Vaccines for Children Program

Provider Operations Manual

CDPH
California Department of Public Health

VFC
www.eziz.org

Summary of 2019 Updates

Chapter One – THE VFC PROGRAM

- VFC Vaccines: new language clarifying routine and non-routine vaccines (to support new addendum requirement #14B)
- Training and Support: additional language clarifying addendum requirements reflected under "Program Requirements;" new language clarifying staff training requirements and recommendations including vaccine transport drills (updated addendum requirement #2G)
- Quick Start Guide: additional language clarifying daily, weekly, monthly, and other routine and recommended tasks

Chapter Two – PATIENT VACCINATIONS

- Conducting Eligibility Screening & Documentation: new language in Table 4 addressing Health-Care Sharing Ministries
- Reviewing Immunization Records: new instruction to not refer patients to other facilities (new addendum requirement #14A); new instruction to provide access to non-routine vaccines to VFC-eligible children (new addendum requirement #14B)
- Administering Vaccines: additional language clarifying addendum requirements reflected under "Program Requirements"
- Billing for Vaccine Administration: additional language clarifying addendum requirements reflected under "Program Requirements;" correction on page 23 for billing uninsured and underinsured patients, and clarification of instruction to not bill parents who are unable to pay waived administration fees (updated addendum requirement #14F)

Chapter Three – VACCINE MANAGEMENT

- Vaccine Management Plan: additional language clarifying addendum requirements reflected under "Program Requirements"
- Vaccine Storage Unit Specifications: additional language clarifying addendum requirements reflected under "Program Requirements;" new language defining purpose-built, pharmacy-grade, auto-dispensing units without doors (updated addendum requirement 3A); clarification of specifications for manual-defrost freezers (new addendum requirement #3B)
- Configuring Vaccine Storage Units: additional language clarifying addendum requirements reflected under "Program Requirements;" additional language clarifying preparation and setup of vaccine storage units for purpose-built, pharmacy-grade, auto-dispensing units without doors; new instructions for defrosting manual-defrost freezers (new addendum requirement 3B).
- Data Logger Specifications: additional language clarifying addendum requirements reflected under "Program Requirements;" new language clarifying device requirements for purpose-built, pharmacy-grade, auto-dispensing units without doors (updated addendum requirement #5A); clarification of requirement for backup, battery-operated devices for vaccine transport (updated addendum #5C)
- Configuring Data Loggers: additional language clarifying addendum requirements reflected under "Program Requirements;" additional language clarifying required key device settings (new addendum requirement #6A); clarification of device requirements for purpose-built, pharmacy-grade, auto-dispensing units without doors (updated addendum #6B); updated instructions to help providers create folders to store downloaded temperature data files on practice computers; clarification of instructions for device calibration testing
- Receiving Vaccine Deliveries: additional language clarifying addendum requirements reflected under "Program Requirements;" additional language clarifying required practice hours (updated addendum #8G)
- Storing Vaccines: additional language clarifying addendum requirements reflected under "Program Requirements;" correction to "Proper Storage Temperatures" to remove reference to Zoster as a frozen VFC vaccine; clarification of storage of medication in vaccine storage units (updated addendum #9A).

- Monitoring Storage Unit Temperatures: additional language clarifying addendum requirements reflected under "Program Requirements;" additional language clarifying requirements for outreach clinics (updated addendum #10B)
- Taking Action for Temperature Excursions: additional language clarifying addendum requirements reflected under "Program Requirements;" additional language clarifying instructions to respond to all data logger alarms (new addendum requirement #10C); new instruction not to administer vaccines until manufacturers determine vaccine viability (updated addendum requirement #11E)
- Conducting a Physical Vaccine Inventory: additional language clarifying addendum requirements reflected under "Program Requirements"
- Transferring Vaccines between Providers: additional language clarifying addendum requirements reflected under "Program Requirements"
- Transporting Vaccines: additional language clarifying addendum requirements reflected under "Program Requirements;" new language clarifying required use of backup, battery-operated data loggers for transport and at approved off-site clinics (updated addendum #13H); clarification that vaccines not monitored according to VFC Program requirements will be deemed non-viable (#13I).
- Responding to Vaccine-Related Emergencies: additional language clarifying addendum requirements reflected under "Program Requirements;" new language clarifying steps for vaccine transport drills (updated addendum #2G); clarification of steps to take in the event of appliance failure, power outages after hours, planned short-term outages, and planned/unplanned long-term outages
- Conducting Off-Site Clinics: additional language clarifying addendum requirements reflected under "Program Requirements;" minor clarification of requirements for mass vaccination and outreach clinics and mobile units

