

California Vaccines for Children (VFC) Program

2016 Program Participation Requirements At A Glance



Requirement	Summary	Resources/Job Aids
<p>Key Clinic Staff</p>	<p>Practices must maintain key program staff contacts in the clinic’s profile, and report key personnel changes to the VFC Program in a timely manner. Key clinic staff, include:</p> <p>Provider of Record (POR), responsible for the clinic’s overall compliance with VFC Program requirements. Usually the clinic’s physician-in-chief or medical director. Must be a licensed Medical Doctor, Doctor of Osteopathy, Nurse Practitioner, Physician Assistant, or a Certified Nurse Midwife with prescription-writing privileges in the State of California</p> <p>Provider of Record Designee, an on-site staff member designated by the POR to act on his/her behalf for VFC Program related matters when the POR is unavailable</p> <p>Vaccine Coordinator, a designated, on-site, and fully trained staff member responsible for all vaccine management activities in the practice</p> <p>Backup Vaccine Coordinator, a designated, on-site, and fully trained staff member responsible for all vaccine management activities in the practice when the Vaccine Coordinator is unavailable</p> <p>Immunization Champion (optional), a staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community</p>	<p>Vaccine Coordinator and Backup Vaccine Coordinate job aid (IMM-968)</p> <p>VFC Key Practice Staff Change Request Form (IMM-1166)</p>
<p>Vaccine Management Plan</p> <p><i>Updated!</i></p>	<p>Develop and maintain a Vaccine Management Plan with practice-specific guidelines, protocols, and contact information. Plans must be easily accessible to staff and readily available to VFC program representatives for review.</p> <p>Update the management plan at least annually, when VFC Program guidelines change, and when staff with vaccine management responsibilities change. Staff with assigned vaccine management responsibilities must review, sign, and date the plans annually and whenever the plans are updated.</p> <p>Names of clinic staff with temperature monitoring responsibilities must be documented on the clinic’s Vaccine Management Plan, Training Log page.</p> <p>If a practice develops their plan(s) using something other than the VFC-provided template(s), the plan(s) must include the same content and elements as the VFC template.</p>	<p>Vaccine Management Plan (IMM-1122)</p>

