Program Requirements

For Section 317-Funded Vaccines

CDPH California Department of Public Health | VFA California Vaccines for Adults Program | LHD 317 Local Health Department 317 Program

Welcome

Thank you for joining a partnership of federal, state, local health departments and providers working to vaccinate Californians against vaccine-preventable diseases.

For patients, you are one of the most trusted sources of information when it comes to vaccines. Your strong recommendation for vaccination leads to more people getting vaccinated, leading to fewer vaccine preventable diseases, hospitalizations, and deaths.

The California Vaccines for Adults (VFA) and Local Health Department (LHD) 317 Programs are both funded by federal Section 317 funds and share the same program requirements apart from ordering cadence and billing for administration fees, which are highlighted and addressed separately. Providers participating in either vaccine program now complete the same lesson to meet federal education requirements for enrollment and annual recertification.

Thank you for the efforts you and your practice staff are making to keep California healthy.

Platforms You'll Use

myCAvax	Local IZ Registry	CAIR Quick Entry (Optional)
Vaccine Management Platform Self-service platform offers sites an all-in-one application for managing locations, ordering vaccine, and submitting reports for inventory management.	**Immunization Registry Platform** A secure and confidential statewide information system that contains the immunization records for all California residents. Most providers use the **CAIR system**. The greater San Joaquin Valley uses **CAIR/Healthy Futures** to access patient IZ records.	**Clinic Management Platform** My Turn supports direct submission of IZ records to CAIR through CAIR Quick Entry. Providers who enroll in My Turn will automatically receive CAIR Quick Entry access. Benefits include: • Single, bulk, and batch record uploads to CAIR • Ability to edit records post-submission • Support for all CAIR vaccines

Provider Call Center

For VFA and LHD 317 questions plus myCAvax and My Turn Clinic IT support at (833) 502-1245 and **providercallcenter@cdph.ca.gov**

Provider Requirements

This section reviews the program requirements listed in the provider agreements for adult patients. Most key requirements in the separate Provider Agreement Addendum are covered in the Vaccine Management section. Providers and key practice staff must comply with all program requirements, which are designed to protect vaccines and ensure all 317-eligible patients are vaccinated at no out-of-pocket costs.

Required For:

Providers & Vaccine Coordinators

VFA Program

- **Provider Agreement (PDF)**
- **VFA/317 Provider Agreement Addendum (PDF)**
- **Requirements at a Glance (PDF)**

LHD 317 Program

- **Provider Agreement (PDF)**
- **VFA/317 Provider Agreement Addendum (PDF)**

Key Practice Staff

Designation of key practice staff responsible for overseeing 317-funded vaccines is an important requirement that ensures successful compliance. Staff fulfilling key practice roles must be knowledgeable and trained in all program requirements. Report in myCAvax any changes to key practice staff assuming these program roles:

- Provider of Record (POR): The on-site physician-in-chief, medical director, or equivalent who signs and agrees to the terms of the provider agreements and is ultimately accountable for the practice's compliance. Must be a licensed MD, DO, NP, PA, pharmacist, or a Certified Nurse Midwife with prescription-writing privileges in California.
- Provider of Record Designee: On-site staff designated by the Provider of Record with sufficient authority to assume responsibility for program-related matters in their absence.
- Vaccine Coordinator: On-site staff who is fully trained and responsible for implementing the practice's vaccine management plan and managing the vaccine inventory. Vaccine Coordinators might be responsible for all vaccine management activities, including training other (especially new) staff. This role might be filled by medical assistants, LVN, RN, office manager, or other trained staff.

- Backup Vaccine Coordinator: On-site staff who is fully trained in and fulfills the responsibilities of the Vaccine Coordinator in their absence.
- Immunization Champion (optional): A staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community.
- Organization Vaccine Coordinator (optional): Large organizations may assign this role to coordinate communications across affiliated sites and ensure staff are properly trained to implement their vaccine management plan. This role must complete all required training for the Vaccine Coordinator role.
- Additional Vaccine Coordinator (optional): Add an additional vaccine coordinator to share vaccine management responsibilities if needed. This role must complete all required training for the Vaccine Coordinator role and should be on-site when feasible.

Importance of Vaccine Coordinators

The Vaccine Coordinator and Backup roles are responsible for implementing the practice's vaccine management plan, which protects the viability of vaccines that might be worth from tens of thousands to more than $500,000 over the course of a year. Make sure staff filling these roles understand the impact they can have and that they have been trained on use of the practice's data loggers. These roles might be filled by medical assistants, LVN, RN, office manager, or other trained staff. (See **Vaccine Coordinator Role & Responsibilities (PDF)**.)