Chapter Four – VACCINE ORDERS

- Submitting Routine Vaccine Orders: additional language clarifying addendum requirements reflected under "Program Requirements"
- Preparing Practices to Fight Flu: New topic
- Ordering Flu Vaccines: additional language clarifying addendum requirements reflected under "Program Requirements"

Chapter Five – PROVIDER ACCOUNTABILITY

- Vaccine Accountability: additional language clarifying addendum requirements reflected under "Program Requirements"
- Site Visits: additional language clarifying addendum requirements reflected under "Program Requirements"
- Record Retention: additional language clarifying addendum requirements reflected under "Program Requirements"

Appendices

- 2019 California VFC Program "Provider Agreement Addendum"

Vaccines for Children Program

Provider Operations Manual

January 2019

California VFC Program

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Preface

Overview

The Vaccines for Children (VFC) Program's *Provider Operations Manual* (POM) is a reference guide that helps health-care providers stay compliant with VFC Program requirements. By complying, providers can increase immunization levels in their patient populations, ensure vaccines are administered at the recommended ages, and protect vaccine viability following manufacturers' recommendations for storage and handling.

How to Use the POM

This reference guide provides clear instructions that help providers incorporate VFC Program requirements and best practices into their existing practice protocols. Providers and key practice staff can reference the POM as they complete necessary patient immunization and vaccine management tasks. Providers are encouraged to store this manual within easy reach and instruct staff to refer to it as needed to ensure tasks are completed in compliance with program requirements that protect patients and vaccines.

Terminology

This manual contains requirements, best practices, and procedures. It is important to understand the intent of each term and how they are used.

- *Program requirements* are federal or state VFC Program policies that enrolled providers have agreed to follow.
- *Procedures* are instructions that walk staff through key immunization tasks. If the instructions are followed, providers will be complying with VFC Program requirements and best practices.
- *Best practices* are recommendations shared by CDC and the California VFC Program to improve efficiencies; best practices often evolve into requirements.

Target Audience

Each topic in the POM is associated with common roles that might assume responsibility for completion of key tasks in compliance with program requirements. In many practices and clinics, the office manager or supervisor might be responsible for completing or overseeing some tasks. However, key program roles should be familiar with the contents of this document. Each practice should determine how to best make use of their staffing resources to incorporate VFC Program requirements into existing practice protocols.

POM Structure

This manual is divided into chapters that assemble related topics, and each topic is structured using repeating elements to increase readability and ease of reference:

overview
requirements
best practices
procedures
notes

Each chapter also includes an organizational graphic (see figure 1) that summarizes key concepts to be addressed across the chapter's topics.

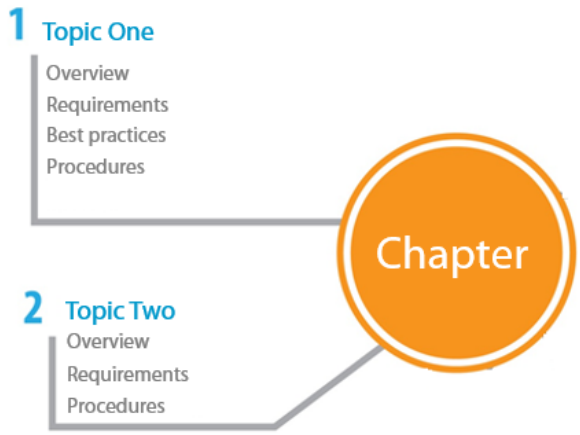

FIGURE 1. Visual illustration of chapter structure.

Keeping the POM Current

The California VFC Program updates and revises information as needed and communicates those changes to providers. Replace relevant sections in this manual as instructed to ensure it reflects current program policies and procedures.