<p>Fraud & Abuse</p>	<p>Providers must operate in a manner intended to avoid fraud and abuse, adhering to proper billing practices for vaccine administration fees, never billing for the cost of VFC vaccine or billing in excess of the established regional fees, and administering VFC supplied vaccine ONLY to eligible populations. VFC doses received from the VFC Program must be fully accounted with each order; and managed according to program requirements. California’s VFC Program has a “NO borrowing policy”.</p> <p>Fraud is an intentional deception or misrepresentation made by a person with the knowledge that deception could result in some unauthorized benefit to himself or other person.</p> <p>Abuse is a provider practice inconsistent with sound fiscal, business, or medical practice which results in unnecessary costs to the Medicaid program.</p>	<p>N/A</p>																																										
<p>Staff Educational Requirements</p>	<p>All key staff must be knowledgeable about VFC Program requirements, VFC eligibility criteria, and be properly trained. All training must be documented. Each practice’s VFC Provider of Record, Vaccine Coordinator, and their designees must complete annual EZIZ lessons to meet federal education requirements.</p> <p>New providers cannot enroll and existing providers cannot recertify until training is completed.</p> <p>Employees assigned to monitor and record temperatures must be properly trained on temperature monitoring, use of the clinic’s temperature monitoring equipment, and how to respond to out-of-range temperatures. For these staff, document completion of required lessons on the training log.</p> <table border="1" data-bbox="506 834 1486 1406"> <thead> <tr> <th colspan="2" rowspan="2">Legend: ✓ = Required Lesson</th> <th colspan="4">Key Clinic Staff</th> </tr> <tr> <th>Vaccine Coordinator</th> <th>Back-up Vaccine Coordinator</th> <th>Provider of Record</th> <th>Provider of Record Designee</th> </tr> </thead> <tbody> <tr> <td rowspan="4">Lessons</td> <td>VFC Program Requirements</td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Storing Vaccines</td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Monitoring Storage Unit Temperatures <i>(NEW)</i></td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Conducting a Vaccine Inventory</td> <td>✓</td> <td>✓</td> <td>Optional</td> <td>Optional</td> </tr> <tr> <td rowspan="2">Review & Acknowledge</td> <td>2016 Refrigerator Temperature Log <i>(NEW)</i></td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>2016 Freezer Temperature Log <i>(NEW)</i></td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> </tbody> </table>	Legend: ✓ = Required Lesson		Key Clinic Staff				Vaccine Coordinator	Back-up Vaccine Coordinator	Provider of Record	Provider of Record Designee	Lessons	VFC Program Requirements	✓	✓	✓	✓	Storing Vaccines	✓	✓	✓	✓	Monitoring Storage Unit Temperatures <i>(NEW)</i>	✓	✓	✓	✓	Conducting a Vaccine Inventory	✓	✓	Optional	Optional	Review & Acknowledge	2016 Refrigerator Temperature Log <i>(NEW)</i>	✓	✓	✓	✓	2016 Freezer Temperature Log <i>(NEW)</i>	✓	✓	✓	✓	<p>Visit the EZIZ training page at http://eziz.org/eziz-training or log into MyVFCVaccines to access lessons.</p>
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<p>Provider Enrollment, Recertification, & Disenrollment</p>	<p>Prospective providers must follow instructions listed EZIZ.org, including</p> <ul style="list-style-type: none"> • specify key practice staff, • complete necessary training requirements, • download and review job aids, • comply with storage unit requirements, and • complete Provider Enrollment Worksheet <p>Each year the Provider of Record must renew their participation in the VFC Program by updating their information, completing training and signing new requirement agreements.</p> <p>The VFC Program may terminate and disenroll a provider for failure to comply with VFC Program requirements. Providers may voluntarily terminate their agreement with the VFC Program at any time.</p>	<p>http://eziz.org/vfc/enrollment/</p>
<p>VFC Patient Eligibility & Screening Requirements</p> <p><i>Updated!</i></p>	<p>Follow VFC Program requirements for patient eligibility screening and documentation, including:</p> <ul style="list-style-type: none"> • Screen all patients 0-18 years of age, for VFC eligibility prior to vaccine administration at every visit • Document all elements of VFC's Eligibility Screening Record Form, including the screening date, whether the patient is VFC eligible or not; and if the patient is eligible, the criteria they meet • Do not deny a VFC-eligible patient because they/their parent is unable to pay the administration fee. • Give VFC vaccine only to children who meet VFC eligibility criteria. <p>Keep all VFC eligibility records on file for 3 years</p>	<p>VFC Patient Eligibility Screening Record form (IMM-1111)</p>
<p>ACIP Recommendations & Current Standards</p>	<p>Comply with recommendations from the ACIP about immunization schedules, dosages, and contraindications. Offer all age-appropriate vaccines according to patient population served.</p> <p>Give the patient or parent the most current version of the Vaccine Information Statement (VIS).</p> <p>Record information about each immunization given, including:</p> <ul style="list-style-type: none"> • the name of vaccine, • the date it was given, • the route and administration site, • the lot number and manufacturer, • the name and title of the person who administered it; • the clinic's name and address; • the VIS publication date and date VIS was provided 	<p>CDC Recommended Immunization Schedules</p> <p>Instructions for using VIS</p> <p>Current Vaccine Information Statements</p> <p>VFC Patient Eligibility Screening Record form (IMM-1111)</p>

