when VFC Program requirements change, and when staff with designated vaccine-management responsibilities change.
C. Designate a staff member responsible for updating the practice's management plan.
D. Staff with assigned vaccine-management responsibilities must review, sign, and date the vaccine management plan annually and each time it is updated.
E. Follow emergency guidelines to prepare for, respond to, and recover from any vaccine-related emergencies.
F. Store the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units.
G. **For practices using mobile units to administer VFC-supplied vaccines:** Mobile-only clinics or clinics with mobile units must maintain a current and complete mobile unit vaccine management plan (IMM-1276) and keep it in the mobile unit.

## 3. Training

A. Anyone acting in VFC roles (Provider of Record and Designee, Vaccine Coordinator and Backup or the optional Organization Coordinator and Additional Vaccine Coordinator roles) must complete the required EZIZ lessons when hired and annually thereafter; staff must demonstrate competency in their assigned VFC roles.
B. Any clinician who administers VFC-supplied vaccines must be knowledgeable of and familiar with all ACIP-recommended immunizations, including schedules, indications, dosages, and new products.
C. All staff who conduct VFC Program eligibility screening, documentation, and billing (e.g., front- or back-office staff) must be knowledgeable of all VFC eligibility categories, documentation, and billing requirements.
D. All staff and supervisors who monitor storage unit temperatures or sign off on temperature logs must complete the related EZIZ lesson when hired and annually thereafter; they must be fully trained on use of the practice's data loggers and actions required after a temperature excursion is discovered.

E. Train staff who are authorized to accept packages to immediately notify the Vaccine Coordinator when VFC-supplied vaccines are delivered.
F. Conduct regular vaccine transport drills to maintain competency and readiness for emergencies.

## 4. Vaccine Storage Units

A. Have refrigerators and freezers that comply with VFC vaccine storage unit requirements: Very high-volume provider locations must use purpose-built (pharmacy-, biologic-, or laboratory-grade) refrigerators. Other provider locations may use refrigerators and freezers that are purpose-built (preferred) or commercial-grade (acceptable). Household-grade, stand-alone refrigerators are discouraged. Purpose-built combination units, including auto-dispensing units without doors, are allowed.

   **NOTES:**

   - Exception for specialty provider locations such as birthing hospitals: Freezer units are not required.
   - Ultra-low temperature freezers are allowed for storage of Pfizer COVID-19 vaccines but are not required.

B. Manual-defrost freezers are allowed for use if the practice has access to an alternate storage unit when defrosting the freezer (Note: Defrost manual-defrost freezers only when frost exceeds 1cm or the manufacturer's suggested limit). The alternate storage unit must have appropriate freezer temperatures and be monitored using a VFC-compliant digital data logger. Never store VFC-supplied vaccines in a cooler.
C. Never use any of the following for routine 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 combination refrigerator/freezers; manual-defrost refrigerators; convertible units; cryogenic (ultra-low) freezers; or any vaccine transport unit (including coolers and battery-operated units).
D. Purchase new refrigerators (purpose-built) or freezers (any grade) if existing storage units malfunction frequently or experience frequent temperature excursions.
E. **For provider locations designated solely as mass vaccinators:** Only use purpose-built, vaccine transport units for transport and on-site storage.

## 5. Vaccine Storage Unit Configuration

A. Prepare vaccine refrigerators and vaccine freezers (IMM-962) following VFC Program requirements.
B. Place water bottles (in refrigerators) and ice packs (in freezers only) to stabilize temperatures. (Exception for pharmaceutical grade and purpose-built, auto-dispensing units without doors. Follow manufacturer's guidance.)
C. Place data logger buffered probes in the center of refrigerators and freezers near vaccines. (Exception for pharmaceutical grade and purpose-built, auto-dispensing units without doors. Follow manufacturer's guidance.)
D. Place data logger digital displays outside vaccine storage units to allow temperature monitoring without opening vaccine storage unit doors. (Exception for purpose-built, auto-dispensing units without doors.)
E. Plug the vaccine refrigerator and freezer directly into nearby, dedicated wall outlets that do not have built-in GFI circuit switches and are not controlled by light switches; never plug vaccine storage units into extension cords, or power strips or surge protectors with an on/off switch.
F. Post "Do Not Unplug" (IMM-744ES) signs on electrical outlets and circuit breakers to prevent interruption of power.
G. Set up vaccine refrigerators and vaccine freezers (IMM-963) following VFC Program requirements.
H. Clearly identify unit space or containers that will store VFC-supplied and privately purchased vaccines.
I. Group vaccines by pediatric, adolescent, and adult types.

