

# 2025 Requirements at a Glance for Vaccine Replacement Model

For Participating Birthing Hospitals, Pharmacies, and Large Healthcare Systems

VFC-approved birthing hospitals, pharmacies and large healthcare systems are invited to apply through the Vaccine Replacement Model to replenish private vaccine stock administered to VFC-eligible children. Facilities must have the capacity to use their private funds to establish initial vaccine stock for use in providing vaccination services to all patients they serve. Once enrolled, entities must always maintain a vaccine inventory that is sufficient to cover both their private and VFC patients. Therefore, replacement model facilities must have the means to purchase private stock for VFC-eligibility children and request replacement for doses administered to eligible patients based on documented vaccine administration (including eligibility at the dose level) and reporting to the California Immunization Registry (CAIR or RIDE/Health Futures). Additional oversight is required, and enrollment must be approved by the Centers for Disease Control and Prevention (CDC).

**Instructions:** See “Summary” column for requirements identified in the [VFC Provider Agreement \(PDF\)](#) and [Provider Agreement Addendum \(PDF\)](#). See “Replacement Model Modifications” for modifications and exceptions to general provider requirements. For detailed coverage of general VFC policies and procedures, please refer to the [VFC Provider Operations Manual \(PDF, 7.7 MB\)](#).

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## Staffing Requirements

Requirements	Summary	Replacement Model Modifications	Resources/Job Aids
<b>Key Practice Staff</b>	<p>Designate and maintain key practice staff in the provider profile.  <b>Immediately report changes to key practice staff to VFC.</b></p> <p>There are four required roles:</p> <p><b>Provider of Record (POR):</b> The on-site physician-in-chief, medical director, or equivalent, who signs 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><b>Provider of Record Designee:</b> The on-site person who is authorized to sign VFC Program documents and assumes responsibility for VFC-related matters in the absence of the Provider of Record.</p> <p><b>Vaccine Coordinator:</b> An on-site employee who is fully trained and responsible for implementing and overseeing the practices vaccine management plan. (Contact the Provider Call Center for changes to this role.)</p> <p><b>Backup Vaccine Coordinator:</b> 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. (Contact the Provider Call Center for changes.)</p> <p><b>Organization Vaccine Coordinator (optional):</b> A fully trained employee who manages and oversees all aspects of meeting VFC Program requirements for all VFC locations within their organization.</p> <p><b>Additional Vaccine Coordinator (optional):</b> Another on-site employee fully trained in the practice’s vaccine management activities who fulfills the responsibilities of the Vaccine Coordinator in his/her absence.</p>	<p>All elements are applicable for every location but with modifications.</p> <p>For each provider location, providers must designate the key practice staff who are expected to coordinate with their regional contacts.</p> <p>Any organization that has multiple affiliated locations is strongly encouraged to appoint a main point of contact (POC) for the VFC Program. This staff person would be fully trained in managing and overseeing the replacement of private doses used on VFC patients. Their responsibilities would include training the immunization coordinators on all aspects of the replacement model.</p>	<p><a href="#">Vaccine Coordinator Roles &amp; Responsibilities (PDF)</a></p>

Requirements	Summary	Replacement Model Modifications	Resources/Job Aids
	<b>Immunization Champion (optional):</b> A staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community.		
<b>Staff Training Requirements</b>	<p>Anyone acting in VFC roles (Provider of Record and Designee; Vaccine Coordinator and Backup) must complete the required EZIZ lessons when hired and annually thereafter; staff must demonstrate competency in their assigned VFC roles.</p> <ul style="list-style-type: none"> <li>Any clinician who administers VFC-supplied vaccines must be knowledgeable of and familiar with all ACIP-recommended immunizations, including schedules, indications, dosages, and new products.</li> <li>All staff who conduct VFC Program eligibility screening, documentation, and billing (e.g., front- or back-office staff) must be knowledgeable of all VFC eligibility categories, documentation, and billing requirements.</li> <li>All staff and supervisors who monitor storage unit temperatures or sign off on VFC temperature logs must complete the related EZIZ lesson when hired and annually thereafter; they must be fully trained on use of the practice's data loggers.</li> <li>Train staff who are authorized to accept packages to immediately notify the Vaccine Coordinator when VFC-supplied vaccines are delivered.</li> <li>Conduct regular vaccine transport drills to maintain competency and readiness for emergencies.</li> <li>Organization Vaccine Coordinator and Additional Vaccine Coordinator roles must complete all required trainings applicable to the Vaccine Coordinator role.</li> </ul> <p>Required training by role (Test-out option available):</p>	<p>All elements are applicable for every location but with modifications.</p> <p>Ensure appropriate staff are trained to use the EHR to screen and document patients for VFC eligibility and ensure doses administered are documented and reported to the California Immunization Registry (CAIR or RIDE/Healthy Futures).</p>	<p><a href="#">EZIZ Training Lessons</a></p> <p>Provider Operations Manual, Chapter 1</p>

