

Updating your CA VFC Provider Operations Manual for 2019

VFC has enhanced the Provider Operations Manual (POM) to provide additional guidance on topics in several chapters.

Instructions: Replace existing pages in your binder with the updated pages in this document. If possible, print on both sides of paper to reduce the number of pages. Because each chapter begins on page one, look to the page headers to ensure replacement pages are inserted in the correct chapters.

VFC Vaccines

Overview

The VFC Program supplies all ACIP-recommended vaccines at no cost to enrolled public and private providers who serve VFC-eligible children from birth through 18 years of age. Providers are required to offer all age-appropriate vaccines—including flu—according to patient populations served.

Available Vaccines & Schedules

Table 1 lists the [ACIP vaccine recommendations](#)¹ available through the VFC Program for children from birth through 18 years of age. For schedules, refer to ACIP's "[Birth-18 Years and 'Catch-up' Immunization Schedules](#)"² or VFC's "[Immunization Timing](#)"³ flyer. Refer to "[VFC Vaccine Fact Sheets](#)"⁴ for one-page flyers about routine schedules, minimum intervals, approved age ranges, and more for each available vaccine.

TABLE 1. ACIP-recommended vaccines for children from birth through 18 years of age

Vaccine	Description
DTaP	Diphtheria, tetanus, and pertussis
DTaP-HepB-IPV*	Diphtheria, tetanus, pertussis, hepatitis B, and polio
DTaP-IPV*	Diphtheria, tetanus, pertussis, and polio
DTaP-IPV/Hib*	Diphtheria, tetanus, pertussis, polio, and <i>Haemophilus influenzae</i> type b
HepA	Hepatitis A
HepB	Hepatitis B
Hib	<i>Haemophilus influenzae</i> type b
HPV	Human papillomavirus
Influenza	Flu
MMR	Measles, mumps, and rubella
MMRV*	Measles, mumps, rubella, and varicella
Meningococcal	MCV4 or MenACWY meningococcal conjugate MenB meningococcal serogroup B
Pneumococcal	PCV13 pneumococcal conjugate (13-valent) PPSV23 pneumococcal polysaccharide (23-valent)
IPV	Polio
RV	Rotavirus
Td	Tetanus and diphtheria
Tdap	Tetanus, diphtheria, and pertussis
VAR	Varicella (chickenpox)

* **Combination vaccines.** In order to reduce the number of shots children must receive to stay current with ACIP-recommended immunizations, manufacturers combine two or more vaccines (that are available to be administered separately) into one shot. Refer to the "[Immunization Schedule with Combination Vaccines](#)"⁵ for more details.

Understanding ACIP Vaccine Recommendations

In 2010, ACIP adopted a graded approach that classifies vaccine recommendations into two categories,⁶ both of which are covered under the Vaccines for Children Program.

Routine vaccine recommendations. This recommendation (formerly known as “universal”) applies to all persons in an *age- or risk-factor-based* group.⁷ For example, the meningococcal conjugate vaccine is routinely recommended for all preteens 11 through 12 years of age.⁸ All children in this population should be routinely vaccinated.

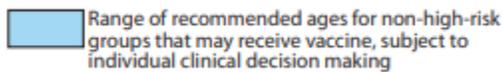
VFC providers agree to order and administer all ACIP-recommended vaccines to VFC-eligible children. Routine vaccine recommendations are identified on ACIP schedules with the following keys:



Non-routine vaccine recommendations. This recommendation (formerly known as “permissive”)⁷ does not apply to everyone but instead identifies opportunities for the clinician to discuss with the patient or parent/guardian whether a particular vaccine is appropriate based on risks, benefits, and the desire to be protected from a specific disease.⁸

For example, according to ACIP’s recommendation, people 16 through 23 years of age (preferred age of 16 through 18) “may be given” the vaccine against meningococcal serogroup B disease. MenB is classified as non-routine because there insufficient evidence to suggest that all children 16 through 18 be vaccinated, but there was enough evidence to suggest that adolescents and young adults be given the choice.⁸

VFC providers agree to ensure that VFC-eligible children have access to non-routine, ACIP-recommended vaccines when indicated or when requested by patients. Non-routine vaccine recommendations are identified on the ACIP schedules with the following key:



Introducing New Vaccines into the VFC Program

New vaccines are incorporated into the national VFC Program only after careful review and consideration by ACIP, which reviews vaccine efficacy data and considers each vaccine’s risks and benefits, the number of doses in a series, the recommended schedule, and contraindications. ACIP then votes whether or not to include each new vaccine.

VFC resolutions. ACIP’s official decision regarding the incorporation of new vaccines into the VFC Program is called a VFC resolution. VFC resolutions are available on CDC’s ["VFC-ACIP Vaccine Resolutions"](#).⁹

Vaccine distribution. Once a VFC resolution is passed, CDC begins the process of making the vaccine available through the VFC Program. CDC negotiates prices for bulk vaccine purchase at the national level, vaccine supplies are assessed, and each state is typically allocated an initial supply during the vaccine’s introductory period. Ordering guidelines are developed and Vaccine Information Statements (VISs) are produced. The entire process might take several weeks to a few months.

Provider notifications. The California VFC Program communicates all new vaccine information to enrolled providers—including the dosing schedule, administration, billing, and ordering information—through e-mailed VFC Program letters.

Best Practices. Providers are strongly encouraged to discuss with staff all new products—including formulations, schedules, vaccine administration, and storage—prior to ordering the product and especially before using it on patients.

Vaccine Availability

California offers a choice of vaccine brands and presentations (e.g., single-dose vials or manufacturer-filled, single-dose syringes)—except for influenza vaccine. Availability might vary due to supply issues and timing of the introduction of new vaccines. The most current list of vaccines and formulations are listed on the [MyVFCvaccines.org](https://www.myvfcvaccines.org) online order form. Vaccine status updates are posted on [EZIZ.org](https://www.eziz.org).

Special Note: Influenza Vaccine

The VFC Program requires providers to provide pediatric influenza vaccines to their VFC-eligible patients during influenza season. Providers are responsible for formulating a vaccination plan to ensure children in their practice or clinic are protected.

VFC providers do not have a choice of influenza vaccine brands and packaging. Instead, the VFC Program, in coordination with CDC, selects influenza products and formulations to meet the needs of VFC providers for each flu season. The VFC Program will issue special instructions regarding availability, brands, and ordering of influenza vaccines in advance of each flu season. VFC's "[Pediatric/Adult Influenza Vaccine](#)"¹⁰ provides guidance on schedules and available brands and presentations. (Refer to "[Ordering Flu Vaccines.](#)")

The California Mercury-Free Vaccines Act

The [California Mercury-Free Vaccines Act of 2004, Chapter 837, Statutes of 2004 \(AB 2943, Pavley\)](#)¹¹ prohibits administration of mercury-containing vaccines to pregnant women, or children younger than three years of age. Thimerosal, a chemical used to prevent contamination of multi-dose vials of vaccines, contains trace amounts of mercury. All routine childhood vaccines, including VFC-supplied vaccines, are available in formulations that meet the Mercury Free Act. All multi-dose vials of influenza vaccine currently exceed the legal limit of mercury content and should not be used in these groups. VFC's preservative-free influenza vaccine formulations should be used for administration to VFC-eligible children younger than 3 years of age and pregnant teens younger than 19 years of age. Refer to "[Thimerosal](#)"¹² or "[Thimerosal and Vaccines](#)"¹³ for more information.

Temporary exemptions. California Health and Safety Code Section 124172 subdivision (c) permits the Secretary of the Health and Human Services Agency to temporarily exempt the use of a vaccine from section 124172 under certain circumstances, such as severe delays or shortages of thimerosal-free influenza vaccines. In such events, CDPH will communicate with providers.

Notes

1. "ACIP Vaccine Recommendations," Centers for Disease Control and Prevention, <http://www.cdc.gov/vaccines/hcp/acip-recs/>.
2. "Birth-18 & 'Catch-up' Immunization Schedules," Centers for Disease Control and Prevention, <http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html>.
3. "Immunization Timing" can be found by searching for "IMM-395" on <http://EZIZ.org>.
4. "VFC Vaccine Fact Sheets" can be found by searching for "vaccine fact sheets" at <http://EZIZ.org>.
5. "Immunization Schedule with Combination Vaccines" can be found by searching for "IMM-922" at <http://EZIZ.org>.
6. "New Framework (GRADE) for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices," Centers for Disease Control and Prevention, <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6118a3.htm>.
7. "Understanding the Category B Recommendation for Serogroup B Meningococcal Vaccine," American Academy of Pediatrics, <http://pediatrics.aappublications.org/content/pediatrics/139/5/e20163484.full.pdf>.
8. "Meningococcal B Vaccine: CDC Answers Your Questions," Immunization Action Coalition, <http://www.immunize.org/catg.d/p2040.pdf>.
9. "VFC-ACIP Vaccine Resolutions," Centers for Disease Control and Prevention, <http://www.cdc.gov/vaccines/programs/vfc/providers/resolutions.html>.
10. "Pediatric/Adult Influenza Vaccine" can be found by searching for "IMM-859" at <http://EZIZ.org>.
11. "H.R.4169 - Mercury-Free Vaccines Act of 2004", Congress.gov website, <https://www.congress.gov/bill/108th-congress/house-bill/4169>.
12. "Thimerosal," Immunization Action Coalition, <http://www.immunize.org/thimerosal/>.
13. "Thimerosal and Vaccines", Food and Drug Administration, <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm#t1>.