J. Allocate enough space to position vaccines or baskets 2-3 inches away from walls, storage unit floor, and other baskets to allow space for air circulation. (Exception for purpose-built, auto-dispensing units without doors.)
K. Post the CDPH universal temperature log on vaccine storage unit doors or in an easily accessible location.

## 6. Digital Data Loggers

A. Equip all refrigerators and freezers (primary, backup, overflow, or any other temporary unit) storing VFC-supplied vaccines with VFC-compliant digital data loggers. (For purpose-built, auto-dispensing units without doors: Built-in, internal data loggers must meet VFC Program requirements—except for buffered probes, which are not required.)
B. Only use data loggers that include the following minimum features: a digital display of current, minimum, and maximum temperatures; minimum accuracy of ±1.0°F (0.5°C); a buffered temperature probe (only use the probe 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®, aluminum); an audible or visual out-of-range temperature alarm; logging interval of 30 minutes; a low-battery indicator; and memory storage of 4,000 readings or more. A battery source is required for backup devices used during vaccine transport.
C. Digital data loggers, including backup digital data loggers, must be able to generate a summary report of recorded temperature data since the device was last reset; summary reports must include minimum and maximum temperatures, total time out of range (if any), and alarm settings. Devices that only generate CSV data files or Excel spreadsheets are not acceptable.
D. Keep on hand at least one backup, battery-operated, digital data logger for emergency vaccine transport. Depending on the size of the practice, additional devices might be needed.
E. Digital data loggers must have a current and valid Certificate of Calibration, including backup digital data loggers.

## 7. Digital Data Logger Configuration & Maintenance

A. Configure key settings for primary and backup digital data loggers, including device name, low and high temperature alarm limits, immediate notification of out-of-range temperatures, and a maximum logging interval of 30 minutes.
B. Store the backup data logger's buffered probe in the vaccine refrigerator and keep its digital display separately in a cabinet; document the device's location on the practice's vaccine management plan (IMM-1122). (Exception for purpose-built, auto-dispensing units without doors: Store the entire device in a cabinet.)
C. Calibrate primary and backup devices every two to three years or according to the manufacturer's suggested timeline (both device and probe together)—ideally by a laboratory with accreditation from an ILAC MRA signatory body.

**NOTES:**

- If the manufacturer supplies a pre-calibrated replacement probe upon device calibration expiration, the device and probe do not need to be calibrated together.
- New devices that only generate CSV data files or Excel spreadsheets are not acceptable. If your current device only generates CSV data files or Excel spreadsheets, it must be replaced with a digital data logger that meets current VFC Program requirements.
- Practices are required to keep on hand at least one backup, battery-operated digital data logger for use during recalibration, when the primary device breaks, when the primary device does not meet calibration requirements, or during emergency vaccine transport.

D. Certificates issued by non-accredited laboratories must meet all VFC Program requirements for certificates of calibration (IMM-1119).
E. Calibrate primary and backup devices on different schedules to ensure all refrigerators and freezers storing VFC-supplied vaccines are equipped with data loggers at all times.
F. Keep certificates of calibration on file and make them available to the VFC Program upon request.
G. Purchase a new data logger if existing device or probe malfunctions, is damaged, or if device provides repeated, inaccurate temperature readings. (Exception for replacement probes recommended and replaced by the device manufacturer.)

## 8. Vaccine Orders & Accountability

A. Order all ACIP-recommended vaccines (including flu, COVID-19, RSV and special-order vaccines), and non-routine vaccines when indicated or requested, to meet the needs of the total VFC-eligible patient populations reported for the provider PIN.
B. Order only one brand and formulation for each vaccine to avoid administration errors.

**NOTES:**

- Under limited circumstances, providers may be allowed to order more than one brand or formulation with VFC Program approval.
- Any changes to vaccine brand ordering require a submitted vaccine change request form.

C. Order all vaccine doses in sufficient quantities to last until the next order period; order quantities must factor in VFC vaccine doses administered (since the previous order) and the VFC doses on hand (at the time of the order).
D. Order vaccines according to the provider location's assigned order frequency or as guided by the VFC Program; provider locations who have not ordered and administered all ACIP-recommended vaccines for their patient population in the past 12 months will be terminated from the VFC Program. Vaccines ordered solely to prevent account termination and are lost due to expiry will be considered a negligent loss.

