KEY PRACTICE STAFF CHANGE REQUEST FORM

(For Provider of Record or Provider of Record Designee)



Complete, sign, and email to the Provider Call Center at ProviderCallCenter@cdph.ca.gov

INSTRUCTIONS: Providers are required to use this form to notify the VFA or LHD 317 Program immediately of any changes to the Provider of Record or the Provider of Record Designee. The Provider of Record must sign the form acknowledging his/her authorization of these changes. Key clinic staff must complete required lessons on www.EZIZ.org. Completion of those lessons must occur before the VFA or LHD 317 Program makes any changes to the practice's VFA or LHD 317 Provider Information.

- Provider of Record (POR): The physician-in-chief, medical director, or equivalent role that signs and agrees to the terms of the "VFA Provider Agreement" or "LHD 317 Agreement" and the California "VFA and LHD 317 Provider Agreement Addendum" and who is ultimately accountable for the practice's compliance. The Provider of Record must be a licensed MD, DO, NP, PA, pharmacist, or a Certified Nurse Midwife with prescription-writing privileges in California.
- Provider of Record Designee: The on-site employee that is designated by the Provider of Record to sign VFA or LHD 317 documents on his/her behalf and assume responsibility for VFA or LHD 317-related matters in the absence of the Provider of Record.
- Vaccine Coordinator: The on-site employee who is fully trained and responsible for implementing and
 overseeing the provider's vaccine management plan. The Vaccine Coordinator might be responsible for
 all vaccine management activities, including training other (especially new) staff. In other practices, a
 different person might have one or more vaccine management responsibilities.
- Backup Vaccine Coordinator: The on-site employee who is fully trained in the practice's vaccine
 management activities and fulfills the responsibilities of the Vaccine Coordinator if the Vaccine Coordinator
 is unavailable.

Practice Information			
Practice Name		PIN	Registry ID
Address			County
City	ZIP	Phone	Fax

Key Practice Staff								
Change	Completed Required Lessons	Role/ Responsibility	Name	Title (MD, DO, NP, PA)	Specialty/ Clinic Title*	National Provider ID*	Medical License*	Contact Information
		Provider of Record			Specialty: Clinic Title:			Direct Phone Number: Email:
		Provider of Record Designee			Specialty: Clinic Title:			Direct Phone Number: Email:
		Vaccine Coordinator	Contact the Provider Call Center at (833) 502-1245 or ProviderCallCenter@cdph.ca.gov					
		Backup Vaccine Coordinator	Contact the Pro	vider Call C	Center at (833) 502-12	45 or Prov	iderCallCe	nter@cdph.ca.gov

^{*}Include if applicable

KEY PRACTICE STAFF CHANGE REQUEST FORM

Signatures

If the Provider of Record has changed since the practice last recertified with the VFA or LHD 317 Programs, these additional forms must be signed on the following pages.

LHD 317 providers, continue to:

• Pages 5-14 (LHD Provider Agreement and VFA/LHD 317 Provider Agreement Addendum)

VFA providers, continue to:

- Pages 3-4 (VFA Provider Agreement) and
- Pages 7-14 (VFA/LHD 317 Provider Agreement Addendum)

By signing this form, I authorize these changes be made to key practice staff with responsibilities related to the VFA or LHD 317 Program.		
Provider of Record Name (print):	Date:	
Provider of Record (signature):		



Vaccines for Adults (VFA) Provider Agreement

To receive federally-funded Section 317 vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent.