Requirements	Summary						Replacement Model Modifications	Resources/Job Aids
	√ = Required Lesson	When to Start	Vaccine Coordinator	Backup Vaccine Coordinator	Provider of Record	Provider of Record Designee		
	VFC Program Requirements	Recertification Launch	✓	✓	✓	✓		
	Storing Vaccines	Recertification Launch	✓	✓	✓	✓		
	Monitoring Storage Unit Temperatures	Recertification Launch	✓	✓	✓	✓		
	Conducting a Vaccine Inventory	Recertification Launch	✓	✓	Encouraged	Encouraged		
	VFC Provider Operations Manual (Review & Acknowledge)	Recertification Launch	✓	✓	✓	✓		
	Vaccine Management Plan (Review & Acknowledge)	Recertification Launch	✓	✓	✓	✓		

## Vaccine Administration Requirements

Requirements	Summary	Replacement Model Modifications	Resources/Job Aids
<b>Patient Visit Checklist</b>	<p>Providers agree to modify their workflows to accommodate program requirements:</p> <ul style="list-style-type: none"> <li>Screen all children from birth through 18 years of age for VFC eligibility.</li> <li>Provide Vaccine Information Statement (VIS) (or Immunization Information Statement for nirsevimab) <b>before</b> administration.</li> <li>Prepare/administer vaccines per package insert.</li> <li>Request recipient's mobile number and email (see <a href="#">Health Officer Order</a>).</li> <li>Report administration data daily using My Turn, EHR/EMR connected to CAIR/RIDE Healthy Futures, or CAIR manual entry.</li> <li>Report any adverse events to <a href="#">VAERS</a>.</li> </ul>	All elements are applicable for every location.	None

Requirements	Summary	Replacement Model Modifications	Resources/Job Aids
	<ul style="list-style-type: none"> <li>Complete vaccination record card per practice protocols.</li> <li>Schedule next appointment (if recommended).</li> <li>Recommend <a href="#">Digital Vaccination Record</a>.</li> </ul>		
<b>VFC Eligibility Screening &amp; Documentation</b>	<p>For children to receive vaccines through the VFC Program, provider locations must screen for VFC eligibility criteria and document VFC Program eligibility in the child's permanent medical record — at each immunization visit. Follow VFC Program requirements for patient eligibility screening and documentation:</p> <ul style="list-style-type: none"> <li>Document eligibility 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) to vaccine administration—at every immunization visit.</li> <li>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.</li> <li>Keep all VFC eligibility records on file for three years, even after your provider location is no longer participating in the VFC Program (due to provider-initiated withdrawal or VFC-initiated termination).</li> </ul>	<p>All elements are applicable for every location but with modifications.</p> <p>Locations will screen and document VFC eligibility status through their EHR for each immunization encounter; eligibility status (including insurance information) will be documented during the registration process and updated as necessary prior to vaccine administration to change the vaccine dose to VFC vaccine, if eligible.</p> <p>Locations will maintain dose-level eligibility through their EHR and report patient eligibility category to CAIR (or RIDE/Healthy Futures) through a data interface or CAIR manual data entry.</p>	<p><a href="#">Eligibility Screening Record for Birthing Hospitals (PDF)</a></p> <p><a href="#">Patient Eligibility Screening Record form (PDF)</a></p> <p><a href="#">Does Your Child Qualify flyer (PDF)</a></p> <p><a href="#">Eligibility &amp; Documentation Requirements (PDF)</a></p> <p>Provider Operations Manual, Chapter 2</p>
<b>ACIP Recommendations</b>	The VFC Program entitles eligible children to all vaccines recommended by the Advisory Committee on Immunization	All elements are applicable for every	<a href="#">CDC Recommended</a>

Requirements	Summary	Replacement Model Modifications	Resources/Job Aids
	<p>Practices (ACIP). As a VFC Program participant, your practice is also required to ensure that VFC-eligible children have access to ACIP-recommended vaccines not routinely administered, such as Meningococcal Group B (MenB) and Pneumococcal polysaccharide (PPSV23) vaccines and make them available when indicated or requested</p> <p>Follow VFC Program requirements:</p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Recommend non-routine, ACIP-recommended vaccines when indicated or when requested.</li> <li>• Acknowledge and follow VFC Program and manufacturer guidance, including revaccination, if non-viable vaccines have been administered to patients.</li> </ul> <p>Exemptions allowed if 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.</p>	<p>location but with modifications.</p> <p><b>Birth Hospitals:</b> Facilities are only required to offer RSV and Hep B vaccines to VFC-eligible children.</p>	<p><a href="#">Immunization Schedules</a></p> <p>Provider Operations Manual, Chapter 1</p>
<b>Vaccine Information Statements</b>	<p>Providers agree to distribute the current Vaccine Information Statement (VIS) (or Immunization Information Statement for nirsevimab) before vaccine administration.</p>	<p>All elements are applicable for every location.</p>	<p><a href="#">Instructions for using VIS (PDF)</a></p> <p><a href="#">Current VISs (CDC)</a></p> <p><a href="#">VISs at Immunize.Org</a></p>
<b>Vaccine Administration at Enrolled Locations</b>	<p>Administer all VFC-supplied vaccines at the approved practice address for the VFC PIN; do not refer patients to other facilities where they might be charged for vaccine administration. Acknowledge and follow VFC Program and manufacturer guidance, including revaccination, if non-viable vaccines have been administered to patients.</p>	<p>All elements are applicable for every location.</p>	<p><a href="#">Vaccine Usage Logs (PDF)</a></p> <p>Provider Operations Manual, Chapter 2</p>