- Note: Newly enrolled providers must order within 3 months to maintain their active enrollment in the VFC Program.

E. Order vaccines using the approved practice address for the provider PIN.
F. Account for every dose of VFC-supplied vaccine ordered and received by the provider location.
G. Report all VFC vaccine doses administered (since the previous order) and doses on hand (at the time of the order) on each vaccine order. Vaccine doses administered must be based on actual vaccine administration logs or registry/EMR administration summary reports.
H. Maintain accurate and separate stock records (e.g., purchase invoices, receiving packing slips) for privately purchased vaccines and make them available to the VFC Program upon request.

## 9. Receiving Vaccine Deliveries

A. Never reject vaccine shipments.
B. Receive, inspect, and store vaccines and diluents within manufacturer-recommended ranges immediately upon delivery.
C. Immediately report any shipment incidents in myCAvax; providers are encouraged to use the "Vaccine Receiving Checklist" (IMM-1112) to gather the necessary reporting data.
D. Keep packing slips for all vaccine shipments received, including publicly funded and private vaccine shipments.

E. The provider location must be open with staff available to receive vaccines at least one day a week (other than Monday) and for at least four consecutive hours.

## 10. Vaccine Storage

A. Dedicate vaccine refrigerators and freezers to the storage of vaccines only; if storage of medications or biologics is necessary, store below vaccines on a different shelf.
B. Store all frozen vaccines (Merck MMR, MMRV, Varicella, and Moderna COVID-19) between -58.0°F and 5.0°F (-50.0°C and -15.0°C) according to manufacturer recommendations.
C. Store all other refrigerated vaccines between 36.0°F and 46.0°F (2.0°C and 8.0°C) according to manufacturer recommendations.
D. Store vaccines in original packaging and allow space for air circulation.
E. Store VFC-supplied and privately purchased vaccines separately and grouped by vaccine type.
F. Do not store vaccines in storage unit doors, drawers, or bins.
G. Place vaccines with the earliest expiration dates toward the front of vaccine storage units and use first.
H. Always store VFC-supplied vaccines at the approved location for the provider PIN. (**For practices conducting outreach clinics:** Obtain VFC Program approval at least 4 weeks prior to the scheduled outreach clinics.)

## 11. Monitoring Storage Unit Temperatures

A. Record vaccine storage unit temperatures on the CDPH universal temperature log.
B. Monitor and record current, minimum, and maximum temperatures (IMM-1029) twice each day: at the beginning and end of each business day. (**For VFC-approved outreach clinics:** Special event clinics, health fairs, special school clinics, and mass vaccination clinics must monitor and record current, minimum, and maximum temperatures on the "Hourly Vaccine Temperature Log" (IMM-1315) and every hour; attach the data logger download or summary report if available to the " Vaccine Transport Log" (IMM-1132).
C. Temperature logs must be legible and completed accurately and in ink.
D. Neatly cross out, correct, initial, and date any inadvertent documentation error immediately.
E. Download temperature data files and review for any unreported out-of-range temperatures at the end of every two-week reporting period.
F. The supervisor must certify and sign that temperatures were recorded twice daily, staff printed names and initials, and corrective actions were taken for each completed temperature log sheet.
G. Replace vaccines (on a dose-for-dose basis) as instructed by the VFC Program if storage unit temperatures are not monitored and documented, if temperature logs or temperature data files are falsified, or if temperature logs or temperature data files are missing during a site visit.
H. Retain temperature logs and temperature data files for three years, even after your provider location is no longer participating in the VFC Program (due to provider-initiated withdrawal or VFC-initiated termination).

## 12. Taking Action for Temperature Excursions

A. Take immediate action to prevent vaccine spoilage and correct any improper storage condition for all out-of-range storage unit temperatures.
B. Staff must respond to all data logger alarms and out-of-range temperatures.
C. Quarantine and do not administer any vaccines exposed to out-of-range temperatures until their viability has been determined by vaccine manufacturers.

D. Identify and report in myCAvax every temperature excursion from any data logger that is recording temperatures for a unit storing VFC-supplied vaccines and comply with any instructions provided.
E. Communicate every temperature excursion to vaccine manufacturers if instructed by the myCAvax system.
F. Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper refrigerated vaccine transport (IMM-983) and frozen vaccine transport (IMM-1130).

