

2017 Program Participation Requirements at a Glance

Requirement	Summary	Resources/Job Aids
<p>Vaccine Management Plan</p> <p><i>Updated for 2017</i></p>	<p>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.</p> <p>Review and update the plan at least once a year, when VFC Program requirements change, and when staff with designated vaccine management responsibilities change.</p> <p>Ensure all staff with assigned vaccine management responsibilities review, sign, and date the plan annually and whenever the management plan is updated.</p>	<p>Vaccine Management Plan (IMM-1122)</p>
<p>Key Practice Staff</p>	<p>Designate and maintain key practice staff in the practice’s profile, and report key practice staff changes to the VFC Call Center. There are four required VFC roles:</p> <p>Provider of Record (POR): The physician-in-chief, medical director, or equivalent role that signs and agrees to the terms of the VFC “Provider Agreement” and the California VFC Program “Provider Agreement Addendum” 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.</p> <p>Provider of Record Designee: The on-site person designated by the Provider of Record to sign VFC documents on his/her behalf and to assume responsibility for VFC matters in his/her absence.</p> <p>Vaccine Coordinator: An on-site employee who is fully trained and responsible for implementing and overseeing the provider’s vaccine management plan.</p> <p>Backup Vaccine Coordinator: An on-site employee fully trained in the practice’s vaccine management activities and fulfills the responsibilities of the Vaccine Coordinator in his/her absence.</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 Roles & Responsibilities (IMM-968)</p> <p>VFC Key Practice Staff Change Request Form (IMM-1166)</p>

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<p>Staff Training Requirements</p>	<p>New providers cannot enroll and existing providers cannot recertify until all key practice staff complete the required EZIZ lessons, which must be documented in the practice’s vaccine management plan.</p> <p>All staff with temperature monitoring responsibilities must be properly trained on temperature monitoring, use of the practice’s temperature monitoring devices, and required actions for out-of-range temperatures. Staff authorized to accept packages must be trained to notify Vaccine Coordinators for vaccine deliveries.</p> <p>Required training by role:</p> <table border="1" data-bbox="367 544 1260 1063"> <thead> <tr> <th colspan="2" rowspan="2">Legend: ✓ = Required Lesson</th> <th rowspan="2">Start Date</th> <th colspan="4">Key Practice Staff</th> </tr> <tr> <th>Vaccine Coordinator</th> <th>Backup 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>December 2016</td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Storing Vaccines*</td> <td>December 2016</td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Monitoring Storage Unit Temperatures*</td> <td>December 2016</td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Conducting a Vaccine Inventory*</td> <td>December 2016</td> <td>✓</td> <td>✓</td> <td>Encouraged</td> <td>Encouraged</td> </tr> <tr> <td rowspan="2">Review & Acknowledge</td> <td>Temperatures Logs</td> <td>December 2016</td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Vaccine Management Plan <i>(NEW)</i></td> <td>December 2016</td> <td>✓</td> <td>✓</td> <td>✓</td> <td>✓</td> </tr> </tbody> </table>	Legend: ✓ = Required Lesson		Start Date	Key Practice Staff				Vaccine Coordinator	Backup Vaccine Coordinator	Provider of Record	Provider of Record Designee	Lessons	VFC Program Requirements*	December 2016	✓	✓	✓	✓	Storing Vaccines*	December 2016	✓	✓	✓	✓	Monitoring Storage Unit Temperatures*	December 2016	✓	✓	✓	✓	Conducting a Vaccine Inventory*	December 2016	✓	✓	Encouraged	Encouraged	Review & Acknowledge	Temperatures Logs	December 2016	✓	✓	✓	✓	Vaccine Management Plan <i>(NEW)</i>	December 2016	✓	✓	✓	✓	<p>EZIZ Training Lessons</p>
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<p>VFC Eligibility Screening & Documentation</p>	<p>Follow VFC Program requirements for patient eligibility screening and documentation:</p> <ul style="list-style-type: none"> • Screen all children from birth through 18 years of age for VFC eligibility (Medi-Cal eligible, uninsured, American Indian/Alaska Native, and underinsured children seen at a FQHC or RHC) prior to vaccine administration—at every immunization visit. • Document all elements of VFC’s “Patient Eligibility Screening Record” form, including the screening date, VFC eligibility (Y/N), and any eligibility criterion (or criteria) if met. • Do not deny vaccine administration because the parent/guardian is unable to pay the administration fee. • Keep all VFC eligibility records on file for three years. 	<p>VFC Patient Eligibility Screening Record form (IMM-1111)</p> <p>VFC’s Who’s Eligible flier (IMM-1088)</p> <p>VFC Eligibility & Documentation Requirements (IMM-1161)</p>																																																	

