

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 VFA/LHD 317 Program requirements listed below.

## 1. Provider Profile

- A. Designate the on-site Provider of Record Designee, who is authorized to sign VFA/LHD 317 Program documents and assume responsibility for VFA/LHD 317-related matters in the absence of the Provider of Record.
- B. Designate the on-site [vaccine coordinator and backup vaccine coordinator \(PDF\)](#), who are responsible for updating and implementing the practice's [vaccine management plan \(Word\)](#).
- 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 VFA/LHD 317 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 \(Word\)](#) 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. Staff with assigned vaccine-management responsibilities must review, sign, and date the vaccine management plan annually and each time it is updated, when VFA/ LHD 317 Program requirements change, and when staff with designated vaccine-management responsibilities change.
- C. Follow emergency guidelines to prepare for, respond to, and recover from any vaccine-related emergencies.
- D. Store or post the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units; and ensure relevant staff are trained to follow guidance when needed.

## 3. Training

- A. Anyone acting in VFA/LHD 317 roles (Provider of Record and Designee, Vaccine Coordinator and Backup, or the optional Organization Vaccine Coordinator and Additional

Vaccine Coordinator roles) must complete the [required EZIZ lessons](#) when hired and annually thereafter; staff must demonstrate competency in their assigned VFA/LHD 317 roles.

- B. Any clinician who administers VFA/LHD 317-supplied vaccines must be knowledgeable of and familiar with all recommendations and guidance from the California Department of Public Health on immunizations, including schedules, indications, dosages, and new products.
- C. All staff who conduct VFA/LHD 317 Program eligibility screening, documentation, and billing (e.g., front- or back-office staff) must be knowledgeable of all VFA/LHD 317 eligibility categories, documentation, and billing for administration and general billing guidelines. Ensure proper training of personnel, including admitting and billing personnel, on processes for screening and billing for administration fees.
- 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 VFA/LHD 317-supplied vaccines are delivered.
- F. Conduct vaccine transport and temperature excursion response drills annually or more frequently as needed (e.g., when hiring new staff or staff errors are discovered) to maintain competency and readiness for emergencies.

## 4. Vaccine Storage Units

- A. Have refrigerators and freezers that comply with [CA VFA and/or CA LHD 317 Program's 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: (1) 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 [CA VFA and/or CA LHD 317-compliant digital data logger](#). Never store VFA/LHD 317-supplied vaccines in a cooler while defrosting a manual defrost freezer.
- 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; update new equipment information in myCAvax and your vaccine management plan.

## 5. Vaccine Storage Unit Configuration

- A. [Prepare vaccine refrigerators and freezers \(PDF\)](#) following CA VFA/LHD 317 Program requirements.
- B. Place water bottles (in refrigerators) and ice packs (in freezers only) to stabilize temperatures. (Exception for purpose-built, auto-dispensing units without doors. Follow manufacturer's guidance.)
- C. Place data logger buffered probes vertically 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 in only one storage unit per electrical outlet that does not have built-in GFI circuit switches and is 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 signs \(PDF\)](#) on electrical outlets and circuit breakers to prevent interruption of power.
- G. [Set up vaccine refrigerators and freezers \(PDF\)](#) following CA VFA/LHD 317 Program requirements.
- H. Clearly identify unit space or containers that will store VFA/LHD 317-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 \(PDF\)](#) 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 VFA/LHD 317-supplied vaccines with [CA VFA/LHD 317-compliant digital data loggers](#). (For purpose-built, auto-dispensing units without doors: Built-in, internal data loggers must meet VFA/LHD 317 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  $\pm 1.0^{\circ}\text{F}$  ( $0.5^{\circ}\text{C}$ ); 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. **Note:** Ultra-low temperature freezers are not required but must be equipped with an air-probe or a probe designed specifically for ultra-cold temperatures.

- 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 use during recalibration, when primary device breaks, when primary device does not meet calibration requirements, or during 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 \(PDF\)](#), including backup digital data loggers.

