

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 Certification of Capacity to Store and Manage Vaccines. Continue to page 2 through 5 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):	

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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) <i>Second individual as needed:</i>	
Signature:	Date:

VACCINES FOR CHILDREN (VFC) PROGRAM

2015 CERTIFICATION OF CAPACITY TO STORE AND MANAGE VACCINES

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 each of the VFC requirements listed below.

1. Comply with Vaccine Storage Equipment Requirements

Providers must have appropriate equipment that can store vaccine and maintain proper conditions. Equipment must comply with VFC vaccine storage equipment requirements. New providers must have separate refrigerator-only and freezer-only units for storage of vaccines. Dormitory refrigerators are not allowed for vaccine storage, under any circumstance. Vaccine storage units must be dedicated to the storage of vaccines. I may be required to purchase a new refrigerator or freezer unit if equipment at my practice is deemed inappropriate for vaccine storage or not able to maintain appropriate temperature.

2. Designate an On-site Vaccine Coordinator and Backup Vaccine Coordinator

Designate one fully trained staff member to be the on-site primary Vaccine Coordinator and at least one backup person able to perform the same responsibilities as the primary Vaccine Coordinator when the primary coordinator is unavailable. Responsibilities are outlined in the Vaccine Coordinator Guide. The Provider of Record is responsible for maintaining compliance with annual training requirements for the Vaccine Coordinator, Backup Coordinator, Provider of Record Designee and other clinic staff handling and storing vaccines. Documentation of training must be maintained in each staff member's personnel file. The VFC Program shall be contacted immediately to report a personnel change in vaccine coordinators.

3. Follow Established Vaccine Storage Guidelines

Refrigerator and freezer units will be set up properly. Vaccine shall be stored in its original packaging and positioned 2-3 inches away from walls, floor and with space for air circulation. VFC vaccine and private vaccine will be kept separate and clearly labeled. Within each supply, vaccines will be grouped by type and clearly labeled in designated spaces for each vaccine type. Vaccine will not be stored in the doors, drawers or bins.

Thermometer probes will be placed in the center of both the refrigerator and freezer, in proximity to vaccines. Warning signs, i.e., "Do Not Unplug" signs, to prevent interruption of power to the vaccine storage units, will be posted on the electrical outlets, and circuit breakers. The refrigerator and freezer will be plugged into separate wall outlets that are not controlled by a light switch. Plug guards will be used when feasible. No food or drinks will be stored in the units. Water bottles shall be placed in the refrigerator and ice packs in the freezer to stabilize the temperatures.

4. Follow Established Guidelines for Vaccine Transport

I will store VFC supplied vaccines only at the facility stipulated in this agreement. Providers must contact the VFC Program for approval prior to transferring vaccines to another VFC provider. Vaccines cannot be transferred to non-VFC program providers and sites not approved by the VFC program under any circumstances. VFC vaccines may be transferred only in limited situations. Routine re-distribution is not allowed. I will only transport vaccines when absolutely necessary and follow the guidelines for proper refrigerated vaccine transport and frozen vaccine transport.

5. Use Certified, Calibrated Thermometers

Each storage unit must have a VFC compliant thermometer centrally located (in proximity to vaccines) within each unit at all times, and a minimum of one VFC compliant backup thermometer for the practice (for use when the primary thermometer is sent for calibration or in case it fails). Practices with multiple vaccine storage units may need more than one backup thermometer. Each device must have a Certificate of Traceability and Calibration Testing (also known as Report of Calibration). Thermometer calibration must be done annually or every other year when the manufacturer recommends calibration done in a period that is longer than two years. Calibration should be conducted by a laboratory with accreditation from an ILAC MRA signatory. Certificate of Calibration conducted by non-accredited laboratories must include required information outlined in the Program's Checklist for Certificate of Traceability and Calibration. Providers are responsible for maintaining a Report of Calibration and make it available to program representatives for review. Thermometers deemed no longer accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$) upon calibration shall be replaced. Thermometers (primary and backup) must have: a digital display of current, minimum, and maximum temperatures; have a minimum accuracy of 1°F (0.5°C); a biosafe glycol-encased (or similar buffered solution) probe; and an out-of range temperature alarm. The digital display of the primary thermometer shall be placed on the outside of the unit to allow temperature monitoring without opening vaccine storage unit's doors. Backup thermometers can be placed in an easily accessible location. The location of backup thermometers must be documented on the clinic's Routine Vaccine Management Plan Worksheet. Batteries, if required, will be replaced every 6 months. New providers that are only open 2 days a week or less, will be required to purchase a digital datalogger for use to continuously monitor temperatures, even while the clinic is closed.

6. Store Vaccines at Recommended Temperatures

Vaccines will be maintained at all times within the recommended ranges. Vaccines stored in freezer (MMR, MMRV, and Varicella) will be maintained at 5.0°F (-15.0°C) or below (aim for 0°F or lower to keep temperatures from getting too warm). All other vaccines will be stored in a refrigerator maintained at a temperature above 35.0°F (2.0°C) and below 46.0°F (8.0°C) (Aim for 40.0°F to keep temperatures from getting too warm or cold).