Eligibility Screening & Documentation

Eligibility screening must be conducted prior to administration to ensure 317-funded vaccines only go to eligible adults. Ensure protocols are in place so vaccinators know when to pull from private or public stock.

What Staff Need to Know

Front Office Staff

Ensure staff are familiar with the **317 Eligibility Based on Insurance Status (PDF)** as a quick reference guide. It clearly identifies who is eligible and who is not.

Billing Staff

Ensure staff are trained on billing requirements for 317-funded vaccines.

- VFA-eligible patients: Do not bill for the cost of the vaccine or an administration fee.
- LHD 317-eligible patients: Do not bill 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.

Key Points

- Screen all adults 19 years of age and older using the **317 Eligibility Based on Insurance Status table (PDF)**.
- Screen prior to vaccine administration—at every immunization visit.

- Document all elements of the **317 Eligibility Screening Record (PDF)** (including the screening date, 317 eligibility (Y/N), and any eligibility criteria in the patient's Electronic Health Record and in the California Immunization Registry record (CAIR or CAIR/Healthy Futures).
- Keep all VFA eligibility records on file for three years.

Vaccine Administration

Administer vaccine doses per written medical order and report all doses administered to the California Immunization Registry (CAIR or CAIR/Healthy Futures). This task results in patient medical records being updated for all doses administered. And those reported doses impact vaccine ordering. Ensure vaccinators are trained in practice protocols for vaccine preparation and administration.

Key Points

- Ensure protocols are in place so vaccinators know when to use 317-funded vaccines versus private vaccines.
- Administer all 317-funded 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.
- Acknowledge and follow VFA or LHD 317 Program and manufacturer guidance, including revaccination, if non-viable vaccines have been administered to patients.
- Report all 317-funded vaccine doses administered to an immunization registry (CAIR or CAIR/Healthy Futures). Data must include all required VFA screening and administration elements. Report doses administered under the Registry ID for the provider PIN receiving vaccines.
- Special event clinics, health fairs, special school clinics, and mass vaccination clinics require prior approval from the VFA or LHD 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.)

Vaccine Administration Fees

Providers must use screening results to ensure patients are billed in compliance with requirements for 317-funded vaccines.

Key Points

To reduce financial barriers for patients and ensure that eligible patients do not incur additional costs outside of any routine copay for the clinic visit, providers must comply with billing requirements:

- VFA-eligible patients: Never bill for vaccine or an administration fee.

  Prominently **post a sign (PDF)** clearly visible to patients which communicates that “FREE vaccines are available to adult patients who are uninsured or have insurance that doesn’t cover

(certain) vaccines. We do not charge these patients for getting the vaccine or for the cost of the vaccine."

- LHD 317-eligible patients: Never bill for vaccine. Providers may bill for an administration fee of up to $26.03.

Vaccine Information Statements (VISs)

Providers are required to distribute the current Vaccine Information Statements (VISs) each time a vaccine is administered and document and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA). Vaccine Information Statements (VISs) are produced by CDC in consultation with panels of experts and parents, to educate the public about the benefits and risks of vaccines.

Key Points

- VISs must be distributed to all patients before vaccine administration—in both private and public settings.
- Providers must distribute the most current version, in either paper or electronic formats. (Some EMR/EHR systems don't update VISs automatically.)
- VISs must be distributed for each dose administered—including combination vaccines.
- VISs should be given in the language that the recipient can easily understand; Vaccine Information Statements in multiple languages can be found **here**.
- Signed consent is not required for a person to be vaccinated.
- VISs must not be altered before distribution to the patient, parent, or guardian.

Enrollment in CAIR

AB 1797 requires all vaccination sites to enroll in and report doses administered to the California Immunization Registry (CAIR). Each location will be assigned an Org Code (IIS ID).

CAIR is a secure, confidential, statewide immunization information system that helps providers and other authorized users track patient immunization records and reduce missed vaccination opportunities. Most providers use the CAIR software application. The greater San Joaquin Valley utilizes **CAIR/Healthy Futures**. See **How to Enroll in CAIR**.

Reporting Options

Providers may report doses administered to CAIR electronically using their EHR with data exchange, CAIR Manual Entry, or My Turn.

CAIR Data Exchange

Your electronic health records system can be configured to automatically push administration data to CAIR. All sites are encouraged to enroll a staff member in the DX Quality Assurance (DX QA) user role. This role does not require formal training and allows staff to monitor data exchange transactions,

look up patients, and access reminder/recall and ad hoc patient reports. See CAIR's **Local Data Exchange Contacts** and **FAQs** or contact your **Local CAIR Representative (LCR)** for assistance.