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<p>ACIP Recommendations & Standards</p>	<p>Follow VFC Program requirements:</p> <ul style="list-style-type: none"> Comply with recommendations about immunization schedules, dosages, and contraindications as established by the ACIP and included in the VFC Program. Offer all age-appropriate vaccines according to patient populations served. Administer VFC-supplied vaccines only to children who meet VFC eligibility criteria. Distribute the current Vaccine Information Statements (VIS) before vaccine administration. 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). Acknowledge that revaccination is recommended if non-viable vaccines have been administered to patients. <p>Record information about each immunization given, including:</p> <ul style="list-style-type: none"> the name of the 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 practice’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>VAERS and VERP flyer (IMM-1153)</p>
<p>Billing for Vaccine Administration</p>	<p>Immunize all VFC-eligible children with VFC-supplied vaccines at no charge to the patient for vaccines.</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. Waive the administration fee if the parent/guardian is unable to pay.</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. Never bill the difference between Medi-Cal’s administration fee and the administration fee cap to the parent/guardian.</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>	

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<p>Vaccine Storage Units</p>	<p>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.</p> <p>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.</p> <p>Dedicate vaccine refrigerators and freezers to the storage of vaccines only.</p> <p>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.</p>	<p>EZIZ Vaccine Storage requirements</p>
<p>Digital Data Loggers</p> <p><i>Updated for 2017!</i></p> <p><i>*Beginning in 2017, all VFC providers will be required to use data loggers.</i></p>	<p>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.</p> <p>Replace with digital data loggers any primary or backup thermometers deemed no longer accurate within +/-1.0°F (+/-0.5°C), or upon expiration of the thermometer’s certificate of calibration (for primary and backups) but no later than December 1, 2017.</p> <p>Ensure all data loggers 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 (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.</p> <p>Never use these devices for vaccine temperature monitoring: 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.</p> <p>Calibrate primary/backup devices annually, or every other year when manufacturers recommend a period longer than two years.</p>	<p>EZIZ Data Logger Requirements</p> <p>Digital Data Logger Pre-Purchase Worksheet (IMM-1236)</p> <p>Data Logger Setup & Use (IMM-1206)</p> <p>Certificate of Calibration Quick Guide (IMM-1119)</p>

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<p>Vaccine Storage Unit Configuration</p>	<p>Prepare vaccine refrigerators and vaccine freezers in compliance with VFC Program requirements.</p> <ul style="list-style-type: none"> Place water bottles in vaccine refrigerators and ice packs in vaccine freezers to stabilize temperatures. Place buffered probes in the center of the refrigerator and freezer near vaccines. Place the data logger’s digital display outside of the storage unit to allow temperature monitoring without opening the vaccine storage unit door. 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. Post “Do Not Unplug” signs on electrical outlets and circuit breakers to prevent interruption of power. <p>Set up vaccine refrigerators and vaccine freezers in compliance with VFC Program requirements.</p> <ul style="list-style-type: none"> Designate separate shelf space or breathable mesh baskets for VFC-supplied and privately purchased vaccines. Clearly label shelves or baskets to 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. Post VFC temperature logs on vaccine storage unit doors or in an easily accessible location. 	<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>Routine Vaccine Orders & Accountability</p>	<p>Trained and authorized clinic staff must submit vaccine orders through the practice’s account on MyVFCvaccines.org following program requirements:</p> <ul style="list-style-type: none"> Conduct a physical vaccine inventory before ordering routine vaccines to determine doses on hand. Account for every dose of VFC-supplied vaccine ordered and received by the provider’s practice. Order routine ACIP-recommended vaccines according to the provider population, category, order frequency, vaccine usage, and on-hand inventory. 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. Stock one brand and formulation for each vaccine to avoid administration errors. 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. Report on each vaccine order the quantity of vaccines administered since the previous order and the current on-hand inventory. Maintain and make available accurate and separate stock records for privately purchased vaccines. 	<p>Vaccine Ordering Worksheet (IMM-1246) – Coming soon!</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>

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<p>Receiving Vaccine Deliveries</p>	<p>Follow VFC Program requirements:</p> <ul style="list-style-type: none"> • Never reject vaccine shipments. • Receive and unpack vaccines immediately upon delivery. • Inspect vaccines for out-of-range temperatures and shipping times during transport. • Check package contents to ensure brands and quantities match the packing slip and approved VFC order. • 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. 	<p>Vaccine Receiving Log and Checklist (IMM-1112)</p>
<p>Vaccine Storage</p>	<p>Always store vaccines within manufacturer recommended ranges:</p> <ul style="list-style-type: none"> • Frozen vaccines (MMR, MMRV, and VAR) between -58.0°F and 5.0°F (-50.0°C and -15.0°C). • All other vaccines in a refrigerator between 35.0°F and 46.0°F (2.0°C and 8.0°C). <p>Store VFC-supplied vaccines according to VFC Program guidelines.</p> <ul style="list-style-type: none"> • Store vaccines in original packaging and within closed boxes to protect from light and allow for air circulation. • Store VFC-supplied and privately purchased vaccines separately and grouped by vaccine type. • Do not store vaccines in the doors, drawers, or bins. • Place vaccines with the earliest expiration dates toward the front of the storage unit and use first. 	<p>EZIZ Storing Vaccines lesson</p>