## 7. Digital Data Logger Configuration & Maintenance

- A. [Configure key settings \(PDF\)](#) 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 \(Word\)](#). (Exception for purpose-built, auto-dispensing units without doors: Store the entire device in a cabinet).
- C. Calibrate primary and backup devices (both device and probe together) every two to three years or according to the manufacturer's suggested timeline ideally by a laboratory with accreditation from an International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) signatory body. **Note:** If the manufacturer supplies a pre-calibrated replacement probe upon device calibration expiration, the device and probe do not need to be calibrated together.
- D. Certificates issued by non-accredited laboratories must meet all CA VFA/LHD 317 Program [requirements for certificates of calibration \(PDF\)](#).
- E. Calibrate primary and backup devices on different schedules to ensure all refrigerators and freezers storing VFA/LHD 317-supplied vaccines are equipped with data loggers at all times.
- F. Keep certificates of calibration on file and make them available to the VFA/LHD 317 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). Update new device information in myCAvax and your vaccine management plan.

## 8. Vaccine Orders & Accountability

- A. Order only one brand and formulation for each vaccine to avoid administration errors.  
**Notes:** (1) Under limited circumstances, providers may be allowed to order more than one brand or formulation with VFA/LHD 317 Program approval. (2) Any changes to vaccine brand ordering will require a submitted a [vaccine brand change request form \(PDF\)](#).
- B. Order all vaccine doses in sufficient quantities to last until the next order period; order quantities must factor in VFA/LHD 317 vaccine doses administered (since the previous order) as reported to the California Immunization Registry (CAIR or CAIR/Healthy Futures) and the VFA/LHD 317 doses on hand (at the time of the order). Order approval will factor limited doses available through the VFA/LHD 317 Program.
- C. Order vaccines according to the provider location's assigned frequency (VFA: quarterly; LHD 317: monthly). Provider locations who have not ordered and administered in the past 12 months will be terminated from the VFA/LHD 317 Program. **Notes:** (1) Vaccines ordered solely to prevent account termination and are lost due to expiry will be considered a negligent loss. (2) Newly enrolled providers must order within 3 months to maintain their active enrollment in the VFA/LHD 317 Program.
- D. Order vaccines using the approved practice address for the provider PIN.
- E. Account for every dose of VFA/LHD 317-supplied vaccine ordered and received by the provider location. Note: Doses administered reported with each VFA order must match doses recorded in an immunization information system (CAIR or CAIR/Healthy Futures) as "317."
- F. Report all VFA/LHD 317 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 \(PDF\)](#) or registry/EMR administration summary reports.
- G. Maintain accurate and separate stock vaccine records (e.g., purchase invoices, receiving packing slips) for privately purchased vaccines if vaccinating non-VFA/LHD 317 patients with ACIP-recommended vaccines and make records available to the VFA/LHD 317 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 \(PDF\)](#) 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 VFA/LHD 317-supplied and privately purchased vaccines separately and grouped by vaccine type.
- F. Do not store vaccines in doors, vegetable bins, floor or near/under cooling vents.
- G. Place vaccines with the earliest expiration dates toward the front of vaccine storage units and use first.
- H. Always store VFA/LHD 317-supplied vaccines at the approved location for the provider PIN.

## 11. Monitoring Storage Unit Temperatures

- A. Record vaccine storage unit temperatures on the [CDPH universal temperature log \(PDF\)](#).
- B. [Monitor and record \(PDF\)](#) current, minimum, and maximum temperatures twice each day: at the beginning and end of each business day.
- 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, review and respond to 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 any temperature excursions were documented with corrective actions taken for each completed temperature log sheet.
- G. Replace vaccines (on a dose-for-dose basis) as instructed by the CA VFA/LHD 317 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 CA VFA/LHD 317 Program (due to provider-initiated withdrawal or VFA/LHD 317 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. Respond to all data logger alarms and temperature excursions. Quarantine and do not administer any vaccines exposed to out-of-range temperatures until you receive further guidance.
- C. Identify and report in myCAvax every temperature excursion from any data logger that is recording temperatures for a unit storing VFA/LHD 317-supplied vaccines and comply with any instructions provided. Communicate temperature excursions to vaccine manufacturers if instructed by the myCAvax system.
- D. Never discard vaccines unless advised by the vaccine manufacturer, the CA VFA/LHD 317 Program or your Field Representative.
- E. Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper [refrigerated \(PDF\)](#) and [frozen vaccine transport \(PDF\)](#).