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	<p><b><i>For VFC-approved outreach clinics:</i></b> Special event clinics, health fairs, special school clinics, and mass vaccination clinics require prior approval from the VFC Program at least 4 weeks before the scheduled event; frozen vaccines may not be administered off-site; the practice must submit a summary report that includes doses administered within 15 days after the end of the clinic.</p>		
<p><b>Reporting and Tracking Doses Administered</b></p>	<p>Report doses administered (including patient eligibility status) to California's immunization registry using My Turn, EHR/EMR connected to CAIR/RIDE Healthy Futures, or CAIR manual entry within 14 days of administration and before the patient is discharged from the hospital. Report data in accordance with all specified elements of <a href="#">AB 1797</a>.</p> <p>Record information about each immunization given, including:</p> <ul style="list-style-type: none"> <li>• Eligibility category by dose</li> <li>• the name of the vaccine</li> <li>• the date it was given</li> <li>• the route and administration site</li> <li>• the lot number and manufacturer</li> <li>• the name and title of the person who administered it</li> <li>• the practice's name and address</li> <li>• the VIS publication date and date VIS was provided</li> <li>• Cell phone and email address are recommended</li> </ul>	<p>All elements are applicable for every location but with modifications.</p> <p>Doses administered including patient eligibility status must be reported to the California Immunization Registry (CAIR) or RIDE/Healthy Futures. Eligibility status (including insurance information) will be documented during the registration process, verified, and updated as necessary prior to vaccine administration to change the vaccine dose to VFC vaccine, if eligible.</p> <p>Replacement of doses is based on administration data</p>	<p>Provider Operations Manual, Chapter 2</p>



Requirements	Summary	Replacement Model Modifications	Resources/Job Aids
		recorded in CAIR or RIDE/Healthy Futures, therefore accuracy must be ensured.	
<b>VAERS/MedWatch/VERP Reporting</b>	<p>Providers agree to maintain records in accordance with the National Vaccine Injury Compensation Program (VICP), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). <b>For nirsevimab:</b> When not co-administered with other vaccines, report all suspected adverse reactions to MedWatch. Report suspected adverse reactions following co-administration of nirsevimab with any vaccine to VAERS.</p> <p>Additionally, providers are encouraged to report all vaccine administration errors to the Vaccine Error Reporting Program (VERP).</p>	All elements are applicable for every location.	<a href="#">VAERS, VERP and MedWatch flyer (PDF)</a>
<b>Billing for Vaccine Administration</b>	<p>Immunize all VFC-eligible children with VFC-supplied vaccines at no charge to the patient for vaccines. Do not deny vaccine administration because the parent/guardian is unable to pay the administration fee.</p> <p>Provider locations 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><b>For non-Medi-Cal, VFC-eligible children:</b> Waive the administration fee if the parent/guardian is unable to pay. Never bill parents who are unable to pay the waived administration fees.</p> <p><b>For Medi-Cal children:</b> 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>All elements are applicable for every location but with modifications.</p> <p>Location will update their EHR to ensure VFC-eligible children are not billed for vaccine cost and are billed for administration based on their VFC eligibility category; the appropriate vaccine charge (or lack thereof), administration charge and diagnostic codes will be applied to the patient's account at administration as</p>	Provider Operations Manual, Chapter 2



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	<p><b>Note:</b> Pharmacies, urgent care and other specialty VFC provider locations 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>	appropriate.	

## Vaccine Management Requirements

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
<b>Vaccine Management Plan</b>	<p>Maintain a current and completed vaccine management plan (VMP) for routine and emergency situations that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and EZIZ lessons completion dates for key practice staff.</p> <ul style="list-style-type: none"> <li>Review and update the VMP at least annually, when VFC Program requirements change, and when staff with designated vaccine-management responsibilities change.</li> <li>Designate a staff member responsible for updating the practice’s VMP.</li> <li>Staff with assigned vaccine-management responsibilities must review, sign, and date the VMP annually and each time it is updated.</li> <li>Follow emergency guidelines to prepare for, respond to, and recover from any vaccine-related emergencies.</li> <li>Store the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units.</li> </ul> <p><b>For practices using mobile units to administer VFC-supplied vaccines:</b> Mobile-only clinics or clinics with mobile units must maintain a current and complete Mobile Unit Vaccine Management Plan and keep it in the mobile unit.</p>	All elements are applicable for every location.	<p><a href="#">Vaccine Management Plan (Word)</a></p> <p><a href="#">Mobile Unit Vaccine Management Plan (Word)</a></p> <p>Provider Operations Manual, Chapter 3</p>
<b>Vaccine Storage Units</b>	Participating provider locations agree to store all VFC-supplied vaccines in vaccine refrigerators and freezers that meet California VFC Program requirements. Adherence to storage and handling requirements is certified as part of annual provider recertification	All elements are applicable for every location but with modifications.	<a href="#">EZIZ Vaccine Storage Units</a>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
	<p>and during both routine and unannounced site visits conducted by VFC Field Representatives.</p> <ul style="list-style-type: none"> <li>• Use only refrigerators and freezers that comply with VFC vaccine storage unit requirements: Very high-volume provider locations must use purpose-built (pharmacy-, biologic-, or laboratory-grade) refrigerators. Other provider locations may use refrigerators and freezers that are purpose-built (preferred) or commercial-grade (acceptable). Household-grade, stand-alone refrigerators are discouraged. Purpose-built combination units, including auto-dispensing doorless units, are allowed.</li> <li>• Manual-defrost freezers are allowed for use if the practice has access to an alternate storage unit when defrosting the freezer. <b>Note:</b> Defrost manual-defrost freezers only when frost exceeds 1cm or the manufacturer's suggested limit). The alternate storage unit must have appropriate freezer temperatures and be monitored using a <a href="#">VFC-compliant digital data logger</a>. Never store VFC-supplied vaccines in a cooler.</li> <li>• Never use any of the following for routine 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, or any vaccine transport unit (including coolers and battery-operated units).</li> <li>• Purchase new refrigerators (purpose-built) or freezers (any grade) if existing storage units malfunction frequently or experience frequent temperature excursions.</li> </ul> <p><b>For provider locations designated solely as mass vaccinators:</b> Only use purpose-built vaccine transport units for transport and on-site storage.</p>	Freezers are not required for birthing hospitals.	Provider Operations Manual, Chapter 3