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<p>Temperature Monitoring & Documentation</p>	<p>Follow program requirements:</p> <ul style="list-style-type: none"> • Ensure vaccine storage unit temperatures are recorded on VFC temperature logs. • 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. • 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. • 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. • Ensure VFC temperature logs are legible and completed accurately. • Immediately cross out, correct, and initial neatly any inadvertent documentation error. • 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. • Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted. • Retain paper logs and electronic files related to temperature monitoring for three years. 	<p>Refrigerators: Recording Refrigerator & Freezer Temperatures (IMM-1029) Refrigerator Temp Log Fahrenheit (IMM-1125) Refrigerator Temp Log Celsius (IMM-1127)</p> <p>Freezers: Freezer Temp Log Fahrenheit (IMM-1126) Freezer Temp Log Celsius (IMM-1128)</p>
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<p>Reporting Storage & Handling Incidents</p> <p>(Temperature Excursions)</p>	<p>Vaccines stored out of range might be deemed non-viable and considered a negligent vaccine loss. Providers are required to report all temperature excursions on SHOTS (Storage and Handling Triage System), which is accessed through your MyVFCvaccines.org account.</p> <p>A temperature excursion does not automatically mean that exposed vaccines are non-viable or unusable. Follow program requirements:</p> <ul style="list-style-type: none"> • 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. • 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. • Download and review temperature data files for every temperature excursion if using digital data loggers. • Report and document all out-of-range temperatures on MyVFCvaccines.org. Depending on the temperatures reported, you will be given results and instructions that no further action is required, or that you must contact the vaccine manufacturers. • Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper refrigerated vaccine transport and frozen vaccine transport. 	<p>MyVFCvaccines - SHOTS</p> <p>SHOTS Guide (IMM-1224)</p>
<p>Vaccine Inventory Management</p> <p>(Spoiled, Expired, & Wasted)</p>	<p>Follow VFC Program requirements:</p> <ul style="list-style-type: none"> • 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. • Never borrow VFC-supplied vaccines to supplement private stock, or vice versa. • For vaccines that will expire within 6 months and cannot be used, notify the VFC Call Center prior to transferring to another VFC provider. • Remove spoiled, expired, and wasted vaccines from storage units immediately to prevent inadvertent use. • Report all VFC-supplied spoiled, expired, or wasted vaccines prior to submitting a new vaccine order. • Monitor vaccine storage units regularly and purchase additional units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements. 	<p>EZIZ Conducting a Vaccine Inventory lesson</p> <p>Inventory:</p> <p>How to Do a Physical Inventory (IMM-1090)</p> <p>Vaccine Inventory Form (IMM-1052)</p> <p>Prevent Vaccine Loss flyer (IMM-1113)</p>

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<p>Vaccine Transfers & Transports</p>	<p>Follow VFC Program transfer requirements:</p> <ul style="list-style-type: none"> • 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. • Never routinely transfer VFC-supplied vaccines to other VFC providers. • Never transfer VFC-supplied vaccines to non-VFC providers. <p>Follow VFC Program transport requirements:</p> <ul style="list-style-type: none"> • Transport vaccines only when absolutely necessary and follow the guidelines for proper refrigerated vaccine transport and frozen vaccine transport. • Store VFC-supplied vaccines only at facilities designated in the provider profile; never store VFC vaccines in personal residences. • Use digital data loggers to monitor temperatures during vaccine transport and at mass vaccination clinics. • Complete a VFC Refrigerated or Frozen Vaccine Transport Log each time vaccines are transported. • Acknowledge that vaccines transported without proper documentation may be deemed non-viable. 	<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>Program Enrollment, Recertification, Withdrawal, & Termination</p>	<p>Prospective providers must specify key practice staff; complete necessary training requirements; download and review job aids; comply with storage unit requirements; and complete and submit the online Provider Enrollment Form</p> <p>Each year the Provider of Record must recertify their participation in the VFC Program by updating their information, completing required EZIZ training, and signing new requirement agreements.</p> <p>Providers may voluntarily withdraw from the VFC Program. The VFC Program also may terminate a VFC “Provider Agreement” and remove the provider from the VFC Program for failure to comply with program requirements.</p> <p>In both cases, the Provider of Record must return or transfer all unused VFC-supplied vaccines. Enrolled providers are responsible for all VFC-supplied vaccines in their practice until their Provider Agreement has been officially terminated.</p>	<p>http://eziz.org/vfc/enrollment/</p>
<p>Fraud & Abuse</p>	<p>Providers agree to participate in a manner intended to avoid fraud and abuse. A provider found guilty of fraud and/or abuse will be subject to vaccine restitution and termination from the VFC Program.</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. Fraud results in a financial gain for the provider but with an inadvertent cost to the VFC Program.</p> <p>Abuse is a provider practice inconsistent with sound fiscal, business, or medical practice which results in unnecessary costs to the Medicaid program. Abuse results in inadvertent costs to the VFC Program and consists of any actions that lead to negligent loss. Providers agree to replace all vaccines deemed non-viable due to provider negligence.</p>	

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<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 vaccine administration, vaccine purchase and accountability records, VFC training records, vaccine management plan, recertification forms, etc.</p>	
<p>Site Visits</p>	<p>Enrolled providers agree to site visits from VFC Program staff, including scheduled compliance visits, unannounced storage and handling visits, and visits for educational and programmatic support</p> <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.</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>	