CAIR Manual Entry

Clinic sites may manually enter vaccine administration data into CAIR. CAIR training is available for Regular and Power users. For local CAIR user support, including local training options or local issue resolution, contact your **Local CAIR Representative (LCR).**

My Turn

My Turn is an all-in-one vaccine administration application for vaccine eligibility, public appointment scheduling, walk-in appointments, dose administration, and reporting for vaccine clinics. **My Turn** supports all recommended pediatric and adult vaccines. See **My Turn Onboarding Guide (PDF).**

Reporting Doses Administered to CAIR

Clinic sites must document vaccine administration in their medical record systems within 24 hours of administration and report doses administered (including eligibility category and funding source) to the local registry (CAIR or CAIR/Healthy Futures) as soon as practicable and no later than 72 hours. Providers must report all required data elements, which are standard for administration data.

Documenting Administration

Providers must maintain records in accordance with the national Vaccine Injury Compensation Program (VICP), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Document the following information in the patient's permanent medical record:

- VIS edition date (found on the back in the bottom right corner)
- date VIS is provided
- practice address
- vaccinator name and title
- date vaccine is administered
- vaccine manufacturer and lot number

Reporting Administration Data to CAIR

Providers must report to the local registry (CAIR or CAIR/Healthy Futures) all required data elements including administration data, funding source, and eligibility category of "317". See **Reporting Doses Administered** for details.

Key Points

- Providers must report "317 Vaccine Eligibility or Vaccine Eligibility Category (HL7) Code V23" doses to the local registry and document administration in an Electronic Health Record (EHR).

- Providers submit vaccine orders in **myCAvax** and must report (1) the total number of patients immunized with Section 317 vaccines and (2) inventory on hand on each vaccine order.
- Review doses reported in the registry at a minimum of every 3 months.
- To ensure your site is properly documenting administered 317-funded vaccines, please review the outlined steps listed on the **Reporting Doses Administered page**.

To Ensure Quality Data Entry

CAIR Data Exchange

- Ensure staff enter accurate and complete demographic and vaccination information.
- Report race and ethnicity of every patient immunized.
- Include email and/or cell number so patients can access their digital vaccination records in **My DVR** (mydvr.cdph.ca.gov).
- Monitor data submissions through EHR and registry reports to ensure data is submitted accurately and successfully.
- Contact your EHR vendor to resolve any issues.

CAIR Manual Entry

If your site enters or plans to manually enter patient vaccination information into CAIR, you will need the user roles:

- At least one Regular user for entering patients and doses given
- One or more Read-Only users as needed for patient look-up/printing patient reports
- One QA user as needed to run clinic-level reports (e.g., Doses Administered)
- One Power/Inventory user (only if your site plans to manage vaccine inventory in the registry)

Record Retention

Providers are required to maintain all original paper and electronic records related to the VFA or LHD 317 Program—even if scanning documents for electronic copies—for a minimum of three years and make them available for review upon request. Records must be kept for three years even if the provider is no longer participating in the vaccine programs. Make records available to public health officials, including local health jurisdictions, CDPH, and Department of Health and Human Services, upon request.

Records Relating to Your Practice

Providers are required to maintain all paper and electronic documents and records for a minimum of three years including these documents:

- CDPH temperature logs
- Data logger temperature data files
- Vaccine accountability records (vaccine daily usage logs and inventory forms)

- Vaccine invoices and packing slips (for private and publicly funded vaccines)
- Certificate of calibration for each data logger including backup devices
- Certificates of completion from required EZIZ lessons
- Vaccine management plan (including any mobile management plans)
- Medical records that verify vaccine administration
- 317 eligibility screening documentation
- Billing records

Storage Units

Vaccine storage units act as an insurance policy to protect patients from administration of damaged vaccines and protect provider locations from costly vaccine replacement due to negligent loss. Participating providers agree to store all 317-funded vaccines in refrigerators and freezers that meet VFA/LHD 317 storage unit requirements. Adherence to these requirements is certified as part of annual provider recertification and during both routine and unannounced site visits.

Acceptable Storage Units

- Providers are encouraged to use purpose-built (pharmacy-, biologic-, or laboratory-grade) refrigerators, and refrigerators and freezers that are purpose-built (preferred) or commercial-grade (acceptable)
- Household-grade, stand-alone units are discouraged
- Purpose-built combination units, including auto-dispensing units without doors
- Manual-defrost freezers are allowed for use if the provider 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 compliant data logger

Never Use These for Vaccine Storage

- Household-grade combination refrigerator-freezers
- Compact household-grade stand-alone refrigerators (with capacity 11 cubic feet or less)
- Dormitory-style units
- Bar-style combined refrigerator/freezers
- Manual-defrost refrigerators
- Convertible unit
- Cryogenic vaccine transport unit (including coolers and battery-operated units)

Digital Data Loggers

Continuous temperature monitoring is an essential component of each provider's vaccine management plan, but data logger reliability is the critical factor that helps to ensure vaccine viability. All staff, including supervisors and new employees, must be properly trained on temperature monitoring including proper use of the practice's data loggers and the required corrective action for out-of-range temperatures.