## 13. Vaccine Inventory Management

- A. Conduct a physical vaccine inventory at least monthly, and before ordering vaccines, using the [vaccine inventory form \(PDF\)](#) or equivalent electronic or paper form.
- B. Never borrow VFA/LHD 317-supplied vaccines to supplement private or other publicly funded vaccine stock, or vice versa.
- C. For vaccines that will expire within 6 months and cannot be used, follow VFA/LHD 317 Program requirements to notify and transfer short-dated doses to another active VFA/LHD 317 provider to prevent a negligent vaccine loss. **Note:** For providers with expired vaccines who ordered the minimum quantity will not be considered a negligent loss.
- D. Remove spoiled, expired, deauthorized and wasted vaccines from storage units to prevent inadvertent use.
- E. Report in myCAvax all spoiled, expired, or wasted doses of VFA/LHD 317-supplied vaccines prior to submitting a new vaccine order.
- F. Confirm with vaccine manufacturers and/or the CA VFA/LHD 317 Program before reporting any VFA/LHD317- 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 CA VFA/LHD 317 Program requirements.

## 14. Vaccine Transfers & Transports

- A. Contact the Provider Call Center to obtain approval to transfer VFA/LHD 317-supplied vaccines; only transfer VFA/LHD 317 vaccines to another active VFA/LHD 317 provider.

- B. Transfer VFA/LHD 317-supplied vaccines only when necessary. Vaccines should never be routinely transferred to and from an existing location.
- C. Report in myCAvax all transfers in and out of inventory.
- D. Transport vaccines only when necessary and follow the guidelines for proper [refrigerated \(PDF\)](#) and [frozen vaccine transport \(PDF\)](#) each time vaccines are transported
- E. Complete a [vaccine transport log \(PDF\)](#) each time vaccines are transported.
- F. In case of an emergency only, transport VFA/LHD 317-supplied vaccines to alternate storage locations equipped with [vaccine storage units](#) and [temperature monitoring devices](#) that meet CA VFA/LHD 317 Program's requirements. Temporary storage of vaccines in a cooler is unacceptable.
- G. Never transport VFA/LHD 317-supplied vaccines to personal residences.
- H. Use backup, battery-operated, digital data loggers to monitor temperatures during vaccine transport.
- I. If instructed by the CA VFA/LHD 317 Program, agree to replace any vaccines that were transported without proper temperature monitoring documentation on a dose-for-dose basis.

## 15. Vaccine Administration

- A. Administer all VFA/LHD 317-supplied vaccines at the approved practice address for the provider PIN; do not refer patients to other facilities where they might be charged for vaccine administration.
- B. Acknowledge and follow VFA/LHD 317 Program and manufacturer guidance, including revaccination, if nonviable vaccines have been administered to patients.
- C. Report all VFA/LHD 317-supplied vaccine doses administered to the California Immunization Registry (CAIR or Healthy Futures/RIDE) under the Registry ID for the corresponding provider PIN receiving vaccines; data must include all required VFA/LHD 317 screening and administration elements.
- D. **For VFA Providers:** For uninsured/underinsured eligible adults, never bill for the cost of the vaccine and the administration fee.
- E. **For LHD 317 Providers:** For uninsured/underinsured eligible adults, never bill for the cost of the vaccine. An administration fee of up to \$26.03 per vaccine dose may be charged. If the individual is unable to pay the administration fee, the vaccine dose will not be denied, and the administration fee will be waived.

## 16. CAIR Documentation

- A. Enter all immunization administration data as well as a patient's race and ethnicity into a California immunization registry (CAIR or CAIR/Healthy Futures) per CA [AB-1797](#).
- B. Report all VFA/LHD 317 vaccine doses administered to an immunization registry (CAIR or CAIR/Healthy Futures); data must include all required elements of eligibility screening (including eligibility code and funding source), NDC and vaccine administration elements.