Additional resources:

- "Protect Your Little Ones with Immunizations" brochure for parents can be found by searching for "IMM-234" on <http://EZIZ.org>.
- "Vaccine Acronyms & Abbreviations for Providers" can be found by searching for "IMM-895" at <http://EZIZ.org>.

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Program Requirements

Overview

In exchange for federally funded vaccines, enrolled providers agree to partner with the VFC Program to ensure that federal and state requirements are met in order to protect the integrity of the program as well as the provider's vaccines and patients. Take the EZIZ training "[VFC Program Requirements](#)" [lesson](#)¹ for an overview of the program.

Program Requirements

VFC Program requirements, which are explained throughout this manual, are summarized in "[Program Participation Requirements at a Glance](#)"² and defined in the

- VFC "[Provider Agreement](#)"³ (federal agreement) and
- California VFC Program "[Provider Agreement Addendum](#)."⁴

Table 2 highlights key compliance areas covered by these requirements documents.

TABLE 2. General description of provider requirements

Requirement	General Description
Provider profile	Estimate populations served annually (VFC and private)
Eligibility screening & documentation	Conduct patient eligibility screening and documentation at every immunization visit
ACIP-recommended vaccines	Comply with ACIP recommendations and offer age-appropriate vaccinations according to population served
Record retention	Maintain all VFC-related documentation for three years
No-cost vaccines	Immunize all VFC-eligible children at no charge to the patient
Vaccine administration fee	Follow VFC requirements for administration fee caps or reimbursement rates; don't deny vaccines due to inability to pay
VISs	Distribute current Vaccine Information Statements before administering vaccines
Vaccine management	Store, manage, order, transfer, and return vaccines according to the California VFC Program " Provider Agreement Addendum ;" ⁴ complete VFC " Vaccine Management Plan " Word template ⁵
Fraud & abuse	Follow VFC Program requirements in a manner to avoid fraud & abuse
Site visits	Agree to scheduled compliance and unannounced storage & handling visits, and make changes per VFC findings
Accountability	Track and document vaccine usage; replace VFC vaccines deemed non-viable due to provider negligence on a dose-for-dose basis.
Recertification	Reaffirm annually that VFC Program requirements will be met, key practice information is up to date, and patient estimates are provided. Failure to recertify might result in temporary suspension of provider account and termination of agreement.

Reviewing Immunization Records

Overview

Providers must use screening results to ensure that only VFC-eligible children receive VFC vaccines. To comply with VFC Program requirements and avoid missed immunization opportunities, providers must review immunization records at each immunization visit and ensure all VFC-eligible children receive all age-appropriate, ACIP-recommended immunizations. Ensuring that accurate immunization records are assessed is one essential strategy for raising immunization levels among the provider's patients. Immunization registries are excellent tools to assess immunization status and history.

Target Audience

Typically licensed providers, nurse practitioners, and other similar roles; Immunization Champion

Program Requirements

Providers have agreed to comply with the following VFC Program requirements:

- Screen patients and document eligibility status at each immunization visit for VFC eligibility and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the VFC eligibility criteria (VFC "Provider Agreement" #2).
- For the vaccines identified and agreed upon in the provider's VFC Provider Profile, comply with immunization schedules, dosages and contraindications that are established by ACIP and included in the VFC program (P.A. #3).
- Discretion may be exercised 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, or if the particular requirements contradict state law, including laws pertaining to religious and other exemptions (P.A. #3).
- Never deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record is unable to pay the administration fee (P.A. #7).

Best Practices

- Consider using the AAP "[Refusal to Vaccinate](#)" form¹ (or equivalent) to document provider's efforts to vaccinate despite patient/parent refusal.
- Consider using an immunization information system. They are directly related to increasing and maintaining vaccination rates² and result in cost savings to practices performing administrative tasks.³
- Strongly recommend to parents all vaccines currently due. According to CDC, "Parents of pediatric patients are likely to follow vaccine recommendations of the child's doctor, and even adults who were initially reluctant were likely to receive an influenza vaccination when the health-care provider's opinion of the vaccine was positive."²
- For multi-dose series, encourage the parent/guardian or patient to make a follow-up appointment for the next dose before leaving.
- Ensure staff are familiar with ACIP recommendations; print and display immunization schedules for staff and parents. Consider these CDC best practices:
 - ✓ Reinforce the need to return for future doses.²
 - ✓ Recommend that families leave with the next appointment booked.²
 - ✓ Issue reminder calls that vaccines are soon due.²

Procedure

Incorporate these instructions into existing practice protocols to review immunization histories in compliance with VFC Program requirements and best practices for children who present for vaccination.

TABLE 5. Instructions for reviewing immunization records

Step	Description
1.	Review the child’s permanent immunization record (electronic or paper) at every immunization visit for VFC-eligible children. <i>No access to an immunization registry or EHR/EMR?</i> Consider using CDPH " Immunization Record and History " form. ⁴
2.	Determine which vaccines are recommended by comparing the child’s immunization record to ACIP’s " Birth-18 Years Recommended Immunization Schedule ". ⁵ A. Review the ACIP " Catch-up Immunization Schedule " ⁶ if the child is not up to date.
3.	Recommend all ACIP-recommended, age-appropriate vaccines (unless provider feels vaccinations are medically inappropriate in accordance with accepted medical practice or as exempted by state law). A. Request that the parent complete the AAP " Refusal to Vaccinate " form ¹ (or equivalent) if appropriate.
4.	Ensure that VFC-eligible children have access to non-routine, ACIP-recommended vaccines when indicated or when requested. A. Answer any questions to help the patient or parent/guardian determine whether a non-routine vaccine is appropriate based on risks, benefits, and the desire to be protected from a specific disease.
5.	Reinforce the need to leave with the next immunization visit scheduled. A. Use written and verbal reinforcements, and tie the visit to some calendar event (e.g., the child’s next birthday or some holiday).
6.	Document a written medical order (electronic or paper) in the child’s permanent medical record for the vaccinator. A. Indicate whether vaccines are to be administered from private or VFC stock.

Notes

1. “Refusal to Vaccinate” form, American Academy of Pediatrics, https://www.aap.org/en-us/Documents/immunization_refusaltovaccinate.pdf.
2. Centers for Disease Control and Prevention; “Immunization Strategies for Healthcare Practices and Providers” (also known as the Pink Book), chap. 3 in *Epidemiology and Prevention of Vaccine-Preventable Diseases*; Edited by Jennifer Hamborsky, Andrew Kroger, and Charles (Skip) Wolfe; 13th edition (Washington, D.C. Public Health Foundation, 2015); chapter 3.
3. “Cost savings associated with using immunization information systems for Vaccines for Children administrative tasks,” National Center for Biotechnology Information, <http://www.ncbi.nlm.nih.gov/pubmed/17984708>.
4. CDPH “Immunization Record and History” form can be found by searching for “IMM-542P” at <http://EZIZ.org>.

5. “Birth-18 Years Recommended Immunization Schedule,” Centers for Disease Control and Prevention, <http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>.
6. “Catch-up Immunization Schedule,” Centers for Disease Control and Prevention, <http://www.cdc.gov/vaccines/schedules/hcp/imz/catchup.html>.

Additional resources:

- “Information for Healthcare Professionals about the Screening Checklist for Contraindications (Children and Teens),” Immunization Action Coalition, <http://immunize.org/catg.d/p4060.pdf>.
- “Immunization Timing” schedule can be found by searching for “IMM-395” at <http://EZIZ.org>.
- “Vaccine-specific ACIP Best Practices,” Centers for Disease Control and Prevention, <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

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Administering Vaccines

Overview

Providers must ensure eligibility status is clearly identified for staff administering vaccines. Administering vaccines is more than simply the injection. It's a process that includes selecting the prescribed vaccines from the correct funding source based on the written order, preparing the vaccines, verifying the correct dose and vaccine for age, giving them to or injecting them into the patient, and documenting the doses administered in the child's permanent medical record.