Key Points

- Equip all refrigerators and freezers (primary, backup, overflow, or any temporary unit) storing 317-funded vaccine with CDPH-compliant digital data loggers. (For purpose-built, auto-dispensing units with doors: built-in, internal data loggers must meet program requirements except for buffered probes, which are NOT required). (See **Pre-Purchase Worksheet (PDF)** if purchasing new devices.)
- 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. See **Data Logger Requirements (PDF)**.
- Data loggers, including backup devices, 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.
- Keep on hand at least one back-up (battery operated) data logger for emergency vaccine transport. Depending on the size of the practice, additional devices might be needed.
- Data loggers, both primary and backup devices, must have a current and valid Certificate of Calibration.

Inventory Management

Vaccine inventory management is an essential practice that can prevent inadvertent vaccine loss due to temperature excursions. Providers and key practice staff must comply with all requirements in the signed provider agreements.

Key Tasks

317-funded vaccines that are deemed non-viable due to provider negligence must be replaced on a dose-for-dose basis and/or require corrective actions. Consistent and accurate inventory management protects your vaccine supply. Inventory management is covered in the next section, but key tasks include:

- Ordering vaccines
- Receiving and storing vaccines
- Monitoring storage unit temperatures

- Conducting routine physical inventory
- Monitoring expiration and beyond-use dates
- Returning spoiled and expired vaccines
- Disposing of wasted vaccine according to practice protocols
- Transferring soon-to-expire vaccines to active VFA or LHD 317 providers upon approval
- Transporting vaccines for off-site clinics upon approval

Ordering Vaccines

- VFA Program: Providers may submit vaccine order requests in myCAvax quarterly. Order all vaccine doses in sufficient quantities to last until the next order period and order only one brand and formulation for each vaccine to avoid administration errors. See EZIZ's **VFA Ordering & Distribution Calendars** for ordering periods and routine and holiday calendars.
- LHD 317 Program: Local Health Department clinics may order 317-funded vaccines in myCAvax monthly. Order all vaccine doses in sufficient quantities to last until the next order period and order only one brand and formulation for each vaccine to avoid administration errors.
- Providers must report doses administered (since the previous order) and doses on hand (at the time of the order) on each vaccine order. Doses administered must be based on actual vaccine administration logs or registry/EMR administration summary reports.
- See **VFA/317 Provider Agreement Addendum (PDF)** for additional details.

Reporting Requirements

Providers must report the following incidents in myCAvax and may refer to job aids in the myCAvax Knowledge Center for detailed instructions:

- Shipment incidents
- Temperature excursions (out-of-range temperatures)
- Spoiled, expired and wasted doses
- Vaccine transfers to active VFA or LHD 317 providers

Fraud & Abuse

Providers agree to participate in a manner intended to avoid fraud and abuse. Federal fraud and abuse laws apply to both VFA and LHD 317 Programs; state laws apply to use of state funds. The California VFA and LHD 317 Programs investigate all suspected and reported cases of fraud and abuse in order to protect the integrity of the programs and ensure federally purchased vaccines remain available to eligible populations. A provider found guilty of fraud and/or abuse will be subject to vaccine restitution and possible removal from the vaccine program.

Examples of Fraud

Fraud results in a financial gain for the provider but with an inadvertent cost to the VFA or LHD 317 Program. Many actions might constitute fraud:

- Failing to screen patients for 317 eligibility
- Administering 317-funded vaccines to ineligible adults
- Selling or otherwise misdirecting 317-funded vaccines
- Billing a third party for 317-funded vaccines
- Failing to fully account for 317-funded vaccines
- Failing to comply with billing requirements for eligible patients

Examples of Abuse

Abuse results in an inadvertent cost to the VFA or LHD 317 Program. Abuse consists of any actions that lead to a negligent loss that could have been prevented by proper vaccine management. Providers agree to replace all vaccines deemed non-viable due to provider negligence. Many actions might constitute abuse leading to negligent loss:

- Allowing 317-funded vaccines to expire or spoil due to inappropriate vaccine management, including temperature monitoring
- Failing to store vaccines upon arrival
- Failing to monitor and document temperatures
- Failing to transport vaccines according to program requirements
- Failing to properly store and handle 317-funded vaccines
- Failing to fully account for 317-funded vaccines

Site Visits

As a condition for participation in the VFA and LHD 317 Programs, providers must allow site visits from authorized CDHP representatives. Site visits are educational opportunities designed to improve compliance with program requirements and thereby improve patient immunization levels. Failure to allow a site visit might result in the temporary suspension from the vaccine program and removal of 317-funded vaccines.