## 13. Vaccine Inventory Management

A. Conduct a physical vaccine inventory at least monthly, and before ordering vaccines, using the "Vaccine Physical Inventory Form" (IMM-1052) 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 to obtain approval prior to transferring short-dated doses to another active VFC provider location to prevent a negligent vaccine loss.
    - Note: For providers with expired vaccines who ordered the minimum quantity or ordered seasonal vaccines (e.g., flu and RSV), vaccines will not be considered a negligent loss.
D. Remove spoiled, expired, and wasted vaccines from storage units after identification to prevent inadvertent use.
E. Report in myCAvax all spoiled, expired, or wasted doses of VFC-supplied vaccines prior to submitting a new vaccine order.
F. Confirm with vaccine manufacturers and/or the VFC Program before reporting any VFC-supplied vaccine as spoiled.
G. Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements.

## 14. Vaccine Transfers & Transports

A. Contact the VFC Call Center prior to transferring VFC-supplied vaccines.
B. If transfers are approved, only transfer VFC-supplied vaccines to other VFC provider locations.
C. Never routinely transfer VFC-supplied vaccines to/from other VFC provider locations.
D. Transport vaccines only when necessary and follow the guidelines for proper refrigerated vaccine transport (IMM-983) and frozen vaccine transport (IMM-1130).
E. Complete the " Vaccine Transport Log" (IMM-1132) each time vaccines are transported.
F. **In case of an emergency:** Only transport VFC-supplied vaccines to alternate storage locations equipped with vaccine storage units and temperature monitoring devices that meet VFC Program requirements.
G. Never transport VFC-supplied vaccines to personal residences.
H. Use backup, battery-operated, digital data loggers to monitor temperatures during vaccine transport and at VFC-approved, off-site clinics—ideally using a portable vaccine refrigerator (if a portable vaccine refrigerator is not available, use qualified containers and packouts) for off-site clinics.
I. Replace any vaccines that were transported without proper documentation of temperature monitoring on a dose-for-dose basis as instructed by the VFC Program.

## 15. Vaccine Administration

A. Administer all VFC-supplied vaccines at the approved practice address for the provider PIN; do not refer VFC-eligible patients to other facilities; vaccinate all VFC-eligible children within your facility. (**For VFC-approved outreach clinics:** Special event clinics, health fairs, special school clinics, and mass vaccination clinics require

prior approval from the VFC Program at least 4 weeks before the scheduled event; frozen vaccines may not be administered off-site; the practice must submit a summary report that includes doses administered within 15 days after the end of the clinic.)

B. Recommend non-routine, ACIP-recommended vaccines when indicated or when requested.
C. Acknowledge and follow VFC Program and manufacturer guidance, including revaccination, if non-viable vaccines have been administered to patients.
D. Report all VFC-supplied vaccine doses administered to an immunization registry (CAIR or RIDE/Healthy Futures) under the Registry ID for the corresponding provider PIN receiving vaccines; data must include all required VFC screening and administration elements.
E. **For non-Medi-Cal, VFC-eligible children:** Waive the administration fee if the parent/guardian is unable to pay. Never bill parents who are unable to pay the waived administration fees.
F. **For Medi-Cal children:** Never bill the difference between Medi-Cal's administration fee and the administration fee cap to the parent/guardian.

## 16. Program Integrity

A. Clinic staff must conduct themselves 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.
C. Make all vaccine administration records (privately and publicly funded) available to representatives from the California Department of Public Health Immunization Branch and VFC Program.
D. Comply with all mandatory corrective actions and the timeline provided by the VFC Program. Unresolved mandatory corrective actions may result in prevention of completion of recertification process and/or placement on a conditional enrollment. Failure to complete required recertification may lead to program termination.
E. Acknowledge that failure to meet conditional enrollment conditions may lead to permanent termination from the VFC Program.

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

***Failure to comply with any of the above could lead to negligent vaccine loss and be grounds for vaccine reimbursement and/or suspension of vaccine ordering privileges and termination from the VFC Program. Multiple warnings prior to account termination will be communicated, but once provider locations are terminated by the VFC Program, they must wait up to one year (or until the next recertification period) before re-enrolling in the program.***

| ***By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.*** | |
|---|---|
| Medical Director or Equivalent Name (print) | |
| Medical License Number | |
| Signature | Date |