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
<b>Vaccine Storage Unit Configuration</b>	<p>Prepare vaccine refrigerators and vaccine freezers following VFC Program requirements.</p> <ul style="list-style-type: none"> <li>Place water bottles (in refrigerators) and ice packs (in freezers only) to stabilize temperatures. (Exception for purpose-built, auto-dispensing doorless units.)</li> <li>Place data logger buffered probes in the center of refrigerators and freezers near vaccines. (Exception for purpose-built, auto-dispensing doorless units.)</li> <li>Place data logger digital displays outside of the storage units to allow temperature monitoring without opening the vaccine storage unit door. (Exception for purpose-built, auto-dispensing doorless units.)</li> <li>Plug the refrigerator and freezer directly into nearby, dedicated wall outlets that do not have built-in GFI circuit switches and are not controlled by light switches; never plug storage units into extension cords, power strips, or surge protectors with an on/off switch.</li> <li>Post “Do Not Unplug” signs on electrical outlets and circuit breakers to prevent interruption of power.</li> <li>Storage units that hold VFC vaccine inventory must be plugged into red emergency backup power outlets at all times (this includes storage unit in patient care areas where VFC vaccines may be stored).</li> </ul> <p>Set up vaccine refrigerators and vaccine freezers following VFC Program requirements.</p> <ul style="list-style-type: none"> <li>Group vaccines by pediatric, adolescent, and adult types.</li> <li>Allocate enough space to position vaccines or baskets 2-3 inches away from walls, floor, and other baskets to allow space for air circulation. (Exception for purpose-built, auto-dispensing doorless units.)</li> <li>Post VFC temperature logs on vaccine storage unit doors or in an easily accessible location.</li> </ul>	<p>All elements are applicable for every location but with modifications.</p> <p>Privately purchased and VFC-supplied vaccine are comingled.</p>	<p><a href="#">Preparing Vaccine Storage Units (PDF)</a></p> <p><a href="#">Setting Up Vaccine Storage Units (PDF)</a></p> <p><a href="#">Do Not Unplug Sign (PDF)</a></p> <p>Provider Operations Manual, Chapter 3</p>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
<b>Digital Data Loggers (DDLs)</b>	<p>All staff, including supervisors and new employees, must be properly trained on temperature monitoring including proper use of the practice's digital data loggers and the required corrective action for out-of-range temperatures.</p> <ul style="list-style-type: none"> <li>• Equip all refrigerators and freezers (primary, backup, overflow, or any other temporary unit) storing VFC-supplied vaccines with VFC-compliant digital data loggers. (For purpose-built, auto-dispensing doorless units: built-in, internal data loggers must meet VFC Program requirements except for buffered probes, which are NOT required.)</li> <li>• Only use data loggers that include the following minimum features: a digital display of current, minimum, and maximum temperatures; minimum accuracy of <math>\pm 1.0^{\circ}\text{F}</math> (<math>0.5^{\circ}\text{C}</math>); a buffered temperature probe (only use the probe 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 audible or visual out-of-range temperature alarm; logging interval of 30 minutes; a low-battery indicator; and memory storage of 4,000 readings or more. A battery source is required for backup devices used during vaccine transport.</li> <li>• Digital data loggers, including backup digital data loggers, must be able to generate a summary report of recorded temperature data since the device was last reset; summary reports must include minimum and maximum temperatures, total time out of range (if any), and alarm settings. Devices that only generate CSV data files or Excel spreadsheets are not acceptable.</li> <li>• Keep on hand at least one backup, battery-operated, DDL for emergency vaccine transport. Depending on the size of the practice, additional devices might be needed.</li> </ul>	All elements are applicable for every location.	<p><a href="#">EZIZ Digital Data Loggers</a></p> <p><a href="#">Digital Data Logger Pre-Purchase Worksheet (PDF)</a></p> <p>Provider Operations Manual, Chapter 3</p>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
	<ul style="list-style-type: none"> <li>Digital data loggers must have a current and valid Certificate of Calibration, including backup digital data loggers.</li> </ul>		
<b>Digital Data Logger Configuration &amp; Maintenance</b>	<p>Digital data loggers must be configured to meet VFC Program requirements.</p> <ul style="list-style-type: none"> <li>Configure key settings for primary and backup digital data loggers, including device name, low and high temperature alarm limits, immediate notification of out-of-range temperatures, and a maximum logging interval of 30-minutes.</li> <li>Store the backup digital data logger's buffered probe in the vaccine refrigerator and its digital display in a cabinet; document the device's location on the practice's vaccine management plan. (Exception for purpose-built, auto-dispensing doorless units: store the entire device in a cabinet.)</li> <li>Calibrate primary and backup devices every two to three years or according to the manufacturer's suggested timeline (both device and probe together) ideally by a laboratory with accreditation from an ILAC MRA signatory body.</li> <li>Certificates issued by non-accredited laboratories must meet all VFC Program requirements for certificates of calibration.</li> <li>Calibrate primary and backup devices on different schedules to ensure all refrigerators and freezers storing VFC-supplied vaccines are equipped with data loggers at all times.</li> <li>Keep certificates of calibration on file and make them available to the VFC Program upon request.</li> <li>Purchase a new data logger if existing device or probe malfunctions, is damaged, or if device provides repeated, inaccurate temperature readings. (Exception for replacement probes recommended and replaced by the device manufacturer).</li> </ul>	All elements are applicable for every location.	<p><a href="#">EZIZ Data Logger Calibration Testing</a></p> <p><a href="#">Data Logger Setup &amp; Use (PDF)</a></p> <p><a href="#">Certificate of Calibration Quick Guide (PDF)</a></p> <p>Provider Operations Manual, Chapter 3</p>