Key Points

Enrolled providers agree to ongoing site visits from program staff (or authorized representative), including scheduled compliance visits, unannounced storage and handling visits, and visits for educational and programmatic support. Providers must immediately report changes in their practice address or account ownership, which may require additional follow-up.

Unannounced storage and handling visits serve as spot checks to ensure 317-funded vaccines are administered to eligible adults and are managed and stored according to program requirements.

Provider of Record or the Designee must sign and acknowledge receipt of site visit findings and agree to complete required follow-up within specified periods.

Program Integrity

Clinic staff must conduct themselves in an ethical, professional, and respectful manner in all interactions with representatives from the VFA and LHD 317 Programs. Failure to meet conditional enrollment conditions may lead to permanent termination from the vaccine program.

End of Provider Requirements

For Provider of Record & Designee

This completes your required training. You may review the Vaccine Management section or skip to the **Conclusion** to get credit for training completion.

For Vaccine Coordinators

Continue to the next section.

Vaccine Management

Efforts to raise immunization levels in provider populations fall short if vaccine inventory is not managed to ensure viability. Vaccine inventory management is an essential practice that can prevent inadvertent vaccine loss due to temperature excursions. To protect vaccines, vaccine coordinators must comply with all requirements in the **VFA/LHD 317 Provider Agreement Addendum (PDF)**.

Required For

Vaccine Coordinators

VFA Program

- **Provider Agreement (PDF)**
- **VFA/317 Provider Agreement Addendum (PDF)**
- **Requirements at a Glance (PDF)**

LHD 317 Program

- **Provider Agreement (PDF)**
- **VFA/317 Provider Agreement Addendum (PDF)**

Vaccine Management Plan

Practices must 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. Vaccine Coordinators are responsible for implementing the plan.

Key Tips

- Review and update your plan at least annually, whenever program requirements change, and when key practice staff with designated vaccine-management responsibilities change.
- Designate a staff member responsible for updating the provider's plan.
- Staff with assigned vaccine-management responsibilities must review, sign, and date the plan annually and each time it is updated.
- Follow emergency guidelines to prepare for, respond to, and recover from any vaccine-related emergencies.
- Store the plan in a location easily accessible by staff, ideally near the vaccine storage units.
- Practices using mobile units to administer 317-funded vaccines must maintain a current and complete **Mobile Vaccine Management Plan (Word)** and keep it in the mobile unit.

Action Items

1. Complete your **vaccine management plan (Word)**. (Separate VFC and VFA/LHD 317 management plans may be required if staff and equipment are different.)
2. Complete your **mobile vaccine management plan (Word)** if applicable.
3. Review your plan(s) with staff to ensure they know how to respond to routine and emergency situations that may impact your vaccine supply.

Storage Unit Configuration

Vaccine storage units should be organized for efficiency and with preparations to stabilize interior temperatures. Carefully grouping and labeling vaccines reduces time spent searching for vaccines, administration errors, and vaccine exposure to room temperatures.

Prepare vaccine refrigerators and freezers

Prepare storage units (PDF) to maintain stable temperatures before storing vaccines. The concepts are identical for both refrigerators and freezers.

- Place water bottles (in refrigerators) and ice packs (in freezers only) to stabilize temperatures (exception for purpose-built, auto-dispensing units without doors).
- Place digital data logger buffered probes in the center of refrigerators and freezers near vaccines (exception for purpose-built, auto-dispensing units without doors).
- Place data logger digital displays outside of the storage units to allow temperature monitoring without opening the vaccine storage unit door (exception for purpose-built, auto-dispensing units without doors).
- Plug the 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 storage units into extension cords, power strips, or surge protectors with an on/off switch.
- Post **Do Not Unplug signs (PDF)** on electrical outlets and circuit breakers to prevent interruption of power.

Set up vaccine refrigerators and freezers

Set up storage unit interiors (PDF) for efficiency. Proper organization reduces time spent with doors open searching for vaccines. The concepts are identical for both refrigerators and freezers.

- Clearly identify unit space or containers that will store 317-funded vaccines, privately purchased vaccines and/or other CDPH program vaccines
- Group vaccines by pediatric, adolescent, and adult types.
- Allocate enough space to position vaccines or baskets 2-3 inches away from walls, floor, and other baskets to allow space for air circulation (exception for purpose-built, auto-dispensing units without doors).