Keys to a Successful Implementation

Overview

Provider involvement. The provider of record should be directly involved in the practice's implementation of VFC Program requirements to ensure high-quality care is provided to patients. Since providers are responsible for replacement of any VFC vaccines spoiled or expired due to negligence, management should also have a clear understanding of the vaccine replacement costs and the clinical implications of mismanaged vaccines.

Well-trained Vaccine Coordinator & Backup roles. The VFC Vaccine Coordinator and Backup roles bear the important responsibility of implementing and overseeing the practice's vaccine management plan, and success requires well-trained staff. However, a national survey conducted by the CDC in 2015 revealed that the Backup Vaccine Coordinator and other key practice staff not routinely performing vaccine management tasks were insufficiently trained, indicating areas where practices can improve. The same survey revealed the following data (see figure 2) about the designation of vaccine management responsibilities by role in California:

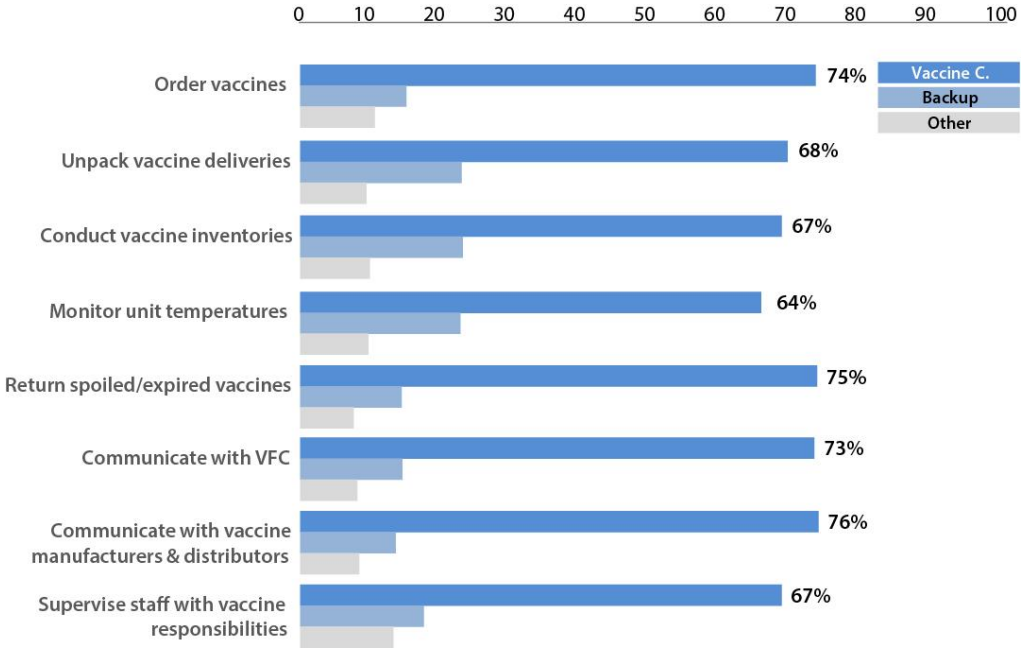

FIGURE 2. 2015 CDC survey results for CA depicting typical designation of tasks by role.

VFC-compliant storage units and digital data loggers. Selection of the appropriate vaccine storage units to meet practice immunization volume is essential to maintaining stable vaccine temperatures. Properly calibrated data loggers ensure that recorded temperatures are accurate.

Well-trained clinical staff knowledgeable about current immunization schedules. Staff should be familiar with ACIP-recommended vaccines, vaccine products and dosages, as well as vaccine administration techniques.

Thorough eligibility screening and documentation at every immunization visit. Providers help ensure program integrity by immunizing only VFC-eligible children with VFC-supplied vaccines and avoiding missed immunization opportunities.

The VFC Program

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clickable topics

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Introduction

The first chapter orients new providers to the VFC Program and its support structure, identifies where program requirements are defined, and outlines the provider enrollment process. By the end of this chapter, providers should have an understanding of the provider and patient benefits and know where to find the requirements that protect provider vaccines and patients and the integrity of the VFC Program.

Figure 1.1 highlights the key topics covered in chapter one.