- 1. Section 317 vaccines will be administered to any individual aged 19 years and older, who is uninsured or underinsured. Patients covered by Medi-Cal are considered insured and NOT eligible for the VFA program. Staff will consult the VFA Vaccine Eligibility Based on Insurance table as needed to determine specific vaccine eligibility for patients. Eligibility screening will be conducted prior to the administration of vaccine doses. Verification of eligibility can be obtained verbally from the individual. All staff, including front office and billing staff, will be knowledgeable of VFA eligibility.
- Section 317 vaccines will be administered in compliance with the most recent immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) unless: a) in making a medical judgment in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the patient; or b) the patient declines particular immunizations.
- 3. Patients immunized with Section 317 vaccines will not be billed for the cost of the vaccine nor be charged an administration fee. All systems will be checked to ensure patients are not charged and vaccine cost will not be billed.
- 4. Current Vaccine Information Statements (VIS) will be offered prior to each vaccination. Vaccine administration records will be maintained in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the <u>Vaccine Adverse Event Reporting System (VAERS)</u>.
- 5. Organization will be enrolled in a local immunization information system (CAIR or RIDE/Healthy Futures).
- 6. Report all VFA vaccine doses administered to an immunization registry (CAIR2 or Healthy Futures/RIDE), and data must include all required VFA screening, patient's race and ethnicity, and administration elements. Report doses administered under the Registry ID for the corresponding VFA PIN receiving vaccines. (CA AB1797)
- 7. Immunization of VFA-eligible patients will be documented in or submitted through data exchange as "317 Vaccine Eligibility or Vaccine Eligibility Category (HL7) Code V07" doses to the local immunization information system (CAIR2 or Healthy Futures/RIDE) 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 periodically, or at a minimum of every 3 months.
- 8. Doses administered reported with each VFA order must match doses recorded in an immunization information system (CAIR2. or Healthy Futures/RIDE) as '317.'" Registry data will be used to approve vaccine orders.
- 9. The patient's recorded 317 eligibility status and all records related to the VFA program will be retained for three (3) years. If requested, these records will be made available to the California Department of Public Health (CDPH). Records include, but are not limited to, vaccine administration documentation, billing records, medical records that verify receipt of vaccine, and vaccine temperature log records. Release of such records will be bound by federal and state privacy laws.



Vaccines for Adults (VFA) Provider Agreement

- 10. Standards for vaccine ordering, reporting and management will be followed as outlined in the <u>Program Provider Agreement Addendum</u>. Detailed information on ordering can be found on the <u>EZIZ website VFA page</u>.
- 11. Order vaccines according to the quarterly VFA order frequency; providers who have not ordered vaccines in the past calendar year may be terminated from the VFA Program.
- 12. Organization will operate in a manner intended to avoid fraud and abuse of Section 317 vaccines. **Fraud:** is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.
 - **Abuse:** provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the program or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care.
- 13. Authorized representatives of the VFA Program will be permitted to visit the facility in order to review compliance with policies and procedures. Provider agrees to implement and complete corrective actions identified during the visit.
- 14. Vaccine purchased with Section 317 federal funds that are deemed non-viable due to provider negligence will be replaced on a dose-for-dose basis.
- 15. The term of this agreement is from **January 1, 2024** until vaccine doses are completely administered. Section 317 vaccines can continue to be administered until its expiration date.
- 16. I understand that the CDPH, Immunization Branch or my practice/organization may terminate this agreement at any time. If the agreement is terminated, any unused Section 317 vaccines will be properly returned to the CDPH Vaccines for Adult (VFA) 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	