Data Logger Configuration & Calibration

Providers must get familiar with their temperature monitoring device and then configure the settings for use according to VFA/LHD 317 Program requirements and best practices. Refer to manufacturer's product guide (or video if available) to learn how to use the device. Call the vendor's support contact number for all questions regarding setup, functionality, or configuration.

Configuration Tips

- **Set up data loggers (PDF)**, both primary and backup devices, including device name, low and high temperature alarm limits, immediate notification of out-of-range temperatures, and a maximum logging interval of 30-minutes.
- Store the backup device's buffered probe in the vaccine refrigerator and its digital display in a cabinet; document the device's location on the practice's vaccine management plan. (Exception for purpose-built, auto-dispensing units without door: store the entire device in a cabinet).

Calibration Tips

- Calibrate primary and backup data loggers every two or three years according to the manufacturer's suggested timeline (both device and probe together)—ideally by a laboratory with accreditation from an ILAC MRA signatory body.
- If the manufacturer supplies a pre-calibrated replacement probe upon device calibration expiration, the device and probe do not need to be calibrated together.
- Devices that only generate CSV data files or Excel spreadsheets are not acceptable.
- Practices are required to keep on hand at least one backup, battery-operated 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.
- Certificates issued by non-accredited laboratories must meet all program **requirements for certificates of calibration (PDF)**.

Vaccine Orders & Accountability

Providers are expected to maintain an adequate inventory of all CDPH-recommended vaccines for their patient population—including private patients. Trained and authorized clinic staff must submit vaccine orders through the practice's account on myCAvax.

Key Tips

- Order CDPH-recommended adult vaccines according to eligible population served by the clinic (age, risk factors, and uninsured/underinsured), vaccine usage, and on-hand inventory.
- Order approval will factor limited doses available through the VFA/LHD 317 Program.
- Order only one brand and formulation for each vaccine to avoid administration errors.
- Order vaccines according to the VFA or LHD 317 order frequency in sufficient quantities to last until the next order period; order quantities must factor in 317-funded vaccine doses administered

(since previous order) and doses on hand (at the time of the order). VFA providers who have not ordered vaccine in the past calendar year may be terminated from the vaccine program.

- Order vaccines using the approved practice address for the provider PIN.
- Account for every dose of 317-funded vaccine ordered and received by the provider's practice.
- Report all 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. Consider using the **317 Adult Vaccine Daily Usage Log (PDF)** as a backup method.
- Maintain accurate and separate stock records (e.g., purchase invoices, receiving packing slips) for privately purchased vaccines and make them available to the program upon request.

Receiving Vaccine Deliveries

Once delivered, providers assume responsibility for ensuring that vaccines are stored in temperature-controlled environments. Shipments that are mishandled after delivery are considered negligent losses, and a replacement vaccine order might not be expedited. The practice 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.

Refrigerated Vaccines

Refrigerated vaccines are shipped by McKesson Specialty and with a TagAlert temperature monitor that alerts the recipient if vaccines were exposed to out-of-range temperatures.

Frozen Vaccines

Frozen varicella-containing vaccines are shipped directly from Merck and with an insert that identifies allowable shipping time. Check the insert to ensure the shipment arrived within the specified window.

Diluent

Vaccine diluents might be packaged separately from its vaccine. Check the lid of the shipping container if diluents appear to be missing.

Key Tips

- Receive, inspect, and store vaccines and diluents within manufacturer-recommended ranges immediately upon delivery. Consider using the **vaccine receiving checklist (PDF)**.
- Never refuse vaccine shipments; never leave a shipper unpacked and unattended. If vaccines and diluent get too warm, they cannot be used.
- Verify vaccine for signs of damage, discrepancies between packing slip and contents, and temperature excursions in transit for vaccines.
- Store vaccines in proper storage units monitored by data loggers configured for the recommended temperatures; place doses soon to expire in front.
- Delivered vaccines exposed to out-of-range temperatures or received outside the shipping time specified on the shipper insert must be labeled "Do Not Use" and stored in vaccine refrigerators or freezers—separate from the rest of the vaccine stock.

- Immediately report Shipping incidents within the same day on the site's myCAvax account. Contact the Provider Call Center for further assistance.
- Providers are encouraged to recycle the cardboard components of shipping containers through their local recycling program.

Reporting Shipment Incidents

Vaccine Coordinators must report shipment incidents in myCAvax. Timing is critical. Report incidents for vaccine the same day shipments arrived. Please make sure data is accurate and complete.

