

VACCINES FOR CHILDREN (VFC) PROGRAM

KEY PRACTICE STAFF CHANGE REQUEST FORM

Complete, sign, and fax to the **CA VFC Program at 1-877-FAXX-VFC (1-877-329-9832)**

INSTRUCTIONS: Providers are required to notify the VFC Program immediately to report changes in key practice staff. Use this form to make any changes to key practice staff with responsibilities related to the VFC Program. The Provider of Record must sign the form acknowledging his/her authorization of these changes.

- **Provider of Record (POR):** The clinic’s Provider of Record (POR) is responsible for the clinic’s overall compliance with VFC Program requirements. This is usually the clinic’s physician-in-chief or the clinic’s medical director (a licensed Medical Doctor, Doctor of Osteopathy, Nurse Practitioner, Physician Assistant, or a Certified Nurse Midwife with prescription privileges in the State of California).
- **Vaccine Coordinator:** A designated, on-site, and fully trained staff member responsible for all vaccine management activities within the practice.
- **Backup Vaccine Coordinator:** A designated, on-site, and fully trained staff member responsible for all vaccine management activities within the practice when the Vaccine Coordinator is unavailable.
- **Provider of Record Designee:** An on-site staff member designated by the clinic’s Provider of Record to act on his/her behalf on VFC Program related matters, such as signing the visit acknowledgement form, when the POR is unavailable.

Key clinic staff must complete required lessons on the VFC website www.EZIZ.org. Completion of those lessons must occur before the VFC Program makes any changes to the practice’s VFC Provider Information.

| Practice Information | | | |
|----------------------|-----|-------|--------|
| Practice Name | | | PIN |
| Address | | | County |
| City | ZIP | Phone | Fax |

| Key Practice Staff | | | | | | | | |
|--------------------------|----------------------------|-----------------------------|------|----------------------|---|--------------------------------------|-----------------------------------|--|
| Change | Completed Required Lessons | Role/Responsibility | Name | Title (MD,DO, NP,PA) | Specialty/Clinic Title (if applicable) | National Provider ID (if applicable) | Medical License # (if applicable) | Contact Information |
| <input type="checkbox"/> | <input type="checkbox"/> | Provider of Record* | | | Specialty: _____ Clinic Title: _____ | | | Direct Phone Number: _____ Email: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | Vaccine Coordinator | | | Clinic Title: _____ | | | Direct Phone Number: _____ Email: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | Backup Vaccine Coordinator | | | Clinic Title: _____ | | | Direct Phone Number: _____ Email: _____ |
| <input type="checkbox"/> | <input type="checkbox"/> | Provider of Record Designee | | | Clinic Title: _____ | | | Direct Phone Number: _____ Email: _____ |

Any changes to the Provider of Record on this form must include a signed copy of the VFC Provider Agreement and the California Provider Agreement Addendum. Continue to page 2 through 6 **ONLY if the Provider of Record has changed since the practice last Recertified with VFC.*

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

VFC PROVIDER ENROLLMENT AGREEMENT

To receive publicly funded 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. I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2. I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:
 - A. Federally Vaccine-eligible Children (VFC eligible)
 1. Are an American Indian or Alaska Native;
 2. Are enrolled in Medicaid;
 3. Have no health insurance;
 4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.
 - B. State Vaccine-eligible Children
 1. In addition, to the extent that my state designates additional categories of children as “state vaccine-eligible,” I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.

Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are not eligible to receive VFC-purchased vaccine.
3. For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:
 - a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
 - b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4. I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5. I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6. I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of \$26.03 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.
7. I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee.
8. I will distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and maintain records 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).

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9. I will comply with the requirements for vaccine management including:

- a) Ordering vaccine and maintaining appropriate vaccine inventories;
- b) Not storing vaccine in dormitory-style units at any time;
- c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet California Department of Public Health Vaccines for Children Program storage and handling requirements;
- d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration

10. I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program:

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 Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

11. I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.

12. For pharmacies, urgent care, or school located vaccine clinics, I agree to:

- a) Vaccinate all "walk-in" VFC-eligible children and
- b) Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.

Note: "Walk-in" refers to any VFC-eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.

13. I agree to replace vaccine purchased with federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis.

14. I understand this facility or the California Department of Public Health Vaccines for Children Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the California Department of Public Health Vaccines for Children Program.

To agree to these federal requirements, print 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 Vaccines for Children enrollment 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:

Name (print) *Second individual as needed:*

Signature:

Date:

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VFC Provider Agreement Addendum**1. Vaccine Management Plan**

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

2. Staffing & Training

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

3. Vaccine Storage Units

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

4. Digital Data Loggers (Continuous Temperature Monitoring Devices)

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

5. Vaccine Refrigerator & Freezer Configuration

- A. [Prepare vaccine refrigerators](#) and [vaccine freezers](#) in compliance with VFC Program requirements.
- B. Place water bottles in vaccine refrigerators and ice packs in vaccine freezers to stabilize temperatures.
- C. Place buffered probes in the center of the refrigerator and freezer near vaccines.

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

6. Vaccine Orders & Accountability

- A. Account for every dose of VFC-supplied vaccine ordered and received by the provider's practice.
- B. Order routine ACIP-recommended vaccines according to the provider population, category, order frequency, vaccine usage, and on-hand inventory.
- C. Order all vaccines for each order period in accordance with the practice's patient estimates and in sufficient quantities to last until the next order period; individual vaccine orders are not permitted.
- D. Stock one brand and formulation for each vaccine to avoid administration errors.
- E. Keep track of VFC vaccine doses administered since the previous order (including influenza) using the [VFC Daily Usage Log](#), [VFC Flu Usage Log](#), an immunization registry, or equivalent electronic or paper form.
- F. Conduct a physical vaccine inventory before ordering routine vaccines to determine current doses on hand.
- G. Report on each vaccine order the quantity of vaccines administered since the previous order and the current on-hand inventory.
- H. Maintain accurate and separate stock records (e.g., purchase invoices) for privately purchased vaccines and make them available upon request.

7. Receiving Vaccine Deliveries

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

8. Vaccine Storage

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

9. Temperature Monitoring

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

10. Reporting Storage & Handling Incidents

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

11. Vaccine Inventory Management

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

12. Vaccine Transport

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

13. Vaccine Administration

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

14. Program Integrity

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

To receive VFC Vaccines, you must confirm acknowledgement of this agreement.

You may be held financially responsible for replacing vaccine doses lost due to negligence if you do not comply with the above requirements.

Provider of Record Name (print)

Date

Provider of Record (signature)