Target Audience

Typically clinical staff; Immunization Champion

Program Requirements

Providers have agreed to comply with the following VFC Program requirements:

- I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories: Are an American Indian or Alaska Native; Are enrolled in Medicaid; Have no health insurance; Are underinsured (VFC "Provider Agreement" #2).
- Providers must maintain all records related to the VFC Program (including medical records that verify receipt of vaccine) for a minimum of three years and upon request make these records available for review (P.A. #4).
- Distribute the current Vaccine Information Statements (VIS) each time a vaccine is administered and 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) (P.A. #8).
- Administer all ACIP-recommended vaccines (including flu) in-house; do not refer patients to other facilities where they might be charged for vaccine administration (California VFC Program "Provider Agreement Addendum" #14A).
- Ensure that VFC-eligible children have access to non-routine, ACIP-recommended vaccines when indicated or when requested (P.A.A. #14B).
- Administer all VFC-supplied vaccines at the approved location for the VFC PIN; administration of doses outside the approved location (e.g., special event clinics, health fairs, special school clinics, or mass vaccination clinics) is not routinely allowed and requires prior approval from the VFC Program (P.A.A. #14C).
- Acknowledge and follow VFC Program and manufacturer guidance, including revaccination, if non-viable vaccines have been administered to patients (P.A.A. #14D).
- Document all VFC vaccine doses administered using the VFC "Daily Usage Log" (IMM-1053), "Flu Usage Log" (IMM-1053F), an immunization registry, or equivalent electronic or paper form (P.A.A. #14E).

Best Practices

- Ensure vaccinators are properly trained on preparing and administering vaccines to children in the correct anatomic site according to practice protocol.
- Use an immunization information system such as EMR/EHR system (or immunization registry) that supports VFC Program documentation requirements to keep track of doses administered (private and publicly funded).

Documentation for Minors Unaccompanied by Parent or Guardian

Family planning and STD clinics confidentially administering VFC-supplied vaccines to unaccompanied minors must document vaccine administration in the patient's confidential medical record and on a VFC-supplied administration log. Due to the confidential nature of services provided, vaccine administration information cannot be entered into an immunization registry; so, alternative documentation must be kept.

Billing Practices

Staff must accurately bill based on the eligibility categories as listed in table 8.

TABLE 8. Billing by VFC eligibility criteria

Criterion	Description
Medicaid eligible (or enrolled)	Cost of Vaccine: Do not bill - provided by VFC Admin Fee: Bill Medi-Cal—not the patient. The difference between Medi-Cal’s administration fee and the regional fee cannot be billed to patient. For pharmacies, administration fees must be waived because Medi-Cal does not reimburse for pharmacies.
American Indian (AI) or Alaskan Native (AN)	Cost of Vaccine: Do not bill - provided by VFC Admin Fee: If billing, bill the patient up to but not exceeding the current maximum regional charge set for California by CMS. However, this fee must be waived if the parent or guardian is unable to pay the fee.
Uninsured	Cost of Vaccine: Do not bill - provided by VFC Admin Fee: If billing, bill the patient up to but not exceeding the current maximum regional charge set for California by CMS. However, this fee must be waived if the parent or guardian is unable to pay the fee. Never bill parents who are unable to pay the waived administration fees.
Underinsured	Cost of Vaccine: Do not bill - provided by VFC through FQHCs or RHCs ONLY Admin Fee: Medicaid-eligible? Bill Medi-Cal; Private insurance? Bill patient/insurance for cost of covered vaccine; otherwise, bill the patient up to but not exceeding the current maximum regional charge set for California by CMS; waive the fee if the parent/guardian is unable to pay the fee.

Vaccine Administration Fees

The provider’s vaccine administration fee for non-Medi-Cal, VFC-eligible children must not exceed the state/territory vaccine administration fee cap established by the Centers for Medicare and Medicaid (CMS). For current fee caps, refer to <http://www.gpo.gov/fdsys/pkg/FR-2012-11-06/pdf/2012-26507.pdf>.¹

Providers will no longer be able to bill for the administration fee after the date of service.

The provider must waive the administration fee if the patient or parent is unable to pay the fee when the service is received, and the provider cannot bill the patient/parent for any waived administration fees at a later time. Unpaid administration fees may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.

Providers may still continue to bill for office visits as allowed under VFC policy, and unpaid bills related to office visit fees or other fees (e.g., labs) may be sent to collections.

Other Fees In addition to vaccine administration fees, providers may charge other visit-related fees such as office visit fees. These fees should be clearly identified in the bill and thoroughly explained to prevent any confusion, misunderstandings, or allegations of abuse of publicly purchased vaccines.

Fees for Combination Vaccines A combination vaccine, even if it contains several antigens, is considered one vaccine dose. The regional vaccine administration fee cap rates are established on a per-vaccine basis—not a per-antigen or per-component basis.

Billing with Medi-Cal as Secondary Insurance Insured children with Medi-Cal as a secondary insurance are VFC-eligible as long as they are enrolled in the state’s Medi-Cal program. Billing might be done in either of two ways, as instructed by the provider or supervisor:

1. ***If vaccine was administered from private stock.*** Bill the patient’s primary insurance for vaccine cost and administration. If the carrier denies payment, the provider may bill Medi-Cal for the administration fee and contact the VFC Call Center to request approval to replace private doses used with VFC-supplied vaccines. A copy of the carrier’s denial must be submitted with the request.
2. ***If vaccine was administered from VFC doses.*** Bill Medi-Cal for the vaccine administration fee. There is no out-of-pocket expense for the parent or guardian with this option.

Important. Providers are encouraged to choose from the vaccine inventory that is most cost-effective for the family and train their staff accordingly.

Questions? For questions about billing for vaccine administration, contact Med-Cal directly.

Notes 1. “Federal Register,” Centers for Medicare and Medicaid Services, <http://www.gpo.gov/fdsys/pkg/FR-2012-11-06/pdf/2012-26507.pdf>.

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Vaccine Storage Unit Specifications

Overview	Vaccine storage units act as an insurance policy to protect patients from administration of damaged vaccines and protect practices and clinics from costly vaccine replacement due to negligent loss. Because providers might maintain an average vaccine inventory ranging from tens of thousands to more than \$500,000 over the course of a year, investing in reliable storage units that meet VFC Program requirements will likely cost less than replacing spoiled vaccines.
Target Audience	Provider of Record and Designee, Vaccine Coordinator & Backup
Program Requirements	<ul style="list-style-type: none"> • Providers have agreed to comply with the following VFC Program requirements: • Never store vaccines in dormitory-style units at any time (VFC “Provider Agreement” #9B). • Use only refrigerators or 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 (California VFC Program “Provider Agreement Addendum” #3A). • Acknowledge that 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. Temporary storage of VFC-supplied vaccines in a cooler is unacceptable (P.A.A. #3B). • 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 combination refrigerator/freezers; manual-defrost refrigerators; convertible units; cryogenic (ultra-low) freezers; or any vaccine transport unit for routine storage (including coolers and battery-operated units) (P.A.A. #3C). • Purchase new refrigerators (purpose-built) or freezers (any grade) if existing storage units experience frequent temperature excursions jeopardizing vaccines, or malfunctioned resulting in spoiled vaccines (P.A.A. #3D).
Best Practices	<ul style="list-style-type: none"> • Use pharmacy-grade units for vaccine storage; they are purpose-built for the storage of biologics and maintain stable temperatures. • Providers using pharmaceutical-grade vaccine storage units should consider purchasing a generator to compensate for electrical-grid insufficiencies as their interior temperatures rise more quickly during outages.
Purchasing New Storage Units	<p>Providers must purchase a new vaccine refrigerator or freezer if</p> <ul style="list-style-type: none"> • vaccine storage units do not meet VFC Program specifications, or • the practice has had storage incidents resulting in spoiled vaccines. <p>Refurbished units. Purchasing refurbished storage units or those outside the warranty is discouraged. These units might not be able to maintain stable temperatures if not properly conditioned, which puts vaccines at risk.</p>

Key Terms

Refrigerators and freezers are available in different types (stand-alone and combination) and grades (pharmaceutical, commercial, and household).

Stand-alone. These types are self-contained units designed as either refrigerator-only or freezer-only and range in size from compact to very large pharmaceutical-grade units.



FIGURE 3.3. Stand-alone refrigerators.



FIGURE 3.4. Stand-alone upright and chest freezers.

Combination. These types typically have a refrigerator and freezer with separate exterior doors, though Figure 3.6 depicts a combination unit without doors.



FIGURE 3.5. Combination purpose-built storage unit.



FIGURE 3.6. Purpose-built, pharmaceutical-grade, auto-dispensing unit without doors.

Purpose-built. These storage units are specifically designed to maintain consistent temperatures for storage of fragile vaccines or biologics. They are available as pharmacy-, biologic-, and laboratory-grades. (See Figure 3.6.)

Commercial. These grades are intended to store food and beverages in commercial settings. They are often larger and more powerful than household units but are not designed to store biologics. They experience some temperature fluctuations.