Agreement for the Use of 317-Funded Vaccines

To red mysel	IDER AGREEMENT seive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of f and all the practitioners, nurses, and others associated with the health care facility of
1.	I am the medical director or equivalent: Federally-funded Section 317 vaccine doses will be administered to any individual aged 19 years and older, meeting one or more of the following eligibility categories:
	 A. 317 vaccine-eligible adults: Uninsured: An adult without any health insurance coverage (public or private coverage). Underinsured: An adult who has health insurance, but the coverage does not include vaccines or a person whose insurance covers only selected vaccines.
	B. fully insured individuals seeking vaccines during identified public health response activities* including: (1) outbreak response (2) post-exposure prophylaxis (3) disaster relief efforts (4) mass vaccination campaigns or exercises for public health preparedness.
	* Requires pre-approval from the California Department of Public Health (CDPH) prior to the use of 317-funded vaccine for the above activities.
	Eligibility screening will be conducted prior to the administration of each vaccine dose and eligibility status will be documented in the program's 317 Eligibility Screening Form, or California Immunization Registry (CAIR), or Electronic Health Record (EHR) containing the required documentation elements found in the 317 Eligibility Screening Form.
2.	Vaccine doses will be administered in compliance with the most recent immunization schedule, dosage, and contraindications established by the Advisory Committee on Immunization Practices (ACIP) unless: a) in making a medical judgment in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the patient; or b) the patient declines particular immunizations.
3.	Patients immunized with 317-funded vaccines will not be billed for the cost of the vaccine, however an administration fee of up to \$26.03 per vaccine dose may be charged to patients. If the individual is unable to pay the administration fee, the vaccine dose will not be denied and the administration fee will be waived.
4.	Current Vaccine Information Statements (VIS) will be offered prior to each vaccination. Vaccine administration records will be maintained in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/
5.	Immunization of patients will be documented in CAIR. The total number of patients immunized with 317 doses and inventory on-hand will be promptly reported to CDPH with each 317-funded vaccine request. Vaccine doses administered as part of CDPH approved outbreak control and prevention activities will be documented, tracked, and reported according to established guidelines.
6.	The patient's written 317 eligibility status and all records related to immunization of adults with 317-funded vaccines will be retained for three (3) years. If requested, these records will be made available to CDPH. Records include, but are not limited to, vaccine administration documentation, billing records, medical records that verify receipt of vaccine, and vaccine temperature log records. Release of such records will be bound by federal and state privacy laws.

Agreement for the Use of 317-Funded Vaccines

7.	Standards for vaccine management outlined in the Vaccines for Children (VFC) Program's Provider Agreement Addendum will be followed, including:
	 a) vaccine ordering and maintaining appropriate vaccine inventories; b) storing vaccine under proper storage conditions at all times; c) monitoring and documenting vaccine storage unit temperatures on VFC temperature logs; d) returning all spoiled/expired 317-funded vaccines to the Centers for Disease Control and Prevention's (CDC) centralized vaccine distributor within six months of spoilage/expiration.
	Refrigerator and freezer vaccine storage units and temperature monitoring equipment must meet CDPH VFC Program storage and handling requirements.
8.	Organization will operate within the 317 Vaccine Program guidelines intended to avoid fraud and abuse as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the 317 Vaccine Program.
9.	Authorized representatives of the 317 Vaccine Program will be permitted to visit the facility in order to review compliance with policies and procedures.
10.	Vaccine purchased with federal funds (317) that are deemed non-viable due to provider negligence may be replaced on a dose-for-dose basis.
11.	I understand that the CDPH, Immunization Branch or my practice/organization may terminate this agreement at any time. If the agreement is terminated, any unused federal 317-funded vaccines will be properly returned to the California Department of Public Health Vaccines for Children Program, who administers the Section 317 Vaccine Program.

To agree to these federal requirements, type your name, your medical license number, today's date, and sign in the boxes below.

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 for the use of 317-funded vaccines 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		
Name (print) Second individual as needed			
Medical License Number			
Signature	Date		



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/317 Program requirements listed below.

1. Provider Profile

- A. Designate the on-site Provider of Record Designee, who is authorized to sign VFA/317 Program documents and assume responsibility for VFA/317-related matters in the absence of the Provider of Record.
- B. Designate the on-site <u>Vaccine Coordinator and Backup Vaccine Coordinator</u> (IMM-968), who are responsible for implementing the practice's vaccine management plan.
- C. Immediately report to the VFA/317 Program changes to key practice staff assuming VFA/317 roles (Vaccine Coordinator or Backup, Provider of Record or Designee); a change in the Provider of Record or Designee requires a signed "Key Practice Staff Change Request Form."
- D. Immediately report to the VFA/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 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 VFA/317 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 VFA/317-supplied vaccines: Mobile-only clinics or clinics with mobile units must maintain a current and complete "Mobile Unit Vaccine Management Plan" and keep it in the mobile unit.