<p>VFC Vaccine Orders</p>	<p>Trained and authorized clinic staff must submit vaccine orders through the practice’s account on MyVFCvaccines.org.</p> <p>Place orders according to the practice’s VFC-assigned ordering category (very high, high, medium, or low volume) and frequency (monthly, bimonthly, or quarterly).</p> <p>Provide all necessary inventory and usage information.</p> <p>The VFC Program encourages providers to choose one brand’s products when multiple vaccine products are available to avoid inadvertent administration errors.</p> <p>The practice should alert the VFC Program of any temporary closures, including vacation and building management issues, which might affect deliveries.</p> <p>Vaccine doses not accounted for or lost due to negligence will be replaced dose for dose by the Provider of Record or the practice organization.</p>	<p>EZIZ training page</p> <p>Vaccine Physical Inventory form (IMM-1052)</p> <p>Usage Logs: VFC Daily Usage Log (IMM-1053) Private Daily Usage Log (IMM-1053P) Flu Daily Usage Log (IMM-1053F)</p>
<p>Receiving, Unpacking & Storing Vaccines</p>	<p>Inspect vaccine shipments immediately upon arrival for damage.</p> <p>Verify that the contents match the information on the packing slip, including vaccine, diluent, brands, lot numbers, and expiration dates. Report any discrepancies within two hours. Never reject vaccine orders, even if the order is not intended for the clinic. Store the vaccine and then immediately contact the VFC Program if there are any discrepancies.</p> <p>Once contents are verified, properly store and label them in the appropriate areas.</p> <p>Clearly label and separate VFC-supplied and private vaccine. When possible, store the vaccines on different shelves in the storage unit. Store diluent in the refrigerator or at room temperature.</p> <p>Maintain inventory and invoices and make them available upon request.</p>	<p>Vaccine Receiving Log and Checklist (IMM-1112)</p> <p>Refrigerators: Preparing Refrigerators (IMM-962) Refrigerator Setup for Vaccine Storage (IMM-963)</p> <p>Freezers: Preparing Freezers (IMM-965) Freezer Setup for Vaccine Storage (IMM-966)</p>

<p>Inventory Monitoring & Maintenance</p>	<p>Maintain VFC-supplied vaccine according to VFC Program guidelines, including provider category and ordering frequency.</p> <ul style="list-style-type: none"> • Borrowing between VFC-supplied and private stock is prohibited. • Store vaccine in its original packaging. • Rotate stock so short-dated stock (earliest expiration) is used first. • Report all expired, spoiled, wasted, and transferred vaccine doses. • Conduct a physical inventory at least once a month and before submitting any vaccine order. 	<p>EZIZ Conducting a Vaccine Inventory lesson</p> <p>Inventory: How to Do a Physical Inventory (IMM-1090) Vaccine Inventory Form (IMM-1052)</p> <p>Usage Logs: VFC Daily Usage Log (IMM-1053) Private Daily Usage Log (IMM-1053P) Flu Daily Usage Log (IMM-1053F)</p>
<p>Vaccine Transfers & Returns</p>	<p>Transfers: Transfer VFC-supplied vaccines only in limited circumstances, following VFC transporting guidelines, and with prior approval from the VFC Program. Routine re-distribution is not allowed.</p> <p>Transfer vaccines only to another VFC provider. VFC-supplied vaccine doses may not be transferred to non-VFC providers or sites.</p> <p>The VFC Program discourages transferring varicella-containing vaccines because of sensitive temperature requirements.</p> <p>Complete a transport log each time vaccines are transported to an alternate or back-up location. Vaccines transported without proper documentation of temperature monitoring may be deemed non-viable.</p> <p>Returns: In certain circumstances, expired or spoiled vaccine may be returned. Doses must be returned to the vaccine distributor within 3 months.</p> <p>Providers must report expired/spoiled doses on a Return or Transfer of VFC Vaccines Report prior to submitting a new vaccine request.</p>	<p>Refrigerated vaccines: Transporting Refrigerated Vaccine job aid (IMM-983) Refrigerated Vaccine Transport Log (IMM-1132)</p> <p>Frozen vaccines: Transporting Frozen Vaccines job aid (IMM-1130) Frozen Vaccine Transport Log (IMM-1116)</p> <p>Transferring vaccines: Return or Transfer of VFC Vaccines Report (IMM-986) Vaccine Receiving Log and Checklist (IMM-1112)</p>