Report These Issues ASAP for Resolution

- Broken, torn, or tampered with
- Not ordered/incorrect recipient
- Out-of-range temperature
- Package never arrived
- Previously opened
- Shipping content discrepancies

Report Shipment Incidents in myCAvax

McKesson requires that shipment incidents be reported the day of receipt for resolution. Gather the information you'll need to report the shipment incident.

1. Note any discrepancies between the packing slip, vaccine order, and contents of the box.
2. Note the box's tracking number (if multiple boxes were received).
3. Navigate to Vaccine Inventory in myCAvax to report the Shipment Incident.
4. Scan and attach the packing slip for all incidents to your incident report.
5. Contact the Provider Call Center for additional assistance.

Vaccine Storage

Vaccines are expensive and fragile. It's important that they are stored in proper equipment and at the correct temperatures to ensure patients are protected against vaccine-preventable diseases.

Key Tips

- Store 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.
- Store refrigerated vaccines between 36.0°F and 46.0°F (2.0°C and 8.0°C) according to manufacturer recommendations.
- Store vaccines in original packaging and allow space for air circulation.

- Store VFA, LHD 317, VFC and privately purchased vaccines separately and grouped by vaccine type.
- Do not store vaccines in storage unit doors, drawers, or bins.
- Place vaccines with the earliest expiration dates toward the front of the storage unit and use first.
- Always store 317-funded vaccines at the approved location for the provider PIN. For practices conducting outreach clinics: obtain approval from the VFA or LHD 317 Program at least 4 weeks prior to the scheduled outreach clinics.

Monitoring Vaccine Storage Unit Temperatures

Monitoring storage unit temperatures consistently and accurately plays an important role in protecting the vaccines that protect your patients.

Key Terms

- ***CURRENT:*** Internal storage unit temperature now.
- ***MIN:*** Minimum (coldest) storage unit temperature since the data logger was reset.
- ***MAX:*** Maximum (warmest) storage unit temperature since the data logger was reset.

Action Items

- Record vaccine storage unit temperatures on the CDPH **universal temperature log (PDF)**.
- **Monitor and record temperatures (PDF)**, including current, minimum, and maximum temperatures twice each day: at the beginning and end of each business day on the CDPH temperature log.
- Download and review temperature data files for any unreported out-of-range temperatures at the end of every two-week reporting period.
- The supervisor must **review and sign (PDF)**the temperature logs at the end of every two-week reporting period.
- Replace doses (on a dose-for-dose basis) following program requirements 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.
- Retain temperature logs and temperature data files for three years.

Taking Action for Temperature Excursions

Vaccines stored out of range might be deemed non-viable and considered a negligent vaccine loss. Vaccine Coordinators must report excursions in myCAvax. If temperatures drift out of recommended ranges, immediately label vaccines **Do Not Use (PDF)** and contact the manufacturer to determine if vaccines are okay to administer.

Key Terms

- ***Temperature excursions:*** Manufacturers might refer to out-of-range temperatures (either too warm or too cold) as temperature excursions. Staff communicating with manufacturers should be familiar with this term.
- ***Temperature data file:*** Your device may have a temperature data file that must be downloaded to get the data that manufacturers will need to determine whether vaccines may be administered. The manufacturer's determination is only as accurate as the data you provide.

Take Action

- **Take immediate action (PDF)** to prevent vaccine spoilage and to correct any improper storage condition for all out-of-range storage unit temperatures.
- Record the myCAvax Excursion ID on the CDPH **universal temperature log (PDF)**.
- Staff must respond to all data logger alarms.
- Quarantine and do not administer any vaccines exposed to out-of-range temperatures until their viability has been determined by **vaccine manufacturers**.
- Identify and report every temperature excursion to myCAvax.
- Communicate every temperature excursion to vaccine manufacturers.
- Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper **refrigerated (PDF)** and **frozen vaccine transport (PDF)**.

Managing Vaccine Inventory

Managing your vaccine inventory to ensure that vials soon to expire are used first helps to minimize vaccine wastage; removing spoiled and expired vaccine immediately prevents inadvertent administration errors than may require patient revaccination. Vaccine Coordinators must report nonviable doses in myCAvax.