3. Training

- A. Anyone acting in VFA/317 roles (Provider of Record and Designee, Vaccine Coordinator and Backup) must complete the required EZIZ lessons when hired and annually thereafter; staff must demonstrate competency in their assigned VFA/317 roles.
- B. Any clinician who administers VFA/317-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 VFA/317 Program eligibility screening, documentation, and billing (e.g., front- or back-office staff) must be knowledgeable of all VFA/317 eligibility categories, documentation, and billing requirements.
- D. All staff and supervisors who monitor storage unit temperatures or sign off on VFA/317 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.



- E. Train staff who are authorized to accept packages to immediately notify the Vaccine Coordinator when VFA/317-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 <u>vaccine storage unit requirements</u>: 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.
- 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 <u>compliant digital data logger</u>. Never store VFA/317-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 barstyle 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 VFA/317 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 "<u>Do Not Unplug</u>" (IMM-744) signs on electrical outlets and circuit breakers to prevent interruption of power.
- G. Set up vaccine refrigerators and vaccine freezers (IMM-963) following VFA/317 Program requirements.
- H. Clearly identify unit space or containers that will store VFA/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 CDPH temperature logs 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/317-supplied vaccines with <u>compliant digital data loggers</u>. (For purpose-built, auto-dispensing units without doors: Built-in, internal data loggers must meet VFA/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 ±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. (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 VFA/317 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 VFA/317 Program <u>requirements for certificates</u> <u>of calibration</u> (IMM-1119).
- E. Calibrate primary and backup devices on different schedules to ensure all refrigerators and freezers storing VFA/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/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.)

8. Vaccine Orders & Accountability

- A. Order only one brand and formulation for each vaccine to avoid administration errors.
- B. Order all vaccine doses in sufficient quantities to last until the next order period; order quantities must factor in VFA/317 vaccine doses administered (since the previous order) and the VFA/317 doses on hand (at the time of the order).
 - Order approval will factor limited doses available through the VFA/317 Program
- C. Provider locations who have not ordered and administered in the past 12 months will be terminated from the VFA/317 Program. Vaccines ordered solely to prevent account termination and are lost due to expiry will be considered a negligent loss.
- D. Order vaccines using the approved practice address for the VFA/317 PIN.
- E. Account for every dose of VFA/317-supplied vaccine ordered and received by the provider location.
 - Doses administered reported with each VFA order must match doses recorded in an immunization information system (CAIR2 or Healthy Futures/RIDE) as '317.'" Registry data will be used to approve vaccine orders.
- F. Report all VFA/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 or registry/EMR administration summary reports.
- G. Maintain accurate and separate stock records (e.g., purchase invoices, receiving packing slips) for privately purchased vaccines and make them available to the VFA/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 all shipment issues using the VFA/317 "Vaccine Receiving Log and Checklist" (IMM-1216).
- 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, , and Varicella) 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/317-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 federally-supplied vaccines at the approved location for the VFA/317 PIN. (For practices conducting outreach clinics: Obtain VFA/317 approval at least 4 weeks prior to the scheduled outreach clinics.)

11. Monitoring Storage Unit Temperatures

- A. Record vaccine storage unit temperatures on CDPH temperature logs.
- B. Monitor and record current, minimum, and maximum temperatures (<u>Fahrenheit</u> IMM-1029 | <u>Celsius</u> IMM1029C) twice each day: at the beginning and end of each business day. (**For VFA/317-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 CDPH "<u>Hourly Vaccine Temperature Log</u>" (IMM-1255) and every hour. Attach the data logger download, or summary report if available, to the VFA/317 "<u>Refrigerated Vaccine Transport Log</u>" (IMM-1213) and VFA/317 "<u>Frozen Vaccine Transport Log</u>" (IMM-1214).)
- C. CDPH 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 when the CDPH temperature log is complete for each two-week reporting period.
- G. Replace vaccines (on a dose-for-dose basis) as instructed by the VFA/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 CDPH temperature logs and temperature data files for three years, even after your provider location is no longer participating in the VFA/317 Program (due to provider-initiated withdrawal or VFA/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. Staff must respond to all data logger alarms.
- 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 every temperature excursion from any data logger that is recording temperatures for a unit storing VFA/317 vaccines, in myCAvax and comply with any instructions provided.
- E. Communicate every temperature excursion to vaccine manufacturers to determine vaccine viability if instructed by myCAvax.
- F. Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper <u>refrigerated vaccine transport</u> refrigerated vaccine transport (IMM-983) and <u>frozen vaccine transport</u> (IMM-1130).