<p>Billing for Administration of VFC-Supplied Vaccines</p>	<p>VFC providers may NOT bill anyone for the cost of VFC-supplied vaccines. Do not deny a VFC-eligible patient because they/their parent is unable to pay the administration fee.</p> <p>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 reimbursement rates set by Medi-Cal or the contracted Medi-Cal health plans.</p> <p>VFC providers may not deny administration of VFC vaccine to an established VFC-eligible patient because the child's parent/guardian is unable 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>VFC’s Who’s Eligible flier (IMM-1088)</p>
<p>Documentation & Record Retention Requirements</p>	<p>Maintain all paper-based and electronic records related to the VFC Program for a minimum of three (3) years.</p> <p>Make records available to public health officials, including local health jurisdictions, CA Dept. of Public Health, and Department of Health and Human Services, upon request.</p> <p>Records includes patient screening/eligibility verification, temperature logs, vaccine ordering records, medical records which verify receipt of vaccine, vaccine purchase and accountability records, VFC training records, Routine and Emergency Vaccine Management Plans, Provider Recertification forms, Certificates of Calibration, etc.</p> <p>Maintain vaccine administration records in accordance with the National Childhood Vaccine Injury Compensation Act, which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Providers also are encouraged to report vaccine administration errors to the Vaccine Error Reporting Program (VERP).</p>	<p>VAERS and VERP flier (IMM-1153)</p>

<p>Vaccine Storage and Equipment</p>	<p>Store all vaccines supplied by the California VFC Program under appropriate temperatures at all times. Acceptable temperature ranges for refrigerated vaccines are 35.0° F and 46.0° F (2.0° C and 8.0° C) and for frozen vaccines between -58.0° F and +5.0° F (-50.0° C and -15.0° C).</p> <p>Equipment used for the storage of refrigerated and frozen vaccines must meet CA VFC Program requirements and maintain acceptable temperature ranges.</p> <p>Providers must have separate refrigerator-only and freezer-only units which must be dedicated to the storage of vaccines.</p> <p>Various brands and models are acceptable. The California VFC Program does not endorse or recommend specific products.</p> <p>Safeguard storage unit’s power supply, posting warning labels on both the plug and the circuit breaker associated with all vaccine storage units to prevent accidental disconnection and/or implementing use of plug guards.</p> <p>Ensure the capacity of the storage units have adequate space for inventory, especially during busier periods like during influenza season and back-to-school time.</p> <p>It may be necessary to purchase additional storage unit(s) if the size of the practice’s current storage units cannot accommodate the practice’s inventory.</p>	<p>Vaccine Storage requirements</p> <p>Refrigerators: Preparing Refrigerators job aid (IMM-962) Refrigerator Setup for Vaccine Storage (IMM-963)</p> <p>Freezers: Preparing Freezers (IMM-965) Freezer Setup for Vaccine Storage (IMM-966)</p> <p>Power Supply: Safeguard Your Power Supply (IMM-967) Do Not Unplug Sign (IMM-744)</p>
<p>Storage & Handling Incidents</p> <p>(Temperature Excursions)</p> <p><i>New!</i></p>	<p>Take immediate action to prevent spoilage for out-of-range temperatures in the vaccine refrigerator and freezer. A temperature excursion does not automatically mean that exposed vaccines are non-viable or unusable. However, vaccines exposed to temperature ranges must be marked “do not use” until guidance is received from the VFC Program or the vaccine manufacturers. Record temperature excursions on SHOTS (Storage and Handling Triage System) on MyVFCvaccines.org.</p> <p>Vaccines stored out of range and with inappropriate temperature monitoring devices may be deemed non-viable, and may be considered a negligent vaccine loss.</p>	<p>SHOTS www.MyVFCvaccines.org</p>