Household. These grades are intended for food storage—typically in homes and offices.

Vaccine Refrigerator Specifications

Providers have agreed to comply with VFC Program vaccine refrigerator specifications. Vaccine refrigerators must meet these requirements:

- Maintain temperatures between 36.0°F and 46.0°F (between 2.0°C and 8.0°C);
- Have enough space to store all the practice’s refrigerated vaccine inventory throughout the year—including during flu and back-to-school seasons;
- Have enough space to store water bottles to stabilize temperatures;
- Defrost automatically;
- Seal tightly and close properly;
- Be used primarily for vaccine storage. If necessary, medications or biologics (not inoculated) may be stored on the shelves below vaccines.

Vaccine Freezer Specifications

Providers have agreed to comply with VFC Program vaccine freezer specifications. Vaccine freezers must meet these requirements:

- Maintain consistent temperatures between -58.0°F and +5.0°F (between -50.0°C and -15.0°C);
- Be a stand-alone unit;
- Have enough space to store all the practice’s frozen vaccines along with sufficient frozen cold packs to stabilize temperatures;
- Defrost automatically (manual is acceptable if the practice has access to an alternate storage unit when defrosting the freezer; the alternate storage unit must be able to maintain recommended temperatures and be monitored using a VFC-compliant data logger; temporary storage of vaccines in a cooler is unacceptable);
- Seal tightly and close properly;
- Be used only for vaccine storage.

Acceptable Vaccine Storage Units

Refrigerators. Not all refrigerators are designed to maintain proper temperatures that protect vaccine viability. When evaluating existing or shopping for new vaccine refrigerators, refer to table 2 to determine required grade and type by practice volume.

TABLE 2. Vaccine refrigerators by practice volume

Grade (Type) Rating	Description	Practice Volume
Pharmacy-, biologic-, or laboratory-grade (any) <i>Best</i>	Purpose-built to maintain consistent temperatures for storage of fragile vaccines or biologics. Come in stand-alone and combination units.	Very high (required) Others: preferred
Compact pharmacy-, biologic-, or laboratory-grade (stand-alone) <i>Best</i>	Purpose-built, under-the-counter storage units suitable for smaller practices with limited space.	Low, Medium, High
Commercial units (stand-alone) <i>Good</i>	Intended to store food and beverages in commercial settings. They are often larger and more powerful than household units but are not designed to store biologics and might experience temperature fluctuations.	Low, Medium, High
Household (stand-alone) <i>Discouraged</i>	Intended for use in homes and offices—typically for food storage. Like commercial units, they are not designed to store biologics and experience frequent temperature fluctuations.	Low, Medium, High

Freezers. Not all freezers are designed to maintain proper temperatures to maintain vaccine viability. When evaluating existing or shopping for new vaccine freezers, refer to table 3 to determine suitable grade and type by practice volume.

TABLE 3. Vaccine freezers by practice volume

Grade (Type) Rating	Description	Practice Volume
Pharmacy-, biologic-, or laboratory- grade (stand- alone) <i>Good</i>	Purpose-built to maintain consistent temperatures for storage of fragile vaccines or biologics.	Any practice
Pharmacy-, biologic-, or laboratory- grade (combination) <i>Good</i>	Purpose-built storage units with more than one compressor, allowing for better and separate temperature control of the refrigerator and freezer compartments.	Any practice
Commercial units (stand-alone) <i>Good</i>	Intended to store food and beverages in commercial settings. They are often larger and more powerful than household units but not designed to store biologics and experience some temperature fluctuations.	Any practice
Household (stand-alone) <i>Good</i>	Intended for use in homes and offices—typically for food storage. Like commercial units, they are not designed to store biologics and experience frequent temperature fluctuations.	Any practice

Unacceptable Vaccine Storage Units

Refrigerators with cooling plates or coils are not allowed. Table 4 lists storage units that do *not* meet VFC Program requirements and may *not* be used to store VFC-supplied vaccines.

TABLE 4. *Unacceptable* storage units

Type	Comments
Compact household refrigerator (stand-alone)	<p>Small, under-the-counter, stand-alone refrigerators with a capacity of 11 cubic feet or less are not allowed.</p>  <p>Compact household refrigerator</p>
Household combination refrigerator/freezer	<p>Household combination units have one compressor with poor temperature control. They can pose a risk to refrigerated vaccines because cold air from the freezer is vented into the refrigerator and can freeze vaccines. The freezer portions of many combination units are not capable of maintaining the consistent temperature for frozen vaccines.</p>  <p>Household combination unit</p>
Dormitory-style and bar-style combined refrigerator/freezers	<p>These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment. These units pose a significant risk of freezing—even when used for temporary storage.</p>  <p>Dormitory-style unit</p>
Manual-defrost refrigerators	<p>These models have a vertical cooling plate at the back of the refrigerator, which poses potential risk of significant temperature variation and freezing vaccines.</p>
Convertible units	<p>These units have an internal switch that converts an all-refrigerator unit to an all-freezer unit.</p>
Cryogenic freezers	<p>These units reach temperatures well below -58.0°F.</p>
Transport units	<p>Coolers and battery-operated units may not be used for routine vaccine storage.</p>

**Final
Considerations
before
Purchasing
Storage Units**

Before purchasing a storage unit, make sure it will fit in a space that meets VFC Program requirements and best practices. Vaccine storage units should be placed

- in rooms with good air circulation;
- away from public spaces, direct sunlight, and any heat sources;
- plugged directly into a nearby, dedicated wall outlet that does not have built-in GFI circuit switches and is not controlled by a light switch; and
- with at least 4 inches of space around the top, back, and sides.

The unit to be purchased must have sufficient storage space to accommodate vaccine stock at the busiest time of year without overcrowding.

If you are unclear about vaccine storage unit requirements, [contact your VFC Field Representative](#) prior to making a purchase.

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Repercussions of Improper Temperature Monitoring

Vaccines not stored at recommended temperatures might be deemed non-viable and the provider held financially accountable for the spoiled vaccines. Improper temperature monitoring includes not recording temperatures, not taking appropriate actions for out-of-range temperatures, and not ensuring staff are adequately trained. Falsifying VFC temperature logs also constitutes improper temperature monitoring.

Improper temperature monitoring might include but is not limited to the following consequences:

- Patients might receive non-viable vaccines and remain unprotected from vaccine-preventable diseases.
- Patients could need to be recalled and revaccinated, which can take a significant amount of clinic resources, manpower, and time.
- Spoiled VFC vaccines and private vaccines could amount to an enormous monetary loss to both the practice and to the VFC Program.
- The provider might be held financially accountable for the spoiled vaccines; doses lost must be compensated dose by dose at the private sector cost.

Notes

1. “Data Logger Setup and Use” can be found by searching for “IMM-1206” at <http://EZIZ.org>.
2. EZIZ “Monitoring Storage Unit Temperatures” lesson can be found on the EZIZ.org website under the “EZIZ Training” menu at <http://EZIZ.org>.
3. “Hourly Vaccine Temperature Log for Mass Vaccination Clinics” can be found by searching for “IMM-1255” at <http://EZIZ.org>.

Additional resources:

- “How to Record Refrigerator and Freezer Temperatures” can be found by searching for “IMM-1029” (Fahrenheit) or “IMM-1029C” (Celsius) at <http://EZIZ.org>.

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Taking Action for Temperature Excursions

Overview	Staff must immediately prevent use of vaccines exposed to out-of-range temperatures and notify relevant staff. Any temperature excursion must be documented and reported to MyVFCvaccines. The information reported on storage and handling incidents is used to determine whether a vaccine is likely to be viable and can be administered to patients. Timely and accurate reporting of temperature excursions is essential to a successful determination of vaccine viability.
Target Audience	Typically Vaccine Coordinator and Backup, or staff designated in the provider's vaccine management plan with responsibilities for monitoring storage unit temperatures
Program Requirements	<p>Providers have agreed to comply with the following VFC Program requirements:</p> <ul style="list-style-type: none"> • Take immediate action to prevent vaccine spoilage and correct any improper storage condition for all out-of-range storage unit temperatures (California VFC Program "Provider Agreement Addendum" #11A). • Mark as "Do Not Use" any vaccines exposed to out-of-range temperatures (P.A.A. #11B). • Download and review temperature data files for every temperature excursion (P.A.A. #11C). • Accurately document all out-of-range temperatures to SHOTS on MyVFCvaccines (P.A.A. #11D). • Do not administer vaccines until vaccine viability has been determined by vaccine manufacturers (P.A.A. #11E). • Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper refrigerated vaccine transport (IMM-983) and frozen vaccine transport (IMM-1130) (P.A.A. #11F).
Reporting Excursions on MyVFCvaccines	<p>VFC Program's Storage and Handling Triage System (SHOTS) allows providers to document temperature excursions and details. If vaccine quarantine is needed, the system directs providers to the manufacturers who determine vaccine viability. Never discard vaccines until advised by the practice's VFC Field Representative or the VFC Call Center.</p> <p>In the event of an excursion, providers must provide incident details including length of temperature excursion, minimum and maximum temperatures, and possible cause. Manufacturers might request an inventory of the affected vaccines.</p> <p>SHOTS can be accessed at MyVFCvaccines.org. (Refer to the "Storage and Handling Triage System (SHOTS)" job aid¹ for details.)</p>

Procedure

Follow the step-by-step instructions to report temperature excursions in compliance with VFC Program requirements and best practices. Contact the vendor for questions about data logger use.

