

California Vaccines for Children (VFC) Program

2014 Program Participation Requirements At-a-glance

Requirement	Summary	Agreement Item (Certification of Capacity to Store and Manage Vaccines Item)	Materials/Job Aids
Key Clinic Staff <i>Updated!</i>	<p>VFC providers must designate a Vaccine Coordinator and Backup Vaccine Coordinator fully trained to oversee and manage the clinic's vaccine supply. Providers must also appoint a designee clinician or person with authority to act on behalf of the practice and participate in program site visits and acknowledge receipt of visit findings when the provider of record is unavailable to participate in such visits.</p> <p>Contact name and information for the primary vaccine coordinator and back-up coordinator must be current in the clinic's profile. Any personnel changes in these roles must be immediately reported to the VFC Program through MYVFCVaccines.</p>	10, 12 (2)	Primary and backup Vaccine Coordinator's role and responsibilities are described in the Vaccine Coordinator job aid (IMM-968).
Annual Educational Requirements. <i>Updated!</i>	<p>Each clinic's VFC Provider of Record and Vaccine Coordinators must complete annual EZIZ lessons to meet new federal education requirements on key program areas.</p> <p>Providers cannot recertify until training has been completed. Lessons to be completed in order to submit 2015 VFC Recertifications will be announced early 2014.</p>	10	VFC providers may log into MYVFCVaccines using the clinic's VFC Provider PIN and zip code to access lessons, register, and certify completion.
Routine and Emergency Management Plans <i>New!</i>	<p>VFC Providers must develop and maintain a Routine Vaccine Management Plan and an Emergency Vaccine Management Plan. Plans should include practice-specific guidelines, protocols, and contact information. Plans must be updated whenever VFC Program guidelines change and when staff with designated vaccine management responsibilities change.</p>	9	<p>Routine Vaccine Management Plan template (IMM-1122)</p> <p>Emergency Vaccine Management Plan template (IMM-1123)</p>
VFC Eligibility Screening & Documentation	<p>Screening for VFC eligibility must occur with all clinic patients 0-18 years of age, prior to vaccine administration, and be documented in the patient's permanent medical record (paper-based or electronic medical record) at each immunization encounter.</p> <p>Eligibility documentation must be kept in the patient's medical record for three years. Documentation of eligibility screening must include the following elements:</p> <ul style="list-style-type: none"> • Date of screening • Whether the patient is VFC eligible or not VFC eligible • If patient is VFC eligible, eligibility criteria met 	1 & 3	VFC's Patient Eligibility Screening Record form (IMM-1111).

<p>Providers must offer and administer immunizations according to ACIP recommendations and populations served</p>	<p>VFC vaccines must be administered according to the guidelines outlined by the Advisory Committee on Immunization Practices (ACIP) in VFC resolutions. VFC providers must comply with immunization schedules, dosages, and contraindications that are established by ACIP and included in the VFC program for populations served, unless:</p> <ul style="list-style-type: none"> • In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate; • The particular requirements contradict state law, including laws pertaining to religious and other exemptions. <p>The most current Vaccine Information Statements (VIS) must be offered before each time a vaccine is administered.</p>	<p>2 & 7</p>	<p>CDC Recommended Immunization Schedules</p>
<p>VFC Recordkeeping <i>Updated!</i></p>	<p>VFC providers must maintain all records related to the VFC program for a minimum of three years and make these records available to public health officials, including the state or Department of Health and Human Services (DHHS), upon request.</p> <p>Recordkeeping includes all paper-based or electronic records related to the VFC program (including but not limited to patient screening/eligibility verification and documentation, temperature logs, vaccine ordering records, medical records that verify receipt of vaccine, vaccine purchase and accountability records, VFC training records, Routine and Emergency Vaccine Management Plans, Provider Recertification forms, etc.).</p> <p>Clinics must also maintain vaccine administration records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).</p>	<p>3 & 7</p>	<p>Instructions for using VIS</p>
<p>VFC Vaccine Costs and Administration Fees</p>	<p>Providers CANNOT bill anyone for the cost of VFC-supplied vaccines. Providers may charge VFC-eligible children not covered by Medi-Cal (i.e., uninsured, American Indian/Alaska Natives, and underinsured children seen at a FQHC or RHC) up to the <u>current</u> federal maximum regional administration charge of \$26.03 per dose (not antigen) of vaccine.</p> <p>For Medi-Cal children, providers must bill Medi-Cal for vaccine administration fees and accept set reimbursement rates set by Medi-Cal or the contracted Medi-Cal health plans.</p> <p>VFC providers cannot deny administration of VFC vaccine to an established VFC-eligible patient because the child's parent/guardian inability to pay the administration fee.</p> <p>Note: pharmacies, urgent care and other specialty VFC providers agree to vaccinate all "walk-in" VFC-eligible children and not refuse to vaccinate these children based on a parent's inability to pay the administration fee.</p>	<p>4, 5 & 6</p>	<p>VFC's Who's Eligible flyer (IMM-1088)</p>