<p>Thermometers & Data Loggers</p> <p><i>Updated!</i></p> <p><i>*Beginning in 2017, all VFC providers will be required to use data loggers.</i></p>	<p>Use a VFC-compliant temperature monitoring device in each vaccine storage unit at all times. Have at least one VFC-compliant back-up device for use when primary devices fail or are being recalibrated.</p> <p>To meet specifications, temperature monitoring devices must:</p> <ul style="list-style-type: none"> • Be accurate within +/-1.0°F (+/-0.5°C); • Be digital, with the digital display placed outside the unit; • Have a buffered temperature probe immersed in one of the following: a vial filled with liquid (e.g. glycol, ethanol, glycerin); a vial filled with loose media (e.g. sand, glass beads); or a solid block of material (e.g. Teflon®, aluminum); • Display current, minimum, and maximum temperatures; • Have a visual or audible alarm to signal out-of-range temperatures; • 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 <u>Certificate of Calibration</u> on file for 3 years and presented upon request. • Memory stores at least 4,000 readings (specific to data loggers only) <p>In order to be valid, a Certificate of Calibration must include:</p> <ul style="list-style-type: none"> • Model and Serial Number; • Date of Calibration Testing (Report/Issue Date); • Measurement results indicate unit passed test and the documented uncertainty is within +/-1° F (+/-0.5° C); and • a statement indicating that calibration meets ISO 17025 standards (non-accredited laboratories). <p>Temperature monitoring devices no longer accurate within +/-1.0°F (+/-0.5°C) as indicated in the calibration measurement results, must be replaced.</p> <p>Practices with multiple vaccine storage units may need more than one backup device.</p> <p>All new VFC providers, practices that are open 2 days a week or less, and practices needing to replace their primary or back-up thermometer will be required to purchase and use data loggers to monitor temperatures. Providers conducting mass vaccination clinics also must use data loggers to monitor temperatures during vaccine transport and at the mass vaccination clinic.</p>	<p>Thermometer requirements</p> <p>Checklist for Thermometer Certificate of Traceability and Calibration(IMM-1119)</p> <p>Data Logger FAQs</p> <p>Data Logger Job Aid</p>
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<p>Temperature Logs and Recording Temperatures</p>	<p>Providers must use current VFC Program temperature logs, available from EZIZ, even if using a continuous temperature recording device or a digital data logger. 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.</p> <p>Twice each day, at the beginning and towards the end of each business day, the Vaccine Coordinator must monitor and record the CURRENT, MAX and MIN temperatures in the refrigerator and freezer, date of each reading and the initials of the person who assessed and recorded the readings.</p> <p>If temperatures are monitored using a continuous temperature device/data logger, download and review of temperature data should occur every two-week period, or at minimum, monthly.</p> <p>If other staff are assigned to monitor and record temperatures, they must be trained on the use of the devices used by the practice, and how to respond to out-of-range temperatures.</p> <p>When the log is complete, the supervisor must certify that temperatures recorded on that log are correct and that corrective actions were taken.</p> <p>Maintain completed temperature logs for three years and make them available upon request.</p>	<p>Refrigerators: Recording Refrigerator Temperatures (IMM-1029) Refrigerator Temp Log Fahrenheit (IMM-1125) Refrigerator Temp Log Celsius (IMM-1127)</p> <p>Freezers: Recording Freezer Temperatures (IMM-1028) Freezer Temp Log Fahrenheit (IMM-1126) Freezer Temp Log Celsius (IMM-1128)</p>
<p>Vaccine Storage Guidelines</p>	<p>Store vaccines within recommended temperatures at all times.</p> <ul style="list-style-type: none"> Refrigerated vaccines between 35.0°F and 46.0°F (2.0°C and 8.0°C) Frozen vaccines between -58.0°F and 5.0°F (-50.0°C and -15.0°C) <p>Store VFC-supplied vaccines according to VFC Program guidelines.</p> <ul style="list-style-type: none"> Set up vaccine storage units properly; Store vaccine in its original packaging; Position vaccine 2-3 inches from the walls and floor, and allow enough space for air to circulate; Separate and label VFC and private vaccines; Group and label vaccine by type; Do not store vaccine on the door or in drawers; Plug storage units into electrical outlets which are not controlled by wall switches. Fill vacant refrigerate space, such as the floor, door, and along the walls, with water bottles to stabilize temperatures; Fill vacant freezer space with cold packs to stabilize temperatures 	<p>EZIZ Storing Vaccines lesson</p> <p>Prevent Vaccine Loss flier (IMM-1113)</p>

Site Visits	<p>Enrolled providers agree to site visits from VFC Program staff, including</p> <ol style="list-style-type: none">1) scheduled compliance visits;2) unannounced storage and handling visits; and3) visits for educational and programmatic support <p>Unannounced storage and handling visits serve as spot checks to ensure VFC-supplied vaccines are administered to VFC-eligible children and are managed and stored according to VFC Program requirements. Any active VFC provider may be chosen to receive an unannounced storage and handling visit.</p> <p>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.</p>	N/A
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