TABLE 16. Instructions for reporting temperature excursions

Step	Description
If an alarm went off:	
1.	<p>Clear the MIN/MAX and any alarm symbol.</p> <p><i>Tip.</i> This step ensures staff don't report the same excursion during the next recording; skip this step if your device resets automatically.</p>
2.	<p>Post the “Do Not Use Vaccines” sign to quarantine all vaccines.</p> <p><i>Tip.</i> This step ensures vaccines are not administered until SHOTS or the vaccine manufacturer determines vaccines are okay to administer.</p>
3.	Alert your supervisor that vaccines might have been damaged by out-of-range temperatures and may not be used until the incident has been resolved.
4.	<p>Immediately report the temperature excursion to SHOTS at MyVFCvaccines.org and follow all instructions given.</p> <p>A. Download and save the temperature data file to the folder created for the device. (For example, Injection_Room_FRIDGE\2019\JAN.)</p> <p>(Refer to “Configuring Data Loggers” for guidance on setting up folders for data storage.)</p> <p><i>Tip.</i> Specify a filename that includes VFC PIN, storage unit ID, and current date. For example: 012345_FRIDGE_01162019.</p>

- B. Look in the data file for any excursion details (alarm results that show temperatures outside the device’s configured alarm limits).

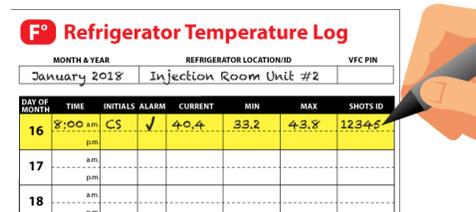


Tip. Refer to the device’s product guide or video to learn how to identify temperatures outside the HI/LO alarm limits in the data file. (See image for sample “Alarm Report.”)

- C. Use the excursion details to report the excursion to SHOTS using the instructions provided.

Important: If all excursions are not reported to SHOTS, vaccine manufacturers can’t accurately determine vaccine viability, and patients might be left unprotected against vaccine-preventable diseases.

- 5. After the incident has been reported to SHOTS, record the assigned SHOTS ID in the appropriate column on the temperature log.



- 6. Return the data logger to its original location and ensure it’s now recording storage unit temperatures.

Tip. Some devices might need to be reconnected and restarted. Check device product guide for instructions.



What to Do If Vaccines Are Damaged

When temperature excursions are reported to SHOTS, staff must follow the instructions provided, which could direct staff to contact vaccine manufacturers. Manufacturers will determine if vaccines might have been damaged by out-of-range temperatures.

If non-viable vaccines were administered to patients. Providers must follow VFC Program and manufacturer guidance. If any affected vaccines deemed non-viable (unable) were administered to patients, please note that the federal Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) recommend that any vaccines given after exposure to inappropriate temperatures should generally be repeated. Please consult with the manufacturer of vaccines deemed non-viable for additional vaccine stability studies and other information to help determine provider revaccination plans.

Troubleshooting

Most temperature excursions can be prevented. If the data logger indicates that the temperature is outside the recommended range, check the storage unit door, the power supply, the thermostat setting, and the data logger settings. These additional factors might lead to vaccine storage incidents:

- ***Inadequate staff training.*** Action: Review the EZIZ “[Monitoring Storage Unit Temperatures](#)” lesson² to address training gaps.
- ***Opening storage unit doors frequently (e.g., during busy days).*** Action: consider upgrading to a pharmaceutical-grade unit, which recovers quickly from door openings.
- ***Not closing the storage unit door tightly.*** Action: Make sure doors are closed properly when not in use; check the integrity of door seals as part of routine maintenance.
- ***Unplugging vaccine storage units.*** Action: Never unplug vaccine storage units.
- ***Unplanned electrical outage.*** Action: Follow protocols in the practice’s vaccine management plan.
- ***Planned electrical outage (e.g., to the room or building).*** Action: Ensure the Vaccine Coordinator has been notified before turning off the power; follow the protocols in the practice’s vaccine management plan.
- ***Taking inventory while storage unit doors remain open.*** Action: Keep doors shut as much as possible.
- ***Normal storage unit cycling.*** Action: Add water bottles (refrigerators) or cold packs (freezers only) to help buffer internal temperatures; if that doesn’t work, consider upgrading to a pharmaceutical-grade storage unit.
- ***Too much empty space in the storage unit.*** Action: Add sufficient water bottles (refrigerators) or cold packs (freezers only) to help buffer internal temperatures.
- ***Not monitoring storage unit temperatures at all.*** Action: Follow VFC Program requirements to monitor and document temperatures.
- ***Malfunctioning, old, and/or poor quality storage units.*** Action: Only use vaccine storage units that meet VFC Program requirements. (Refer to “[Vaccine Storage Unit Specifications.](#)”)
- ***Turning off or ignoring alarm alerts.*** Action: Do not ignore alarm alerts. If temperature alarms go off repeatedly, do not disconnect the alarm until it has been confirmed as a false alarm.
- ***Unacceptable temperatures during transfers and transport.*** Action: Use VFC-compliant data logger during transport and follow VFC [refrigerated](#)³ or [frozen vaccines](#)⁴ transport job aids.

Notes

1. “Storage and Handling Online Triage System (SHOTS)” can be found by searching for “IMM-1224” at <http://EZIZ.org>.
2. EZIZ “Monitoring Storage Unit Temperatures” lesson can be found on the EZIZ.org website under the “EZIZ Training” menu at <http://EZIZ.org>.
3. VFC “Transporting Refrigerated Vaccines” job aid can be found by searching for “IMM-983” at <http://EZIZ.org>.
4. VFC “Transporting Frozen Vaccines” job aid can be found by searching for “IMM-1130” at <http://EZIZ.org>.

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Conducting a Physical Vaccine Inventory

Overview

Physical vaccine inventories help practices maintain sufficient doses to meet patient needs by estimating future doses needed for routine periods as well as back-to-school and flu seasons. As part of vaccine management, practices should order proper quantities and use vaccines to prevent expiration. An accurate understanding of doses on hand helps to prevent over-ordering (doses might expire before use) or under-ordering (could result in missed vaccination opportunities). Accurate on-hand inventory must be reported with each VFC vaccine order.

Target Audience

Typically Vaccine Coordinator and Backup

Program Requirements

Providers have agreed to comply with the following VFC Program requirements:

- Providers agree to replace vaccine purchased with federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis (VFC “Provider Addendum” #13).
- Conduct a physical vaccine inventory at least monthly, and before ordering vaccines, using the VFC "[Vaccine Physical Inventory Form](#)" (IMM-1052) or equivalent electronic or paper form (California VFC Program “Provider Agreement Addendum” #12A).
- Never borrow VFC-supplied vaccines to supplement private stock, or vice versa (P.A.A. #12B).
- 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 (P.A.A. #12C).
- Remove spoiled, expired, and wasted vaccines from storage units after identification to prevent inadvertent use (P.A.A. #12D).
- Report all spoiled, expired, or wasted doses of VFC-supplied vaccines prior to submitting a new vaccine order (P.A.A. #12E).
- Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements (P.A.A. #12F).

Rational

Because VFC providers might maintain an average vaccine inventory ranging from tens of thousands to more than \$500,000 over the course of a year, providers are required to report the number of VFC doses on hand (as well as doses administered) every time they place an order. This system of checks and balances helps practices account for their vaccines on a regular schedule and prevents inadvertent over-ordering or under-ordering.

Best Practices

- Check vaccine expiration dates weekly and rotate stock to place vaccines that will expire soonest in front of those with later expiration dates.
- Create a calendar appointment or task reminder to conduct physical vaccine inventories monthly and before every routine VFC vaccine order.
- Be mindful that leaving storage unit doors open too long might expose vaccines to out-of-range temperatures that can damage vaccines.
- VFC providers are strongly encouraged to enroll in an immunization registry because registries efficiently track vaccine lot numbers and expiration dates, and they can identify patients to recall in the event of revaccination.

Notes

1. VFC “Refrigerated Vaccine Transport Log” can be found by searching for “IMM-1132” at <http://EZIZ.org>.
2. VFC “Frozen Vaccine Transport Log” can be found by searching for “IMM-1116” at <http://EZIZ.org>.