<p>Thermometers</p> <p><i>Updated!</i></p>	<p>Providers must have VFC-compliant thermometers in the practice’s vaccine storage units at all times. A primary thermometer must be centrally located in each vaccine storage unit in proximity with vaccines. A minimum of one back-up thermometer, located in an easily accessible practice area, must be available for use when primary thermometers are being calibrated or fail. Practices with multiple vaccine storage units may need more than one back-up thermometer.</p> <p>Thermometer must meet the following specifications:</p> <ul style="list-style-type: none"> • Temperatures must be accurate within +/- 1°F (+/-0.5°C). • Thermometers must be digital, with the digital display placed outside the unit to allow for temperature monitoring without opening the unit door. • Thermometers must have a biosafe glycol-encased probe (or similar buffer solution), placed in proximity with vaccines. • Thermometers must display current temperature, as well as the minimum and maximum temperatures, and have an out-of-range temperature alarm (visual or audible). 	<p>9 (4)</p>	<p>EZIZ Lessons: Monitoring Refrigerator Temperatures AND Monitoring Freezer Temperatures.</p>
<p>Thermometer Calibration & Certification</p> <p><i>Updated!</i></p>	<p>All thermometers (primary and back-up) must be calibrated annually (or every other year when the manufacturer recommends calibration done in a period that is longer than two years), and have a valid Certificate of Traceability and Calibration Testing, also known as a Certification of Calibration. A valid Certification of Calibration must be kept on file according to recordkeeping requirements and be readily available for review during VFC visits.</p> <p>Calibration should be conducted by an ILAC/MRA accredited laboratory. If calibration is conducted by non-accredited laboratories, calibration certificates must include additional items marked with an “*”:</p> <ul style="list-style-type: none"> • Name and address of laboratory conducting testing • Date of calibration • Thermometer Identification (serial and model #) • Measurement results (instrument pass or in-tolerance testing results) • Statement of conformance with ISO/IEC17025 calibration procedure standards* <p>Thermometer no longer accurate within +/-1°F (+/-0.5°C) as indicated in calibration measurement results must be replaced at the next calibration due date.</p>	<p>9 (4)</p>	<p>Details and FAQs are available on the Thermometer Calibration page (http://eziz.org/vaccine-storage/calibrated-thermometers/)</p> <p>Checklist for Certificate of Traceability and Calibration (IMM-1119)</p>