Spoiled Vaccine

Careful storage and handling should minimize spoiled vaccines. Vaccines still in their original container (vial or syringe) are considered spoiled and nonviable if the vaccine manufacturer has determined that vaccines were exposed to out-of-range temperatures. Vaccines could spoil as a result of these conditions:

- Data logger indicates that storage unit temperatures are out of the recommended range
- Storage unit temperatures were not monitored as required
- Vaccines were not stored properly upon receipt
- Vaccines spoiled during transfer
- Natural disaster, power outage, or mechanical failure

Expired Vaccine

Careful vaccine management (including stock rotation) should minimize expired vaccines. Vaccines are considered expired and nonviable if their expiration dates are past the manufacturer expiration

date on the vial or the expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

Wasted Vaccine

Careful vaccine management and administration should minimize wasted vaccines. Vaccines may be designated wasted as a result of the following conditions:

- Unable to draw the maximum doses printed on the vial label because low dead-volume needles/syringes were not available; any remaining unused doses will be identified as waste (never pool vaccine from multiple vials to make a single dose)
- Opened multidose vials not used
- Vaccines were drawn into the syringe but not administered
- Vials are damaged (e.g., due to a drop causing damage to vial integrity or sterility)
- Vaccines are lost or unaccounted, unable to draw a dose in vial

Action Items

- **Conduct a physical vaccine inventory (PDF)** at least monthly and before ordering vaccines.
- Use the **317 Vaccine Physical Inventory Form (PDF)** or equivalent electronic or paper form.
- Never borrow 317-funded vaccines to supplement private stock, or vice versa.
- For vaccines that will expire within 6 months and cannot be used: Notify **ProviderCallCenter@cdph.ca.gov** and your Field Representative prior to transferring to another VFA or LHD 317 Program provider to prevent negligent provider loss.
- Remove spoiled, expired, and wasted vaccines from storage units to prevent inadvertent use.
- Report all spoiled, expired, and wasted vaccines doses of 317-funded vaccines in myCAvax prior to submitting a new vaccine order.
- Do not report any 317-funded vaccines as spoiled without guidance from vaccine manufacturers and/or the program.
- Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with program requirements.

Reporting Spoiled, Expired and Wasted Vaccines

Providers must **report spoiled, expired, and wasted vaccines** in myCAvax. Spoiled or expired vaccines may be returned for excise tax credit. Doses reported as returned must match actual doses received by McKesson.

Action Items

- Remove spoiled and expired vaccines from storage units to prevent inadvertent use and administration errors.
- Report all spoiled, expired, and wasted vaccines doses of 317-funded vaccines in myCAvax prior to submitting a new vaccine order.

- Package and ship spoiled or expired vaccine to McKesson within six months; label the package using the return shipment label. (Cold packs are not necessary since the vaccines are not viable.)
  Ship to:
  McKesson Specialty Distribution Center
  170 Clermont Rd.
  Shepherdsville, KY 40165
- Dispose of wasted vaccines according to practice protocols.

Vaccine Transfers & Transports

Never routinely transfer 317-funded vaccines to/from other VFA or LHD 317 Program providers. Vaccine transfers can be minimized by consistent inventory management, but providers might need to transfer vaccines to other providers if vaccines are likely to expire before administration or in the event of an emergency. If vaccines need to be transferred, follow program requirements. Do not ship vaccines. Never transport 317-funded vaccines to personal residences.

Action Items

- Contact the Provider Call Center and your Field Representative prior to transferring VFA vaccines.
- If transfers are approved, only transfer VFA vaccines to other VFA providers.
- Never transport 317-funded vaccines to personal residences.
- Transport vaccines only when necessary and follow the guidelines for **refrigerated (PDF)** or **frozen vaccine (PDF)** transport.
- Complete a **vaccine transport log (PDF)** each time vaccines are transported.
- In case of emergency: Only transport 317-funded vaccines to alternate locations equipped with vaccine storage units and temperature monitoring devices that meet program requirements.
- Use backup, battery-operated, digital data loggers to monitor temperatures during vaccine transport and at VFA or LHD 317 Program-approved off-site clinics—ideally using a portable vaccine refrigerator (if a portable vaccine refrigerator is not available, use qualified containers and pack-outs) 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 vaccine program.

End of Vaccine Management Section

For All Roles

Skip to the **Conclusion** to get credit for training completion.

Conclusion

This completes your training! Bookmark this **Program Requirements** lesson and close the browser to get credit for this training.

Resources to Help You

- **EZIZ website**
- **EZIZ Storage & Handling job aids**
- **VFA Program Overview** | **VFA Resources**
- **LHD 317 Resources**

CDPH Field Reps

Field Representatives act as the primary liaison between the VFA and LHD 317 Programs, Vaccines for Children (VFC) Program, and California's prospective and enrolled providers. They work out of the CDPH Immunization Program regional offices and perform a variety of support services for enrolled providers:

- approve sites for enrollment
- conduct site visits
- assist with vaccine orders
- provide on-site training as learning gaps are identified
- provide answers for all things VFC and VFA

Providers can locate their regional Field Representative by clicking the **Find a Field Representative** link on EZIZ.org.