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	<ul style="list-style-type: none"> <li>• <b>Note:</b></li> <li>• If the manufacturer supplies a pre-calibrated replacement probe upon device calibration expiration, the device and probe do not need to be calibrated together.</li> <li>• New devices that only generate CSV data files or Excel spreadsheets are not acceptable. If your current device only generates CSV data files or Excel spreadsheets, it must be replaced with a digital data logger that meets current VFC Program requirements.</li> <li>• Practices are required to keep on hand at least one backup, battery-operated digital data logger for use during recalibration, when the primary device breaks, when the primary device does not meet calibration requirements, or during emergency vaccine transport.</li> </ul>		
<b>Vaccine Orders</b>	<p>Trained and authorized staff must submit vaccine order requests at myCAVax following VFC Program requirements.</p> <ul style="list-style-type: none"> <li>• Order all ACIP-recommended vaccines (including flu and special-order vaccines) to meet the needs of the total VFC-eligible patient population reported for the provider PIN (replaces VFC PIN - see your myCAVax provider profile).</li> <li>• Order only one brand and formulation for each vaccine to avoid administration errors; changes to brand preference must be submitted using the change request form and approved.</li> <li>• Order all vaccine doses in sufficient quantities to last until the next order period; order quantities must factor in doses administered (since the previous order) and doses on hand (at the time of the order).</li> <li>• Order vaccines according to the location's assigned <i>order frequency</i> (see your myCAVax program location profile) or as guided by the VFC Program; provider locations who have not ordered and administered all ACIP-recommended vaccines for their patient population in the past 12 months will be terminated from the VFC Program.</li> </ul>	<p>All elements are applicable for every location, but with modifications.</p> <p>Organizations with multiple enrolled locations are strongly encouraged to designate key regional contacts to be responsible for training designees at the individual location to complete and submit replacement requests.</p> <p>Facilities purchase an initial vaccine inventory supply for all children with privately purchased vaccine and</p>	<p><a href="#">Vaccine Ordering Worksheet (PDF)</a></p> <p><a href="#">Vaccine Brand Change Request Forms (PDF)</a></p> <p>Provider Operations Manual, Chapter 4</p>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
	<p>Vaccines ordered solely to prevent account termination and are lost due to expiry will be considered a negligent loss. <b>Note:</b> Newly enrolled providers must order within 3 months to maintain their active enrollment in the VFC Program.</p> <ul style="list-style-type: none"> <li>• Order vaccines using the approved practice address for the provider PIN.</li> <li>• Account for every dose of VFC-supplied vaccine ordered and received by the provider location.</li> <li>• Report all vaccine doses administered (since the previous order) and doses on hand (at the time of the order) on each vaccine order; doses administered must be based on registry/EMR administration summary reports.</li> <li>• Smaller practices may use daily usage logs to track doses administered for VFC and private doses then report doses to the registry.</li> <li>• Maintain accurate and separate stock records (e.g., purchase invoices, receiving packing slips) for privately purchased vaccines and make them available to the VFC Program upon request.</li> </ul> <p><b>Pharmacies:</b> Order flu vaccines within 30 days of enrollment approval, then weekly or as needed. Other VFC vaccines may be ordered quarterly.</p>	<p>submit a vaccine order to replace private doses administered to VFC-eligible children over the previous month.</p> <p>Submit vaccine orders and supporting documentation of eligible patients monthly and at same time (+/- a couple of days).</p> <p>The California VFC Program will assess aggregate administration data and replace private doses used on VFC-eligible patients.</p> <p>Facilities must report a calculated virtual inventory of public doses on hand on each vaccine order by applying the percentage of location's VFC-eligible population to current inventory.</p> <p>With replacement model, only doses</p>	