- C. Report doses administered under the Registry ID for the corresponding VFA/LHD 317 PIN receiving vaccines.
- D. Immunization of VFA/LHD 317-eligible patients will be documented in or submitted through data exchange as “317 Vaccine Eligibility or Vaccine Eligibility Category (HL7) Code V07 or V23” doses to the local immunization information system (CAIR or CAIR/Healthy Futures) and documented in an Electronic Health Record (EHR). The total number of patients immunized with Section 317 vaccines and inventory on-hand will be reported to the California Department of Public Health (CDPH) according to reporting guidelines. Review doses reported in the immunization information system a minimum of every six months.
- E. Doses administered reported with each VFA order must match doses recorded in an immunization information system (CAIR or CAIR/Healthy Futures) as '317.'" Registry data may be used to approve vaccine orders.

## 17. Program Integrity

- A. Clinic staff must conduct themselves in an ethical, professional, and respectful manner in all interactions with CDPH Program staff. Providers agree to allow [CDPH Field Representatives](#) to conduct visits without requiring personal information.
- B. Never destroy, alter, or falsify immunization VFA/LHD 317 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 VFA/LHD 317 Program.
- D. Comply with all mandatory corrective actions and the timeline provided by the VFA/LHD 317 Program. Unresolved mandatory corrective actions may result in prevention of completion of recertification and/or placement on a conditional enrollment. Failure to complete required annual recertification may lead to program termination.
- E. Acknowledge that failure to meet conditional enrollment conditions may lead to permanent termination from the VFA/LHD 317 Program.

## 18. Temporary Mobile & Off-Site Clinics

### Mobile Clinics

- A. The CA VFA/LHD 317 Program must approve use of mobile units administering VFA/LHD 317-supplied vaccines.
- B. Providers must designate a Vaccine Coordinator to travel with the mobile unit when it goes into the field. The Vaccine Coordinator must complete all required training before traveling in the mobile unit.
- C. Mobile clinics must maintain a current and complete [mobile unit vaccine management plan \(Word\)](#) and keep it in the mobile unit.
- D. Providers must make mobile units and all relevant equipment and documentation available during CDPH site visits.

- E. Mobile clinics must monitor and record current, MIN, and MAX temperatures on the [universal temperature log \(PDF\)](#) at the beginning and end of each clinic day.
- F. Mobile clinics must report excursions to myCAvax as soon as possible and follow requirements for responding to excursions.
- G. Mobile clinics must report doses administered to the regional immunization registry the same day or no longer than 15 days after the end of the clinic.

### Off-Site Clinics

- A. Providers must obtain approval from the CA VFA/LHD 317 Program at a minimum of four weeks **prior** to any off-site clinic.
- B. Off-site clinics must administer all VFA/LHD 317 vaccines offered at the event for which the patient is eligible. Frozen vaccines may not be administered off-site unless there is prior approval from CA VFA/LHD 317 Program.
- C. Provider locations designated solely as mass vaccinators must use purpose-built, vaccine transport units for transport and on-site storage.
- D. Off-site clinics must complete the [vaccine transport log \(PDF\)](#) every time vaccines are transported in and out of the stationary clinic.
- E. Off-site clinics must use backup, battery-operated, digital data loggers to monitor temperatures—ideally using a portable vaccine refrigerator (if a portable vaccine refrigerator is not available, use qualified containers and pack outs).
- F. Off-site clinics must monitor and record current, MIN, and MAX temperature on the [hourly temperature log \(PDF\)](#) and every hour; attach the data logger download or summary report to the [vaccine transport log \(PDF\)](#).
- G. Off-site clinics must report excursions to myCAvax as soon as possible and follow requirements for responding to excursions.
- H. Off-site clinics must report doses administered to the regional immunization registry the same day or no longer than 15 days after the end of the clinic.

**Instructions:** To receive VFA/LHD 317-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 VFA/LHD 317 Program. Multiple warnings prior to account termination will be communicated, but once provider locations are terminated by the VFA/LHD 317 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: