# 2019 Program Participation Requirements at a Glance

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Summary</th>
<th>Resources/Job Aids</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Management Plan</td>
<td>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. Review and update the plan at least annually, when VFC Program requirements change, and when staff with designated vaccine-management responsibilities change. Designate a staff member responsible for updating the practice’s management plan, and execute planned actions in emergency situations. Conduct vaccine management drills to maintain competency and readiness for emergency procedures, such as vaccine transport. Ensure staff with assigned vaccine-management responsibilities review, sign, and date the vaccine management plan annually and each time it is updated. Keep the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units.</td>
<td>EZIZ VFC Program Requirements lesson Vaccine Management Plan (IMM-1122) Provider Operations Manual (IMM-1248) Chapter 3</td>
</tr>
<tr>
<td>Key Practice Staff</td>
<td>Designate and maintain key practice staff in the practice’s profile, and report key practice staff changes immediately online on MyVFCVaccines. Changes to the Provider or Provider of Record Designee cannot be made online, and a Key Practice Staff Change Request form needs to be completed and submitted to the VFC Program. Add new key practice staff to the practice’s vaccine management plan; ensure required EZIZ lessons are taken. There are four required VFC roles: <strong>Provider of Record (POR):</strong> 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. <strong>Provider of Record Designee:</strong> 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. <strong>Vaccine Coordinator:</strong> An on-site employee who is fully trained and responsible for implementing and overseeing the provider’s vaccine management plan. <strong>Backup Vaccine Coordinator:</strong> 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. <strong>Immunization Champion (optional):</strong> A staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community.</td>
<td>Vaccine Coordinator Roles &amp; Responsibilities (IMM-968) VFC Key Practice Staff Change Request Form (IMM-1166) Provider Operations Manual (IMM-1248) Chapter One, Program Requirements</td>
</tr>
</tbody>
</table>
**2019 Program Participation Requirements at a Glance**

**Staff Training Requirements**

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.

Ensure staff are knowledgeable about and familiar with all ACIP-recommended immunizations, including schedules, indications, dosages, and new products.

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.

Required training by role:

<table>
<thead>
<tr>
<th>Legend: ✓ = Required Lesson</th>
<th>Start Date</th>
<th>Key Practice Staff</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>Vaccine Coordinator</td>
</tr>
<tr>
<td>VFC Program Requirements *</td>
<td>Recertification Launch</td>
<td>✓</td>
</tr>
<tr>
<td>Storing Vaccines*</td>
<td>Recertification Launch</td>
<td>✓</td>
</tr>
<tr>
<td>Monitoring Storage Unit Temperatures*</td>
<td>Recertification Launch</td>
<td>✓</td>
</tr>
<tr>
<td>Conducting a Vaccine Inventory*</td>
<td>Recertification Launch</td>
<td>✓</td>
</tr>
<tr>
<td>Provider Operations Manual <em>(NEW)</em></td>
<td>Recertification Launch</td>
<td>✓</td>
</tr>
<tr>
<td>Vaccine Management Plan <em>(Updated)</em></td>
<td>Recertification Launch</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Test-out option available

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**EZIZ Training Lessons**

Provider Operations Manual (IMM-1248) Chapter One, Training & Support
## 2019 Program Participation Requirements at a Glance

### Vaccine Storage Units

Participating providers agree to store all VFC-supplied vaccines in vaccine refrigerators and freezers that meet California VFC Program requirements. Adherence to storage and handing requirements is certified as part of annual provider recertification and during both routine and unannounced site visits conducted by VFC Field Representatives.

- Use only refrigerators and freezers that comply with VFC vaccine storage unit requirements: Very high-volume providers must use purpose-built (pharmacy-, biologic-, or laboratory-grade) refrigerators. Other providers may use refrigerators and freezers that are purpose-built (preferred) or commercial-grade (acceptable). Household-grade, stand-alone units are discouraged. Purpose-built combination units, including auto-dispensing units without doors, are allowed.
- Manual-defrost freezers are acceptable if the practice has access to an alternate storage unit when defrosting the freezer. The alternate storage unit must comply with VFC vaccine storage unit requirements and be monitored using a VFC-compliant Digital Data Logger (DDL). Temporary storage of VFC-supplied vaccines in a cooler is unacceptable.
- 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).
- Purchase new refrigerators (purpose-built) or freezers (any grade) if existing storage units experience frequent temperature excursions jeopardizing vaccine supply, or malfunction resulting in spoiled vaccines.

### Vaccine Storage Unit Configuration

Prepare vaccine refrigerators and vaccine freezers in compliance with VFC Program requirements.

- Place water bottles (in refrigerators) and ice packs (in freezers only) to stabilize temperatures. (Exception for purpose-built, auto-dispensing units without doors.)
- Place buffered probes in the center of the refrigerator and freezer near vaccines. (Exception for purpose-built, auto-dispensing units without doors.)
- Place the data logger’s digital display outside of the storage unit to allow temperature monitoring without opening the vaccine storage unit door. (Exception for purpose-built, auto-dispensing units without doors.)
- 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.
- Post “Do Not Unplug” signs on electrical outlets and circuit breakers to prevent interruption of power.

Set up vaccine refrigerators and vaccine freezers in compliance with VFC Program requirements.

- Clearly identify VFC-supplied and privately purchased vaccines. 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.
## 2019 Program Participation Requirements at a Glance

### Digital Data Loggers (DDLs)

**UPDATED!**

- 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 units without doors.)

- Post VFC temperature logs on vaccine storage unit doors or in an easily accessible location.

- 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.

  - 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 units with doors: built-in, internal data loggers must meet VFC Program requirements except for buffered probes, which are NOT required.)

  - Ensure each device has a valid certificate of calibration.

  - 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; 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.

  - Configure key settings for primary and backup DDLs, including device name, low and high temperature alarm limits, and a 30-minute logging interval.

  - Keep on hand at least one back (battery operated) DDL for emergency vaccine transport. Depending on the size of the practice, additional devices might be needed.

  - 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 units without door: store the entire device in a cabinet.)

  - Calibrate primary and backup devices annually (both device and probe together), or every other year when manufacturers recommend a period longer than two years—ideally by a laboratory with accreditation from an ILAC MRA signatory body. Ensure certificates issued by non-accredited laboratories are valid.

  - Keep certificates of calibration on file and make them available to the VFC Program upon request.

  - If any data logger or probe is damaged, replace the entire device.

- Never use these devices to monitor vaccine temperatures: 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.

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California Department of Public Health, Immunization Branch

IMM-1240 (12/2018)
## 2019 Program Participation Requirements at a Glance

<table>
<thead>
<tr>
<th>Vaccine Orders &amp; Accountability</th>
<th>Trained and authorized clinic staff must submit vaccine orders through the practice’s account on MyVFCvaccines.org following program requirements:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Conduct a physical vaccine inventory before ordering routine vaccines to determine doses on hand.</td>
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<tr>
<td></td>
<td>• Account for every dose of VFC-supplied vaccine ordered and received by the provider’s practice.</td>
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<td></td>
<td>• Order all routine ACIP-recommended vaccines (including flu) according to the provider population, category, order frequency, vaccine usage, and on-hand inventory.</td>
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<tr>
<td></td>
<td>• 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.</td>
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<td></td>
<td>• Stock one brand and formulation for each vaccine to avoid administration errors.</td>
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<tr>
<td></td>
<td>• 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.</td>
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<tr>
<td></td>
<td>• Report on each vaccine order the quantity of vaccines administered since the previous order and the current on-hand inventory.</td>
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<tr>
<td></td>
<td>Maintain and make available accurate and separate stock records for privately purchased vaccines.</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Receiving &amp; Inspecting Vaccine Deliveries</th>
<th>Follow VFC Program requirements:</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• Never reject vaccine shipments.</td>
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<td></td>
<td>• Receive, inspect, and store vaccines and diluents within manufacturer-recommended ranges immediately upon delivery.</td>
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<tr>
<td></td>
<td>• Inspect vaccines for out-of-range temperatures and shipping times during transport.</td>
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<tr>
<td></td>
<td>• Check package contents to ensure funding source, brands, and quantities match packing slips and approved VFC orders.</td>
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<tr>
<td></td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• Keep packing slips for all vaccine shipments received, including publicly-funded and private vaccine shipments.</td>
</tr>
<tr>
<td></td>
<td>Ensure the clinic is open with the appropriate staff available to receive vaccines at least one day each week (other than Monday) and for at least four consecutive hours.</td>
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</tbody>
</table>
2019 Program Participation Requirements at a Glance

Vaccine Storage

**UPDATED!**

Dedicate vaccine refrigerators and freezers to the storage of vaccines only; if storage of medications or biologics is necessary, store them below vaccines on a different shelf.

- Store frozen vaccines (MMR, MMRV, and VAR) between -58.0°F and 5.0°F (-50.0°C and -15.0°C) according to manufacturer recommendations.
- Store refrigerated vaccines between 36.0°F and 46.0°F (2.0°C and 8.0°C) according to manufacturer recommendations.
- Store vaccines in original packaging and in 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 storage unit doors, drawers, or bins.
- Place vaccines with the earliest expiration dates toward the front of the storage unit and use first.
- Obtain VFC approval before storing vaccines at mass vaccination and outreach clinics; always store and administer vaccine at the approved location for the VFC PIN.

For mobile units, follow all VFC Program requirements including vaccine storage, transport, and temperature monitoring. List mobile unit’s vaccine storage units in your practice’s Recertification.

Temperature Monitoring

Monitoring storage unit temperatures consistently and accurately plays an important role in protecting the vaccines that protect your patients.

- 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. For VFC-approved mass vaccination and outreach clinics, monitor and record temperatures every hour and attach the data logger download (or summary report) to the transport log.
- Ensure staff respond to all data logger alarms by reporting temperature excursions to SHOTS (Storage and Handling Triage System).
- Download and review temperature data files for out-of-range temperatures at the end of every two-week reporting period—or sooner if an excursion is identified. Look for temperature trends that might indicate storage unit performance issues.
- Acknowledge that if temperatures are not monitored and documented, if temperature logs or downloaded data files are missing or falsified, all affected vaccines will be automatically deemed non-viable and considered a negligent vaccine loss.
- Ensure VFC temperature logs are legible, completed accurately, and in ink.
- Neatly cross out, correct, initial, and date any inadvertent documentation error immediately.

EZIZ Storing Vaccines lesson
Provider Operations Manual (IMM-1248) Chapter 3, Storing Vaccines

EZIZ Monitoring Storage Unit Temperatures lesson

Refrigerators:
- Recording Refrigerator & Freezer Temperatures (IMM-1029)
- Refrigerator Temp Log Fahrenheit (IMM-1125)
- Refrigerator Temp Log Celsius (IMM-1127)

Freezers:
- Freezer Temp Log Fahrenheit (IMM-1126)
- Freezer Temp Log Celsius (IMM-1128)
## 2019 Program Participation Requirements at a Glance

### Reporting Storage & Handling Incidents (Temperature Excursions)
- 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.
  - A temperature excursion does not automatically mean that exposed vaccines are non-viable or unusable. Follow program requirements:
    - Take immediate action to prevent vaccine spoilage and to correct any improper storage condition for all out-of-range storage unit temperatures.
    - Mark as “Do Not Use” any vaccines exposed to out-of-range temperatures.
    - Download and review temperature data files for every temperature excursion.
    - Accurately document all out-of-range temperatures to SHOTS on MyVFCvaccines.org.
  - Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper refrigerated vaccine transport and frozen vaccine transport.

### Vaccine Inventory Management (Spoiled, Expired, & Wasted)
- Efforts to raise immunization levels in provider populations fall short if vaccine inventory is not managed to ensure viability. Vaccine inventory management is an essential practice that can prevent inadvertent vaccine loss.
  - Conduct a physical vaccine inventory at least monthly and before ordering vaccines. Use 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 to prevent negligent provider loss.
  - Once identified, remove spoiled, expired, and wasted vaccines from storage units to prevent inadvertent use.
  - Report all spoiled, expired, or wasted vaccines doses of VFC-supplied vaccines prior to submitting a new vaccine order.

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California Department of Public Health, Immunization Branch

IMM-1240 (12/2018)
## 2019 Program Participation Requirements at a Glance

### Vaccine Transfers & Transports

<table>
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<tr>
<th>Requirement</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements.</td>
<td>Provider Operations Manual (IMM-1248) Chapter 3, Conducting a Physical Inventory</td>
</tr>
</tbody>
</table>

Vaccine transfers can be minimized by consistent inventory management, but providers might need to transfer vaccines to other providers when vaccines will likely expire before administration or in the event of an emergency. In the event that vaccines need to be transferred follow VFC Program Requirements:

- Contact the VFC Call Center prior to transferring VFC-supplied vaccines.
- Only transfer to alternate locations that have VFC-approved vaccine storage units and digital data loggers.
- Never routinely transfer VFC-supplied vaccines to other VFC providers.
- Never transfer VFC-supplied vaccines to non-VFC providers.
- Transport vaccines only when necessary and follow the guidelines for proper refrigerated vaccine transport and frozen vaccine transport.
- Complete a VFC Refrigerated or Frozen Vaccine Transport Log each time vaccines are transported.
- Transport VFC-supplied vaccines only to facilities designated in the provider profile and never to personal residences.
- Use backup, battery-operated, digital data loggers to monitor temperatures during vaccine transport and at VFC-approved off-site clinics—ideally using portable, battery-operated or other temporary-powered coolers.
- Acknowledge that vaccines transported without proper documentation will be deemed non-viable.