7. Monitor and Record Refrigerator and Freezer Temperatures Twice a Day

The Vaccine Coordinator shall monitor and record the temperatures (including current, minimum and maximum temperatures) in the refrigerator and freezer twice each day, at the beginning and towards the end of each business day. If other staff will be assigned to monitor the temperatures, they must be trained on use of thermometers and how to respond to and document out-of-range temperatures. The current temperature and minimum/maximum temperatures will be recorded on VFC-provided temperature logs. The logs will be posted on the vaccine storage unit door or in a nearby accessible location. Logs will be maintained for a period of three years, and be readily available for review upon request from the VFC Program (during site visits or during randomly selected provider temperature review process). Temperatures shall be taken and recorded twice each day, even if a continuously recording/graphing thermometer or datalogger is in use. After completion of the temperature log, a supervisor will review and sign the log acknowledging that temperatures recorded are correct and that any out-of-range temperatures have been properly addressed. If the temperature is identified as out-of-range, immediate action will be taken to prevent spoilage of the vaccine and correct improper vaccine storage condition. Corrective action will be documented on the temperature log and the VFC Program will be contacted immediately. If temperatures are not monitored and documented for a prolonged period of time, the affected vaccines will be automatically deemed non-viable and this will be considered a negligent vaccine loss.

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8. Clearly Identify VFC Vaccine from Privately Purchased Vaccine

VFC vaccine and private vaccine will be kept separate and clearly labeled to allow easy identification and prevent use on ineligible patients. Vaccines will be labeled either VFC or private for clear identification and ideally, kept on different shelves to minimize potential for confusion. Accurate and separate stock records (purchase invoices) of privately purchased vaccines (if applicable to clinic’s population) must be maintained and be available for review upon request.

9. Maintain and Rotate Stock

Inventory management shall be conducted by the practice’s Vaccine Coordinator or designee at least once a month and before ordering vaccine. Vaccine stock must be maintained in accordance with actual vaccine need for VFC and non-VFC-eligible patients. Borrowing of vaccines between private and VFC stock must not occur, and is not allowed by the program. An additional two weeks of safety stock may be maintained to prevent vaccine shortage in the event of shipment delays. Vaccine stock will be rotated to place the vaccine with the earliest expiration date for use. The VFC Program will be notified of any vaccine that will expire in 3 months that will not be used. Vaccine will be maintained in its original packaging until it is used. Spoiled and expired vaccine will be removed from the vaccine storage unit immediately to prevent inadvertent use. A report of all expired or spoiled VFC supplied vaccines will be submitted to the VFC program prior to submitting a new vaccine request. Affected vaccines will be returned to the program’s vaccine distributor for excise tax credit within 6 months of expiration/spoilage.

10. Monitor Vaccine Storage Unit Capacity to Store Vaccines

The Vaccine Coordinator shall continuously monitor the capacity of the vaccine storage units to ensure adequate space for inventory, especially during flu season. Additional vaccine storage units may be purchased if the size of the current unit cannot accommodate the inventory in a manner consistent with VFC requirements.

11. Immediately Notify the VFC Program of Storage and Handling Incidents or Vaccine Shipment Issues

If the refrigerator or freezer units experience out-of-range temperatures, immediate action will be taken to prevent vaccine spoilage. This includes extended power outages and vaccine storage unit malfunctions. Depending on the situation, this may necessitate transporting vaccines as outlined in the clinic’s Emergency Vaccine Management plan. Vaccines exposed to out-of-range temperatures will be marked “Do Not Use” until direction is received from the vaccine manufacturers and the VFC Program. Contact the VFC Program immediately after identification of the out-of-range temperatures for further guidance. Any shipment discrepancies or issues must be reported to the VFC program immediately.

12. Order and Account for all VFC Vaccines in Accordance with Practice’s Patient Estimates and VFC Guidelines

Vaccines will be ordered in accordance with practice-based eligibility data, assigned order frequency, vaccine usage, and inventory on hand at the time of order placement. Practice shall order all vaccines at one time. An accurate report of each VFC vaccine dose administered within each ordering period will be maintained using the VFC Program Vaccine Usage Log or equivalent form. A summary of vaccine administration and on hand inventory shall be submitted with each vaccine request. All VFC vaccine doses will be accounted for. Vaccine doses not accounted for or lost due to negligence will be replaced dose for dose by the enrolled Provider of Record or the practice organization.

13. Receive and Unpack Vaccine Shipments Immediately Upon Arrival

Vaccine shipments will not be rejected. All staff who may accept packages for the clinic must be aware that vaccine shipments require immediate attention. When new shipments arrive, vaccines must be unpacked immediately. Immediately upon receipt, vaccine shipments will be inspected to verify the temperature during transport has not been out of range and that the vaccines included in the shipment match those listed on the invoice. Any shipment discrepancies or issues must be reported to the VFC Program immediately utilizing the program’s Vaccine Receiving Log and Checklist. Any change in the practice’s availability to receive vaccine shipments will be immediately reported to the VFC Program. Practice will assume responsibility for all VFC vaccine shipped to the site.

14. Maintain, update and routinely review Routine and Emergency Vaccine Management Plans

Routine vaccine management and emergency vaccine management plans are developed and maintained by the practice. Plans include practice-specific guidelines, protocols and contact information related to all key areas listed in this certification. Plans are updated whenever VFC Program guidelines change and when staff with designated vaccine management responsibilities change. Staff with assigned vaccine management responsibilities will review, sign, and date the plans annually and whenever the plans are updated. If the practice chooses to develop a vaccine management plan other than the template the VFC program has provided, it must contain the same required content outlined in VFC’s Routine and Emergency Vaccine Management Plans.

To receive VFC Vaccines, you must confirm acknowledgement of this agreement.	
<i>You may be held financially responsible for replacing vaccine doses lost due to negligence if you do not comply with the above requirements.</i>	
Provider of Record Name (print)	Date
Provider of Record (signature)	