Additional resources:

- The “Transporting Refrigerated Vaccine” job aid can be found by searching for “IMM-983” at <http://EZIZ.org>.
- The “Transporting Frozen Vaccine” job aid can be found by searching for “IMM-1130” at <http://EZIZ.org>.

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Responding to Vaccine-Related Emergencies

- Overview** CDC requires every practice to have a vaccine management plan, which includes guidance on what to do in the event of refrigerator or freezer malfunction, power failure to vaccine storage units, and natural disasters or other emergencies that might compromise vaccine viability. The plan must be readily available in a location known to staff and reviewed at least annually with all key practice staff.
- Target Audience** Typically Vaccine Coordinator and Backup
- Program Requirements** Providers have agreed to comply with the following VFC Program requirements:

 - Providers agree to replace vaccine purchased with federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis (VFC “Provider Agreement” #13).
 - Maintain a current and completed [vaccine management plan](#) (IMM-1122) for routine and emergency situations that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and required EZIZ lesson completion dates for all key practice staff (California VFC Program “Provider Agreement Addendum” #1A).
 - Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper [refrigerated vaccine transport](#) (IMM-983) and [frozen vaccine transport](#) (IMM-1130) (P.A.A. #11F).
- Rationale** Because VFC providers might maintain an average vaccine inventory ranging from tens of thousands to more than \$500,000 over the course of a year, providers must be prepared to respond to emergencies to help ensure that vaccines remain viable and minimize provider liability due to negligence.
- Best Practices** Most emergencies happen suddenly. Practices should be prepared for emergency transport of vaccine by always having the necessary supplies ready:

 - hard-sided cooler
 - frozen water bottles and cold packs
 - digital data logger (or other continuous temperature monitoring device)
 - bubble wrap
- Checklist: Before an Emergency** Proper preparation for emergency situations is essential to protecting the viability of vaccines. The table below provides a checklist that must be completed to help ensure practices are ready for planned or unexpected situations that might impact vaccines.

TABLE 22. Checklist of preparations before an emergency situation

Step	Description
1.	Maintain current emergency contact information for key practice staff.
2.	Maintain current contact information for alternate vaccine storage location(s), including the facility name, address, and telephone number.
3.	Be familiar with backup power sources for commercial- and pharmacy-grade storage units.
4.	Know the location of the backup digital data logger used for vaccine transport.
5.	Stock vaccine packing and transport supplies, including a hard-sided cooler, frozen gel packs, and bubble wrap.

6. Keep copies of the VFC ["Refrigerated Vaccine Transport Log"](#) and ["Frozen Vaccine Transport Log"](#) and floor plans (when available) for easy access during a vaccine-related emergency.
7. **Vaccine Transport Drill:** Practice packing the transport cooler using packing supplies and materials that simulate vaccine boxes. Do NOT practice with actual vaccines.

**Procedure:
During an
Emergency**

Due to the risk to vaccines of improper packing and transporting, follow these step-by-step instructions during an emergency to determine whether vaccines should be transported or sheltered in place.

TABLE 23. Instructions during vaccine-related emergencies

Step	Description
1.	Do not open the storage unit(s).
2.	Place a "DO NOT OPEN" sign on storage unit(s) and leave door(s) shut to conserve cold air mass.
3.	Notify the emergency contacts identified on the vaccine management plan's "Worksheet for Emergency Vaccine Management."
4.	Note the time the outage started and storage unit temperatures (CURRENT, MIN and MAX).
5.	Assess the situation to determine the cause of the power failure and estimate the time it will take to restore power.
6.	Take appropriate action.
	<i>In the event of appliance failure.</i> Place vaccines in any VFC-approved backup storage unit with a VFC-compliant data logger, or transport vaccines to the designated alternate storage facility. (Refer to "Transporting Vaccines" for instructions.)
	<i>For power outages after hours.</i> Report any excursion to SHOTS the next morning and take appropriate action. (Refer to "Taking action for Temperature Excursions.")
	<i>For planned outages expected to be short-term (approximately fewer than 4 hours).*</i> Monitor storage unit temperature and report any excursions once power has been restored. (Refer to "Taking action for Temperature Excursions.")
	<i>For planned/unplanned outages expected to be longer than approximately 4 hours,* or for any outage that extends beyond the current business day.</i> Transport vaccines to the designated alternate storage facility. (Refer to "Transporting Vaccines" for instructions.) Important. If transport or relocation is not feasible (e.g., alternate location is not available or travel conditions are unsafe), keep vaccine storage units closed and notify the VFC Call Center as soon as possible.
7.	Monitor vaccine storage unit temperatures until power is restored.
8.	Once power has been restored, follow the steps in TABLE 24.

* **Note:** Practices using purpose-built (pharmacy-, biologic-, and laboratory-grade) and commercial-grade storage units may need to transport vaccines to an alternate location sooner than **2 hours** as temperatures in these units tend to increase faster during power failures if there is no backup power generator.

**Procedure:
After an
Emergency**

Follow these step-by-step instructions after vaccine-related emergencies in compliance with VFC Program requirements and best practices.

TABLE 24. Instructions after vaccine-related emergencies

Step	Description
1.	Verify storage units are functioning properly.
2.	If vaccine storage units are outside the required temperatures ranges, note the time that power was restored and storage unit temperatures (CURRENT, MIN and MAX).
3.	Once vaccine storage unit temperatures have stabilized, notify the emergency contacts identified on the vaccine management plan’s “Worksheet for Emergency Vaccine Management.”
4.	If vaccines were transported due to an emergency situation: <ul style="list-style-type: none"> A. Follow the same transportation procedures and transfer vaccines back to the original storage unit. (Refer to the "Transporting Vaccines" for instructions.) B. If vaccines were kept at the proper temperature during the power outage, notify supervisor that the vaccines may be used.
5.	If vaccines were maintained at required temperatures: <ul style="list-style-type: none"> A. Remove the “DO NOT OPEN” sign from storage unit(s). B. Notify supervisor that vaccines may be used.
6.	If vaccines were exposed to out-of-range temperatures: <ul style="list-style-type: none"> A. Label affected vaccines “Do Not Use”. B. Document and report the excursion at MyVFCvaccines.org to receive further guidance. (Refer to the "Taking Action for Temperature Excursions" for instructions.)

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Vaccines	Previous Inventory	Previous Order	Doses Used since last order	Calculated Inventory	Vaccine Inventory (Doses On Hand) Number of doses on hand and vaccine type Lot Number Expiration Date
Rotavirus	15	10	5	Over by 10 doses	RotaTeq Single Dose Tubes - 25 per Box 20 L026741 05 18 2019 Doses Lot Number Expiration mm/dd/yyyy --Choose vaccine-- 0 Doses Lot Number Expiration mm/dd/yyyy --Choose vaccine-- 0 Doses Lot Number Expiration mm/dd/yyyy

- Once the order has been correctly updated, add comments to explain the corrections and click the “Update Order” button.

In the example below, the Vaccine Coordinator would indicate that private vaccines were mistakenly reported.

Comments (optional):

Private vaccines were mistakenly reported as VFC vaccines.

Notes

- VFC “Vaccine Ordering Worksheet” can be found by searching “IMM-1246” at <http://EZIZ.org>.

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Preparing Practices to Fight Flu

Flu is a Serious Illness

Influenza can result in hospitalization or death in young children—especially those with certain health conditions. In 2018, CDC reported overall estimates of flu impact across age groups and risk groups since 2010.

Deaths: between 12,000 and 56,000 annually¹

Hospitalizations: 140,000 and 710,000 annually¹

Illnesses: between 9.2 million and 35.6 million annually¹

2017-18 Flu Season

This flu season was the first to be classified as high severity for all age groups, and was characterized by record-breaking illness levels, hospitalization rates, and pediatric deaths.



FIGURE 4.7. Hospitalization Rates in 2017-18 Flu Season.

Vaccination can offer substantial benefits and reduce the likelihood of severe outcomes—even when vaccine effectiveness is reduced.

How to Respond to Questions of Vaccine Effectiveness

The flu vaccine reduces the likelihood of hospitalization and death, —even during years when vaccine effectiveness is reduced. Because the flu virus is constantly mutating, the flu vaccine is constantly evolving as well to anticipate strains of flu that might be circulating during the upcoming flu season. Some seasons the flu vaccine is more effective than others.

Tip. If patients have concerns about flu vaccination based on past experience, remind them that the flu vaccine is different each year, and the protection against the burden of disease (missed school or work, flu symptoms, risk of progression to pneumonia) is *increased* with vaccination—even when vaccine effectiveness is reduced.

High-Risk Group: Young Children

CDC has released results of a study that found flu vaccination significantly reduced the risk of flu-related death for healthy children and those in high-risk groups.