<p>Temperature Monitoring</p>	<p>Temperatures for each unit (current, minimum, and maximum temperatures) must be read and documented twice each workday, at the beginning of the day and prior to closing, utilizing the program's temperature logs. Temperature logs must be maintained for 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).</p> <ul style="list-style-type: none"> • Thermometer temperatures must be cleared after each daily MIN/MAX readings. • Temperatures must be recorded on VFC-provided temperature logs, even if using a continuous temperature-recording device or digital data logger. • Temperature logs must be posted in a visible location. 	<p>9 (6)</p>	<p>EZIZ Lessons: Monitoring Refrigerator Temperatures AND Monitoring Freezer Temperatures.</p> <p>Recording Refrigerator Temperatures job aid (IMM-1029)</p> <p>Refrigerator Temp Log Fahrenheit (IMM-1125)</p> <p>Refrigerator Temp Log Celsius (IMM-1127)</p> <p>Recording Freezer Temperatures job aid (IMM-1028)</p> <p>Freezer Temp Log Fahrenheit (IMM-1126)</p> <p>Freezer Temp Log Celsius (IMM-1128)</p> <p>Acceptable Temperatures for Vaccines (IMM-985)</p>
<p>Vaccine Ordering & Accountability</p>	<p>Adequate vaccine supply must be maintained in accordance with practice patient population (VFC and non-VFC-eligible patients). Stock records (vaccine orders and privately purchased vaccine invoices) for both VFC and privately purchased vaccines must be readily available for review during VFC visits.</p> <p>VFC vaccine supply and private vaccines should be kept separate and clearly labeled to allow easy identification and to mitigate use on ineligible patients. Borrowing between public and private vaccine inventories is not allowed.</p> <p>Providers must carefully track vaccine usage and account for all doses of VFC supplied vaccine within each ordering cycle. Usage logs must be kept for a period of 3 years.</p>	<p>8 (7 & 8)</p>	<p>Vaccine usage may be tracked using the VFC Program's Daily Vaccine Usage Log (IMM-1053), similar form, or using an electronic Immunization Information System.</p> <p>EZIZ Lessons: Storing Vaccines</p> <p>Daily Usage Log (IMM-1053)</p> <p>Vaccine Physical Inventory form (IMM-1052)</p> <p>How to Do a Physical Inventory (IMM-1090)</p>

<p>Vaccine Transfers & Returns</p>	<p>Transfers Ordered vaccines must be stored only at the facility indicated in the vaccine order.</p> <ul style="list-style-type: none"> • VFC vaccines should be transferred in limited situations (routine re-distribution is not allowed). • Providers must contact the VFC Customer Service Center for approval prior to transferring vaccines to another VFC provider. • VFC-supplied vaccine doses cannot be transferred to non-VFC provider sites. <p>Returns Reconciliation of all expired/wasted vaccine doses returned to the VFC Program’s vaccine distributor by participating providers must occur within 3 months of Return Report.</p> <ul style="list-style-type: none"> • Providers must return all reported doses of expired or spoiled VFC vaccines to the program’s vaccine distributor soon after the submission of a Return Report. • Return Reports must be submitted prior to submitting a new vaccine request. 	<p>9 (8)</p>	<p>Transporting Refrigerated Vaccine job aid (IMM-983)</p> <p>Refrigerated Vaccine Transport Log (IMM-1132)</p> <p>Transporting Frozen Vaccines job aid (IMM-1130)</p> <p>Frozen Vaccine Transport Log (IMM-1116)</p> <p>Return or Transfer of VFC Vaccines Report (IMM-986)</p> <p>Vaccine Receiving Log and Checklist (IMM-1112)</p>
<p>Site Visits <i>Updated!</i></p>	<p>Actively enrolled VFC providers agree to VFC Program site visits, including 1) scheduled compliance visits, also known as Quality Assurance Reviews; 2) Unannounced storage & handling visits; and 3) other visits for educational and programmatic support.</p> <p>Unannounced storage and handling visits serve as spot checks to ensure VFC-supplied vaccines administered to VFC-eligible children are managed and stored according to program requirements; any active VFC provider may be chosen to receive an unannounced storage and handling visit.</p> <p>Provider of Record or Designee must sign and acknowledge receipt of site visit findings, and agree to complete required follow up within specified periods.</p>	<p>10</p>	<p>N/A</p>

Note: This document summarizes 2014 VFC Program participation requirements. For a complete listing of all participation requirements please refer to your clinic’s Provider Agreement and Certification of Capacity to Store and Manage Vaccines completed during 2014 VFC Program Recertification.