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		used are replaced – not wasted doses. Facilities may not request replacement doses for wasted doses of private vaccine.	
<b>Vaccine Accountability</b>	<p>Account for every dose of VFC-supplied vaccine ordered and received by the provider location.</p> <ul style="list-style-type: none"> <li>Report all vaccine doses administered (since the previous order) and doses on hand (at the time of the order) on each vaccine order; doses administered must be based on registry/EMR administration summary reports.</li> <li>Smaller practices may use daily usage logs to track doses administered for VFC and private doses then report doses to the registry.</li> <li>Maintain accurate and separate stock records (e.g., purchase invoices, receiving packing slips) for privately purchased vaccines and make them available to the VFC Program upon request.</li> </ul>	All elements are applicable for every location.	None
<b>Receiving &amp; Inspecting Vaccine Deliveries</b>	<p>Follow VFC Program requirements:</p> <ul style="list-style-type: none"> <li>Never reject vaccine shipments.</li> <li>Receive, inspect, and store vaccines and diluents within manufacturer-recommended ranges immediately upon delivery.</li> <li>Immediately report all shipment incidents at myCAvax using the vaccine receiving checklist.</li> <li>Keep packing slips for all vaccine shipments received, including publicly funded and private vaccine shipments.</li> <li>The practice must be open with staff available to receive vaccines at least one day a week (other than Monday) and for at least four consecutive hours.</li> <li>Federal vaccine may not be repackaged or redistributed to other provider locations at any time. However, it is</li> </ul>	All elements are applicable for every location.	<p><a href="#">Vaccine Receiving Checklist (PDF)</a></p> <p><a href="#">TagAlert Cooler Insert (PDF)</a></p> <p>Provider Operations Manual, Chapter 3</p>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
	acceptable to receive a vaccine shipment from the centralized distributor at a central location within the facility where the shipping boxes can be opened and vaccines within can then be delivered to individual clinics within the same building or building complex.		
<b>Vaccine Storage</b>	<p>Dedicate vaccine refrigerators and freezers to the storage of vaccines only; if storage of medications or biologics is necessary, store below vaccines on a different shelf.</p> <ul style="list-style-type: none"> <li>• Store all frozen vaccines (Merck MMR, MMRV, and Varicella) between -58.0°F and 5.0°F (-50.0°C and -15.0°C) according to manufacturer recommendations.</li> <li>• Store all other refrigerated vaccines between 36.0°F and 46.0°F (2.0°C and 8.0°C) according to manufacturer recommendations.</li> <li>• Store vaccines in original packaging and allow space for air circulation.</li> <li>• Store VFC-supplied and privately purchased vaccines separately and grouped by vaccine type.</li> <li>• Do not store vaccines in storage unit doors, drawers, or bins.</li> <li>• Place vaccines with the earliest expiration dates toward the front of the storage unit and use first.</li> <li>• Always store VFC-supplied vaccines at the approved location for the VFC PIN. (<b>For practices conducting outreach clinics:</b> Obtain VFC approval at least 4 weeks prior to the scheduled outreach clinics.)</li> </ul>	<p>All elements are applicable for every location, but with modifications.</p> <p>Note: Freezers are not required for birthing hospitals.</p> <p>Facilities maintain one vaccine inventory supply for private and public patients and inventories are comingled.</p>	Provider Operations Manual, Chapter 3
<b>Monitoring Storage Unit Temperatures</b>	<p>Monitoring storage unit temperatures consistently and accurately plays an important role in protecting the vaccines that protect your patients.</p> <ul style="list-style-type: none"> <li>• Monitor and record storage unit temperatures on the universal temperature log (PDF) (for Fahrenheit and Celsius temperature scales, all storage unit types and all funding sources). BAP providers may write in “BAP” as the</li> </ul>	<p>All elements are applicable for every location, but with modifications.</p> <p>Locations may use the editable PDF version of the <a href="#">universal</a></p>	<p><a href="#">How to Record Temperatures (PDF)</a></p> <p><a href="#">Temperature Log for Hospitals (PDF)</a></p>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
	<p>funding source on the universal temperature log or use the updated <a href="#">COVID-19 Temperature Log (PDF)</a>.</p> <ul style="list-style-type: none"> <li>Record current, minimum, and maximum temperatures twice each day: at the beginning and end of each business day on temperature logs. <b>(For VFC-approved outreach clinics:</b> Special event clinics, health fairs, special school clinics, and mass vaccination clinics must monitor and record current, minimum, and maximum temperatures on the Hourly Vaccine Temperature log for Outreach Clinics every hour. Attach the data logger download, or summary report, if available, to the VFC Refrigerated Vaccine Transport log.)</li> <li>Temperature logs must be legible and completed accurately in ink.</li> <li>Neatly cross out, correct, initial, and date any inadvertent documentation error immediately.</li> <li>Download temperature data files and review for any unreported out-of-range temperatures at the end of every two-week reporting period.</li> <li>The supervisor must review and sign the temperature logs at the end of every two-week reporting period, acknowledging that the log is complete, temperatures were recorded twice daily, staff initialed each entry, and necessary corrective actions were taken.</li> <li>Replace doses (on a dose-for-dose basis) as instructed by the VFC Program if vaccines are deemed non-viable due to storage unit temperatures not monitored or documented, if temperature logs or temperature data files are falsified, or if temperature logs or temperature data files are missing during a site visit.</li> <li>Retain temperature logs and temperature data files for three years, even after your provider location is no longer participating in the VFC Program (due to provider-initiated withdrawal or VFC-initiated termination).</li> </ul>	<a href="#">temperature log for hospitals (PDF)</a> .	<a href="#">Hourly Temperature Log for Off-Site Clinics (PDF)</a>  Provider Operations Manual, Chapter 3