Conduct regular vaccine transport drills to maintain competency and readiness for emergencies.

Providers operating mobile units must follow all VFC Program requirements related to vaccine storage, transport, and temperature monitoring while vaccines are outside of their permanent vaccine storage units.

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**Refrigerated vaccines:**
- Transporting Refrigerated Vaccine Job aid (IMM-983)
- Refrigerated Vaccine Transport Log (IMM-1132)

**Frozen vaccines:**
- Transporting Frozen Vaccines Job aid (IMM-1130)
- Frozen Vaccine Transport Log (IMM-1116)

**Vaccine Management Plan (IMM-1122)**

**Provider Operations Manual (IMM-1248) Chapter 3, Transferring Vaccines between Providers.**
### VFC Eligibility Screening & Documentation

In order for children to receive vaccines through the VFC Program, providers must screen for 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:

- 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.
- Keep all VFC eligibility records on file for three years.

### ACIP Recommendations & Standards

**UPDATED!**

The VFC Program entitles eligible children to all vaccines recommended by the Advisory Committee on Immunization 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.

Follow VFC Program requirements:

- 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.

Record information about each immunization given, including:

- 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
## 2019 Program Participation Requirements at a Glance

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<tr>
<th><strong>Vaccine Administration</strong></th>
<th><strong>Vaccine Administration Fees</strong></th>
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<tr>
<td><strong>UPDATED!</strong></td>
<td><strong>UPDATED!</strong></td>
</tr>
<tr>
<td>Administer all ACIP-recommended vaccines, including flu, in-house; do not refer patients to other facilities where they might be charged for vaccine administration.</td>
<td>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.</td>
</tr>
<tr>
<td>Ensure that VFC-eligible children have access to non-routine, ACIP-recommended vaccines when indicated or when requested.</td>
<td>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 current federal maximum regional administration charge of $26.03 per dose (not antigen) of vaccine.</td>
</tr>
<tr>
<td>Administer all VFC-supplied vaccines at the approved location for the VFC PIN; administration of doses away from the approved location (e.g. special even clinics, health fairs, special school clinics, or mass vaccination clinics) is not routinely allowed and requires prior approval from the VFC Program.</td>
<td>Waive the administration fee if the parent/guardian is unable to pay. Never bill parents who are unable to pay the waived administration fees.</td>
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<tr>
<td>Report clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS). Report vaccine administration errors (incorrect doses, wrong or expired vaccines, and wrong administration sites) to the national Vaccine Errors Reporting Program (VERP).</td>
<td>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.</td>
</tr>
<tr>
<td>Acknowledge and follow VFC Program and manufacturer guidance, including revaccinations, if non-viable vaccines have been administered to patients.</td>
<td>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.</td>
</tr>
<tr>
<td>Document all VFC vaccine doses administered using the VFC Daily Usage Log, Flu Usage Log, an immunization registry, or equivalent electronic or paper form.</td>
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# 2019 Program Participation Requirements at a Glance

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<tr>
<th>Program Enrollment, Recertification, Withdrawal, &amp; Termination</th>
<th>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. 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. 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. 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.</th>
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<tr>
<td>Fraud &amp; Abuse</td>
<td>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.</td>
</tr>
<tr>
<td><strong>Fraud</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Abuse</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Documentation &amp; Record Retention Requirements</td>
<td>Maintain all paper-based and electronic records related to the VFC Program for a minimum of three (3) years. 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. 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.</td>
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</tbody>
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### Site Visits

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.

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.

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.

**Provider Operations Manual (IMM-1248) Chapter 5, Site Visits**

### Program Integrity

Ensure that clinic staff conduct themselves in an ethical, professional, and respectful manner in all interactions with VFC Program staff.

Never destroy, alter, or falsify immunization or VFC Program-related records.

Acknowledge that providers must make all privately- and publicly-funded vaccine administration records available to representatives from the California Department of Public Health Immunization Branch and the VFC Program.

**Provider Operations Manual (IMM-1248) Chapter 5**