Healthy children: 65% reduction of death risk¹

High-risk group: 51% reduction of death risk¹

Strongly Recommend Flu Vaccination

Consider bundling flu with other routine vaccines. Patients are more apt to be vaccinated against flu if the health-care provider strongly recommends and offers the flu vaccine during the same office visit. By referring a patient outside the medical home, an immunization opportunity is lost, and VFC-eligible children might be charged for any administration fees—if they get vaccinated at all.

If Patients Refuse Vaccination

Many patients do not understand that flu is a serious illness that can lead to death, particularly in young children. Practices can directly influence vaccination rates in their practices by preparing staff to address common concerns.

Tips. If patients refuse vaccination, ask questions to uncover any reasons behind patient concern. Provide answers and recommend vaccination again. If the patient still declines, share an information handout and follow up at their next visit.

Techniques to Improve Vaccination Rates

- Empower all staff to recommend flu vaccination
- Offer flu vaccination during routine visits
- Bundle flu with other routine vaccines
- Use standing orders
- Assess flu vaccination status at every visit from September through March
- Send e-mail or phone reminders to patients to make appointments before flu season and follow up as needed

Sample Dialogue

CDC suggests using their five-point approach (SHARE) to making a strong vaccine recommendation.

SHARE the reasons for the flu vaccine. “This vaccine can protect you and your family from getting the flu, which is a serious illness that can lead to hospitalization and even death, particularly in young children. By getting the shot today, you’ll be protecting yourself and the people around you.”

HIGHLIGHT positive experiences. “The CDC recommends that everyone get a flu vaccine each year. I always get one so I don’t pass along the flu along to my patients and family.”

ADDRESS patient questions. “To answer your question, a flu shot cannot cause the flu. There can be some mild side effects, but it can’t cause the flu.”

REMIND patients that the flu vaccine protects children and their loved ones. “Flu activity is going to start to pick up, and CDC says to expect more cases in the coming months. That’s why I want to make sure I help protect you and your loved ones.”

EXPLAIN the potential costs of flu. “It’s important to get vaccinated this season because flu vaccination can reduce the likelihood of hospitalization, flu illnesses, doctor visits, and missed work and school.”

Notes

1. “Prepare Your Practice to Fight Flu,” EZIZ.org, “<http://eziz.org/assets/docs/NCIRDFightFluSlideDeck.pdf>.”

Additional resources:

- “Make a Strong Flu Vaccine Recommendation,” Centers for Disease Control and Prevention, <https://www.cdc.gov/flu/professionals/vaccination/flu-vaccine-recommendation.htm>.

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Ordering Flu Vaccines

Overview

Providers do not order influenza vaccines the same way they order routine vaccines. Flu vaccines are allocated to enrolled providers by the VFC Program in advance of the flu season. If additional doses are needed beyond the initial allocation, providers may request additional doses during the supplemental flu ordering window.

Target Audience

Typically Vaccine Coordinator and Backup

Program Requirements

Providers have agreed to comply with the following VFC Program requirements:

- For the vaccines identified and agreed upon in the provider's VFC Provider Profile, comply with immunization schedules, dosages and contraindications that are established by ACIP and included in the VFC program (Provider Agreement #3).
- Order vaccine and maintain appropriate vaccine inventories (VFC "Provider Agreement" #9A).
- Order all ACIP-recommended vaccines (including flu) according to the provider population, category, order frequency, vaccine usage, and on-hand inventory (California VFC "Provider Agreement Addendum" #7A).
- Document all VFC vaccine doses administered using the VFC "Daily Usage Log" (IMM-1053), "Flu Usage Log" (IMM-1053F), an immunization registry, or equivalent electronic or paper form (P.A.A. #14F).

Rationale

Unlike routine pediatric vaccines, VFC books a set number of flu doses in advance of the flu season. In order to ensure demand and full utilization of vaccines, each provider is allocated doses. Doses must be confirmed by the announced deadline or vaccines are released into the general supply. Providers must accurately document flu vaccine usage and account for any return unused, expired vaccines from the previous season before confirming the current season's allocation.

Best Practices

Prepare in advance to ensure your allocations are accurately confirmed:

- Review with staff the annual VFC Program influenza letter, which includes detailed information regarding this season's ACIP influenza vaccination recommendations, product dosage and administration, storage and handling guidelines, and other important information. The letter will be released once recommendations are published by CDC.
- Ensure that key practice staff responsible for confirming flu allocations are aware of the announced timeline so that allocations are confirmed by the two-week review and confirmation deadline.
- Consider your seasonal flu vaccine needs for your VFC-eligible patients; influenza vaccine is routinely recommended for all VFC-eligible children 6 months through 18 years of age. And children under eight years of age might need two doses of flu vaccine to complete the series.
- Ensure that key practice staff fill out the VFC "Flu Usage Log"¹ (or an immunization registry or EHR/EMR system) to track flu doses administered; vaccines used and on-hand inventory must be accounted for during supplemental flu vaccine ordering.

Initial Allocations

The VFC Program allocates provider doses at the beginning of the flu season based on

- the available vaccine supply (including specific products) pre-booked for distribution to California VFC Program providers,



I, on behalf of myself and any and all practitioners associated with this medical office, group practice, Health Maintenance Organization (HMO), health department, community/migrant/rural clinic, hospital, or other entity of which I am the physician-in-chief, medical director or equivalent, agree to comply with all VFC Program requirements listed below.

1. Vaccine Management Plan

- A. Maintain a current and completed vaccine management plan (IMM-1122) for routine and emergency situations that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and required EZIZ lesson completion dates for all key practice staff.
- B. Review and update the plan at least annually, when VFC Program requirements change, and when staff with designated vaccine-management responsibilities change.
- C. Designate a staff member responsible for updating the practice's management plan.
- D. Ensure staff with assigned vaccine-management responsibilities review, sign, and date the vaccine management plan annually and each time it is updated.
- E. Store the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units.

2. Training & Staffing

- A. Designate an on-site Provider of Record Designee authorized to sign VFC Program documents and assume responsibility for VFC-related matters in the absence of the Provider of Record.
- B. Designate fully trained, on-site Vaccine Coordinator and Backup Vaccine Coordinator as detailed in "[Vaccine Coordinator Roles & Responsibilities](#)" (IMM-968).
- C. Ensure Provider of Record and Designee, Vaccine Coordinator and Backup, and other key practice staff comply with federal VFC educational requirements, such as annual EZIZ trainings; ensure staff demonstrate competency in their assigned VFC responsibilities.
- D. Ensure that staff are knowledgeable of and familiar with all ACIP-recommended immunizations, including schedules, indications, dosages, and new products.
- E. Ensure staff, including supervisors and new employees, are properly trained on temperature monitoring including proper use of the practice's digital data loggers and the required corrective actions for out-of-range temperatures.
- F. Ensure staff authorized to accept packages are trained to immediately notify the Vaccine Coordinator when vaccines are delivered.
- G. Conduct regular vaccine transport drills to maintain competency and readiness for emergencies.
- H. Immediately report to the VFC Program any changes in key practice staff who have immunization-related responsibilities; a change in the Provider or Record or Designee requires a signed "[Key Practice Staff Change Request Form](#)" (IMM-1166).

3. Vaccine Storage Units

- A. Use only refrigerators or 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.
- B. Acknowledge that 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](#). Temporary storage of VFC-supplied vaccines in a cooler is unacceptable.

- C. 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 combination refrigerator/freezers; manual-defrost refrigerators; convertible units; cryogenic (ultra-low) freezers; or any vaccine transport unit (including coolers and battery-operated units).
- D. Purchase new refrigerators (purpose-built) or freezers (any grade) if existing storage units experience frequent temperature excursions jeopardizing vaccine supply, or malfunctioned resulting in spoiled vaccines.

4. Vaccine Storage Unit Configuration

- A. [Prepare vaccine refrigerators](#) (IMM-962) and [vaccine freezers](#) (IMM-965) following VFC Program requirements.
- B. Place water bottles (in refrigerators) and ice packs (in freezers only) to stabilize temperatures. (Exception for purpose-built, auto-dispensing units without doors.)
- C. Place buffered probes in the center of the refrigerator and freezer near vaccines. (Exception for purpose-built, auto-dispensing units without doors.)
- D. Place the data logger's digital display outside the storage units to allow temperature monitoring without opening vaccine storage unit doors. (Exception for purpose-built, auto-dispensing units without doors.)
- E. Plug the vaccine 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 vaccine storage units into extension cords, or power strips or surge protectors with an on/off switch.
- F. Post "[Do Not Unplug](#)" (IMM-744) signs on electrical outlets and circuit breakers to prevent interruption of power.
- G. [Set up vaccine refrigerators](#) (IMM-963) and [vaccine freezers](#) (IMM-966) following VFC Program requirements.
- H. Clearly identify VFC-supplied and privately purchased vaccines. Designate and label separate shelf space or mesh baskets.
- I. Clearly label shelves or baskets to group vaccines by pediatric, adolescent, and adult types.
- J. Allocate enough space to position vaccines or baskets 2-3 inches away from walls, storage unit floor, and other baskets to allow space for air circulation. (Exception for purpose-built, auto-dispensing units without doors.)
- K. Post [VFC temperature logs](#) on vaccine storage unit doors or in an easily accessible location.