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
<b>Taking Action for Temperature Excursions</b>	<p><b>Vaccine ordering and inventory management is in myCAvax!</b></p> <p>Vaccines stored out of range might be deemed non-viable and considered a negligent vaccine loss. A temperature excursion does not automatically mean that exposed vaccines are non-viable or unusable. Follow VFC Program requirements:</p> <ul style="list-style-type: none"> <li>• Take immediate action to prevent vaccine spoilage and to correct any improper storage condition for all out-of-range storage unit temperatures.</li> <li>• Staff must respond to all data logger alarms.</li> <li>• Quarantine and do not administer any vaccines exposed to out-of-range temperatures until their viability has been determined by vaccine manufacturers.</li> <li>• Report every temperature excursion at myCAvax for all funding sources and comply with any instructions provided; report for any data logger that is recording temperatures for a unit storing VFC vaccines.</li> <li>• Contact vaccine manufacturers as indicated to determine if vaccines are okay to use.</li> </ul>	All elements are applicable for every location.	<p><a href="#">How to Record Temperatures (PDF)</a></p> <p>Provider Operations Manual, Chapter 3</p>
<b>Vaccine Inventory Management</b>	<p>Vaccine inventory management is an essential practice that can prevent inadvertent vaccine loss.</p> <ul style="list-style-type: none"> <li>• Conduct a physical vaccine inventory at least monthly and before ordering vaccines. Use the Vaccine Physical Inventory Form or equivalent electronic or paper form.</li> <li>• Rotate stock and move short-dated vaccines to the front of storage unit.</li> <li>• Never borrow VFC-supplied vaccines to supplement private stock, or vice versa.</li> <li>• <b>For vaccines that will expire within 6 months and cannot be used:</b> Notify the VFC Call Center to obtain approval prior to transferring short-dated doses to another active VFC provider location to prevent negligent vaccine loss. <b>Note:</b> For low volume providers who have ordered the minimum quantity, vaccines spoiled due to expiration will not be considered a negligent loss.</li> </ul>	<p>All elements are applicable for every location, but with modifications.</p> <p>Facilities maintain one vaccine inventory supply for private and public patients. Borrowed and transferred vaccines do not apply. Locations should manage inventory to minimize expired doses. The VFC Program only</p>	<p><a href="#">How to Do a Physical Inventory (PDF)</a></p> <p><a href="#">Vaccine Inventory Forms (PDF)</a></p> <p><a href="#">Prevent Vaccine Loss flyer (PDF)</a></p> <p>Provider Operations Manual, Chapter 3</p>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
	<ul style="list-style-type: none"> <li>Remove spoiled, expired, and wasted vaccines from storage units after identification to prevent inadvertent use.</li> <li>Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements.</li> </ul>	<p>replaces doses that have been administered, so any loss due to expiration is on the private side.</p> <p>Negligent doses do not apply.</p>	
<b>Reporting Waste &amp; Returns</b>	<ul style="list-style-type: none"> <li>Report all spoiled, expired, or wasted vaccines doses of VFC-supplied vaccines at myCAVax prior to submitting a new vaccine order.</li> <li>Do not report any VFC-supplied vaccines as spoiled without guidance from vaccine manufacturers and/or the VFC Program.</li> <li>Providers may request return labels for spoiled and expired vaccines in myCAVax.</li> </ul>	<p>All elements are applicable for every location, but with modifications.</p> <p>If loss is related to spoiled or expired doses in inventory, the public portion of the inventory must be identified and the spoiled/expired doses returned to the centralized distributor.</p> <p>Facilities must report a calculated virtual inventory of public vaccine waste at myCAVax by applying the percentage of location's VFC-eligible population to total vaccine returns and then request return label.</p>	None