13. Vaccine Inventory Management

- A. Conduct a physical vaccine inventory at least monthly, and before ordering vaccines, using the VFA/317 "Vaccine Physical Inventory Form" (IMM-1227) or equivalent electronic or paper form.
- B. Never borrow VFA/317-supplied vaccines to supplement private stock, or vice versa.
- C. For vaccines that will expire within 6 months and cannot be used: Notify the Provider Call Center to obtain approval prior to transferring short-dated doses to another active VFA/317 provider location to prevent a negligent vaccine loss.
- D. Remove spoiled, expired, and wasted vaccines from storage units after identification to prevent inadvertent use.
- E. Report all spoiled, expired, or wasted doses of VFA/317-supplied vaccines prior to submitting a new vaccine order.
- F. Do not report any VFA/317-supplied vaccines as spoiled without guidance from vaccine manufacturers and/or the VFA/317 Program.
- G. Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with VFA/317 Program requirements.

14. Vaccine Transfers & Transports

- A. Contact the Provider Call Center prior to transferring VFA/317-supplied vaccines.
- B. If transfers are approved, only transfer VFA/317-supplied vaccines to other VFA/317 provider locations.
- C. Never routinely transfer VFA/317-supplied vaccines to/from other VFA/317 provider locations.
- D. Transport vaccines only when necessary and follow the guidelines for proper <u>refrigerated vaccine transport</u> (IMM-983) and <u>frozen vaccine transport</u> (IMM-1130).
- E. Complete the VFA/317 "Refrigerated Vaccine Transport Log" (IMM-1213) or "Frozen Vaccine Transport Log" (IMM-1214) each time vaccines are transported.
- F. **In case of an emergency:** Only transport VFA/317-supplied vaccines to alternate storage locations equipped with vaccine storage units and temperature monitoring devices that meet VFA/317 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 VFA/317-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.
- Replace any vaccines that were transported without proper documentation of temperature monitoring on a dose-for-dose basis as instructed by the VFA/317 Program.

15. Vaccine Administration

- A. Administer all VFA/317-supplied vaccines at the approved practice address for the VFA/317 PIN; do not refer patients to other facilities where they might be charged for vaccine administration. (For VFA/317-approved outreach clinics: Special event clinics, health fairs, special school clinics, and mass vaccination clinics require prior approval from the VFA/317 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. Acknowledge and follow VFA/317 Program and manufacturer guidance, including revaccination, if non-viable vaccines have been administered to patients.



- C. Report all VFA/317 vaccine doses administered to an immunization registry (CAIR2, RIDE), and data must include all required VFA screening and administration elements. Report doses administered under the Registry ID for the corresponding VFA/317 PIN receiving vaccines.
- D. For uninsured/underinsured eligible adults: Never bill for the cost of the vaccine and the administration fee.

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 RIDE/Healthy Futures) CA AB1797.
- B. Report all VFA vaccine doses administered to an immunization registry (CAIR2 or Healthy Futures/RIDE), and data must include all required VFA screening (317 eligibility) and vaccine administration elements.
- C. Report doses administered under the Registry ID for the corresponding VFA PIN receiving vaccines.
- D. Immunization of VFA-eligible patients will be documented in or submitted through data exchange as "317 Vaccine Eligibility or Vaccine Eligibility Category (HL7) Code V07" doses to the local immunization information system (CAIR2 or Healthy Futures/RIDE) 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 (CAIR2. or Healthy Futures/RIDE) as '317.'" Registry data will 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.
- B. Never destroy, alter, or falsify immunization or VFA/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/317 Program.
- D. Comply with all mandatory corrective actions and the timeline provided by the VFA/317 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 VFA/317 Program.



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