5. Digital Data Loggers

- A. 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 without doors: Built-in, internal data loggers must meet VFC Program requirements—except for buffered probes, which are not required.)
- B. Ensure all data loggers include the following minimum features: a digital display of current, minimum, and maximum temperatures; minimum accuracy of $\pm 1.0^{\circ}\text{F}$ (0.5°C); a buffered temperature probe (use only 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.
- C. Keep on hand at least one backup (battery-operated) digital data logger for emergency vaccine transport. Depending on the size of the practice, additional devices might be needed.



6. Digital Data Logger Configuration & Maintenance

- A. Configure key settings for primary and backup digital data loggers, including device name, low and high temperature alarm limits, and a 30-minute logging interval.
- B. Store the backup 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 (IMM-1122). (Exception for purpose-built, auto-dispensing units without doors: Store the entire device in a cabinet.)
- C. 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.
- D. Ensure certificates issued by non-accredited laboratories are valid certificates of calibration (IMM-1119).
- E. Keep certificates of calibration on file and make them available to the VFC Program upon request.
- F. If any data logger or probe is damaged, replace the entire device.

7. Vaccine Orders & Accountability

- A. Order all ACIP-recommended vaccines (including flu) according to the provider population, category, order frequency, vaccine usage, and on-hand inventory.
- B. 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.
- C. Stock one brand and formulation for each vaccine to avoid administration errors.
- D. Account for every dose of VFC-supplied vaccine ordered and received by the provider's practice.
- E. Report on each vaccine order the VFC vaccine doses administered since the previous order and the current doses on hand.
- F. 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.

8. Receiving & Inspecting Vaccine Deliveries

- A. Never reject vaccine shipments.
- B. Receive, inspect, and store vaccines and diluents within manufacturer-recommended ranges immediately upon delivery.
- C. Inspect vaccines for out-of-range temperatures and shipping times during transport.
- D. Check package contents to ensure funding source, brands, and quantities match packing slips and approved VFC orders.
- E. Report immediately all shipment issues using the VFC ["Vaccine Receiving Log and Checklist"](#) (IMM-1112).
- F. Keep packing slips for all vaccine shipments received, including publicly funded and private vaccine shipments.
- G. Ensure the clinic is open with the appropriate staff available to receive vaccines at least one day a week (other than Monday) and for at least four consecutive hours.

9. Vaccine Storage

- A. 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.
- B. Store frozen vaccines (MMR, MMRV, and Varicella) between -58.0°F and 5.0°F (-50.0°C and -15.0°C) according to manufacturer recommendations.
- C. Store all other refrigerated vaccines between 36.0°F and 46.0°F (2.0°C and 8.0°C) according to manufacturer recommendations.



- D. Store vaccines in original packaging and within closed boxes to protect from light and allow for air circulation.
- E. Store VFC-supplied and privately purchased vaccines separately and grouped by vaccine type.
- F. Do not store vaccines in storage unit doors, drawers, or bins.
- G. Place vaccines with the earliest expiration dates toward the front of vaccine storage units and use first.
- H. Obtain VFC approval before storing vaccines at mass vaccination and outreach clinics; always store and administer vaccines at the approved location for the VFC PIN.
- I. For mobile units, follow all VFC Program requirements including vaccine storage, transport, and temperature monitoring.

10. Temperature Monitoring

- A. Ensure vaccine storage unit temperatures are recorded on [VFC temperature logs](#).
- B. Monitor and record current, minimum, and maximum temperatures ([Fahrenheit](#) IMM-1029 | [Celsius](#) IMM-1029C) in vaccine refrigerators and freezers twice each day: at the beginning and end of each business day—even though using digital data loggers; for any VFC-approved mass vaccination and outreach clinics, monitor and record temperatures every hour and attach the data logger download (or summary report if available) to the transport log.
- C. Ensure staff respond to all data logger alarms by reporting temperature excursions to SHOTS (Storage and Handling Online Triage System).
- D. 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.
- E. Acknowledge that if temperatures are not monitored and documented, or 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.
- F. Ensure VFC temperature logs are legible, and completed accurately and in ink.
- G. Neatly cross out, correct, initial, and date any inadvertent documentation error immediately.
- H. 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 two-week reporting period.
- I. Retain paper logs and electronic files related to temperature monitoring for three years.
- J. Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted.

11. Reporting Storage & Handling Incidents

- A. Take immediate action to prevent vaccine spoilage and correct any improper storage condition for all out-of-range storage unit temperatures.
- B. Mark as “Do Not Use” any vaccines exposed to out-of-range temperatures.
- C. Download and review temperature data files for every temperature excursion.
- D. Accurately document all out-of-range temperatures to SHOTS on MyVFCvaccines.
- E. Do not administer vaccines until vaccine viability has been determined by vaccine manufacturers.
- F. Transport vaccines in the event of extended power outages or unit malfunctions following the guidelines for proper [refrigerated vaccine transport](#) (IMM-983) and [frozen vaccine transport](#) (IMM-1130).



12. Vaccine Inventory Management

- A. Conduct a physical vaccine inventory at least monthly, and before ordering vaccines, using the VFC ["Vaccine Physical Inventory Form"](#) (IMM-1052) or equivalent electronic or paper form.
- B. Never borrow VFC-supplied vaccines to supplement private stock, or vice versa.
- C. 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.
- D. Remove spoiled, expired, and wasted vaccines from storage units after identification to prevent inadvertent use.
- E. Report all spoiled, expired, or wasted doses of VFC-supplied vaccines prior to submitting a new vaccine order.
- F. Monitor vaccine storage units regularly and purchase additional storage units if capacity cannot accommodate the inventory in a manner consistent with VFC Program requirements.

13. Vaccine Transfers & Transports

- A. Contact the VFC Call Center prior to transferring VFC-supplied vaccines.
- B. Only transfer to alternate locations that have VFC-approved [vaccine storage units](#) and [digital data loggers](#).
- C. Never routinely transfer VFC-supplied vaccines to other VFC providers.
- D. Never transfer VFC-supplied vaccines to non-VFC providers.
- E. Transport vaccines only when necessary and follow the guidelines for proper [refrigerated vaccine transport](#) (IMM-983) and [frozen vaccine transport](#) (IMM-1130).
- F. Complete the VFC ["Refrigerated Vaccine Transport Log"](#) (IMM-1132) or ["Frozen Vaccine Transport Log"](#) (IMM-1116) each time vaccines are transported.
- G. Transport VFC-supplied vaccines only to facilities designated in the provider profile and never to personal residences.
- H. 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 for off-site clinics.
- I. Acknowledge that vaccines transported without proper documentation of temperature monitoring will be deemed non-viable.

14. Vaccine Administration

- A. Administer all ACIP-recommended vaccines (including flu) in-house; do not refer patients to other facilities where they might be charged for vaccine administration.
- B. Ensure that VFC-eligible children have access to non-routine, ACIP-recommended vaccines when indicated or when requested.
- C. Administer all VFC-supplied vaccines at the approved location for the VFC PIN; administration of doses outside the approved location (e.g., special event clinics, health fairs, special school clinics, or mass vaccination clinics) is not routinely allowed and requires prior approval from the VFC Program.
- D. Acknowledge and follow VFC Program and manufacturer guidance, including revaccination, if non-viable vaccines have been administered to patients.
- E. Document all VFC vaccine doses administered using the VFC ["Daily Usage Log"](#) (IMM-1053), ["Flu Usage Log"](#) (IMM-1053F), an immunization registry, or equivalent electronic or paper form.
- F. For non-Medi-Cal, VFC-eligible children, waive the administration fee if the parent/guardian is unable to pay. Never bill parents who are unable to pay the waived administration fees.
- G. For Medi-Cal children, never bill the difference between Medi-Cal's administration fee and the administration fee cap to the parent/guardian.



15. Program Integrity

- A. Ensure that clinic staff conduct themselves in an ethical, professional, and respectful manner in all interactions with VFC Program staff.
- B. Never destroy, alter, or falsify immunization or VFC Program-related records.
- C. Acknowledge that providers must make all vaccine administration records (privately and publicly funded) available to representatives from the California Department of Public Health Immunization Branch and VFC Program.

To receive VFC-supplied vaccines, confirm acknowledgement of this agreement.

Failure to comply with any of the above could lead to negligent vaccine loss and be grounds for vaccine reimbursement and/or suspension of vaccine ordering privileges and termination from the VFC Program.