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
<b>Vaccine Transfers &amp; Transports</b>	<p>Vaccine transfers can be minimized by consistent inventory management, but provider locations might need to transfer vaccines to other VFC provider locations if vaccines are likely to expire before administration or in the event of an emergency. If vaccines need to be transferred, follow VFC Program Requirements.</p> <p>If necessary, 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> <ul style="list-style-type: none"> <li>• Contact the VFC Call Center prior to transferring VFC-supplied vaccines.</li> <li>• If transfers are approved, only transfer VFC-supplied vaccines to other VFC provider locations.</li> <li>• Report all vaccine transfers at myCAvax.</li> <li>• Never routinely transfer VFC-supplied vaccines to/from other VFC provider locations.</li> <li>• Transport vaccines only when necessary and follow the guidelines for proper refrigerated vaccine transport and frozen vaccine transport.</li> <li>• Complete the vaccine transport log each time vaccines are transported.</li> <li>• <b>In case of emergency:</b> Only transport VFC-supplied vaccines alternate storage locations equipped with vaccine storage units and temperature monitoring devices that meet VFC Program requirements.</li> <li>• Never transport VFC-supplied vaccines to personal residences.</li> <li>• Use backup, battery-operated, digital data loggers to monitor temperatures during vaccine transport and at VFC-approved off-site clinics—ideally using a portable vaccine refrigerator (if a portable vaccine refrigerator is not available, use qualified containers and pack-outs) for off-site clinics.</li> </ul>	<p>All elements are applicable for every location, but with modifications. Vaccine transfers are not applicable to the Replacement Model.</p> <p>All vaccine transport from any holding location or receiving pharmacy to the medical clinics must be compliant with VFC Program requirements. Doses wasted due to improper transport won't be replaced.</p>	<p><a href="#">Transporting Refrigerated Vaccine job aid (PDF)</a></p> <p><a href="#">Transporting Frozen Vaccines job aid (PDF)</a></p> <p><a href="#">Vaccine Transport Log (PDF)</a></p> <p>Provider Operations Manual, Chapter 3</p>

Requirements	Summary	Replacement Model Modifications	Resources/ Job Aids
	<ul style="list-style-type: none"> <li>Replace any vaccines that were transported without proper documentation of temperature monitoring on a dose-for-dose basis as instructed by the VFC Program.</li> </ul>		

## Other Participation Requirements

Requirement	Summary	Replacement Model Modifications	Resources/ Job Aids
<b>Program Enrollment, Recertification, Withdrawal, &amp; Termination</b>	<p>Prospective provider locations 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. Failure to recertify will lead to termination. A waiting period to request re-enrollment will apply.</p> <p>Provider locations may voluntarily withdraw from the VFC Program. The VFC Program also may terminate a VFC “Provider Agreement” and remove the provider location from the VFC Program for failure to comply with program requirements.</p> <p>In both cases, the Provider of Record must return spoiled/expired viable vaccine or transfer all unused VFC-supplied vaccines. Enrolled provider locations are responsible for all VFC-supplied vaccines in their practice until their Provider Agreement has been officially terminated.</p>	<p>All elements are applicable for every location, but with modifications.</p> <p>If loss is related to spoiled or expired doses in inventory, the public portion of the inventory must be identified and the spoiled/expired doses returned to the centralized distributor.</p> <p>Facilities must report a calculated virtual inventory of public vaccine waste at myCAvax by applying the percentage of location’s VFC-eligible population to total vaccine returns and then request a return label before accounts may be closed. Upon</p>	<p><a href="#">EZIZ VFC Recertification</a></p> <p><a href="#">Participation Withdrawal Request Form (PDF)</a></p> <p>Provider Operations Manual, Chapter 1</p>



		termination, locations are responsible for submitting final vaccine replacement requests in order to complete repayment.	
<b>Fraud &amp; Abuse</b>	<p>Provider locations agree to participate in a manner intended to avoid fraud and abuse. Fraud and/or abuse of VFC-supplied vaccines will require restitution and may lead to termination from the VFC Program.</p> <ul style="list-style-type: none"> <li>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 location but with an inadvertent cost to the VFC Program.</li> <li>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. Provider locations agree to replace all vaccines deemed non-viable due to provider negligence.</li> </ul>	<p>All elements are applicable for every location, but with modifications.</p> <p>At month end, location runs a monthly vaccine administration report; the California VFC Program will assess administration data and replace private vaccine inventory supply with VFC vaccines according to the data over the prior month. Knowingly requesting replacement doses in excess of doses used would constitute fraud.</p>	Provider Operations Manual, Chapter 5
<b>Documentation &amp; Record Retention</b>	<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>	All elements are applicable for every location.	Provider Operations Manual, Chapter 5

<b>Site Visits</b>	<p>Enrolled provider locations agree to site visits from VFC Program staff, including scheduled compliance visits, unannounced storage and handling visits, and visits for educational and programmatic support. Provider locations must immediately report changes in their practice address or account ownership, which may require additional follow-up.</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>	<p>All elements are applicable for every location, but with modifications.</p> <p>Facilities agree to an initial site visit and a follow-up visit after approval for Replacement model. Field Representatives will conduct a random review of patient charts to validate VFC eligibility was documented accurately and reported.</p>	Provider Operations Manual, Chapter 5
<b>Program Integrity</b>	<p>Clinic staff must conduct themselves in an ethical, professional, and respectful manner in all interactions with VFC Program staff.</p> <ul style="list-style-type: none"> <li>• Never destroy, alter, or falsify immunization or VFC Program-related records.</li> <li>• Make all vaccine administration records (privately and publicly funded) available to representatives from the California Department of Public Health Immunization Branch and the VFC Program.</li> <li>• Comply with all mandatory corrective actions and the timeline provided by the VFC Program. Unresolved mandatory corrective actions will result in prevention of completion of recertification process and/or placement on a conditional enrollment. Failure to complete required recertification may lead to program termination.</li> </ul>	All elements are applicable for every location.	Provider Operations Manual, Chapter 5