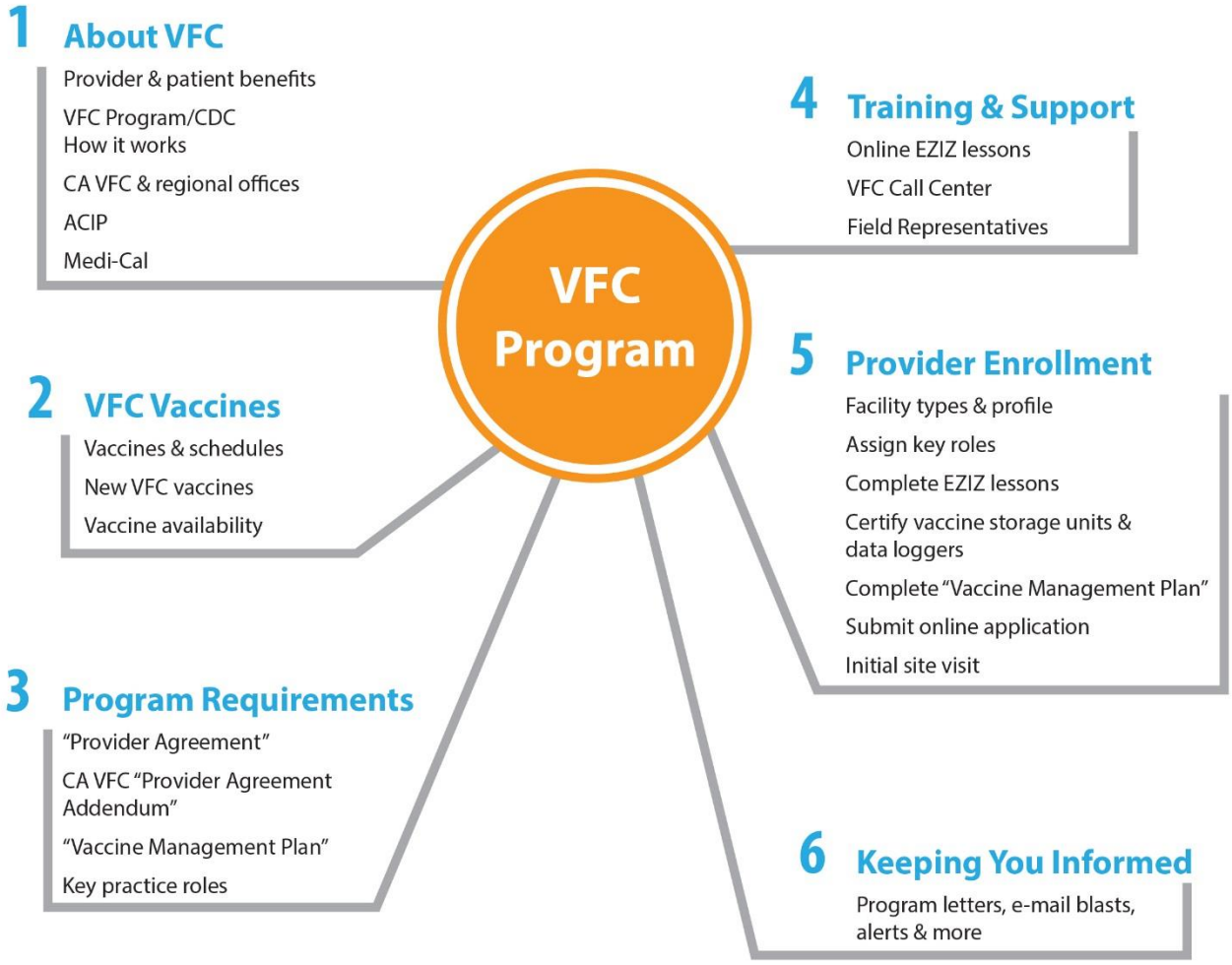

FIGURE 1.1. Overview of the topics orienting new providers to the VFC Program.

About VFC

Overview

A severe resurgence of measles in the Unites States between 1989 and 1991 resulted in more than 55,000 reported measles cases with over 11,000 hospitalizations and 123 deaths. Access to vaccines was not readily available at that time. The cases were mostly unvaccinated preschoolers, and the VFC Program launched emergency campaigns to respond to the outbreaks.[1]

In partial response to that epidemic, Congress passed the Omnibus Budget Reconciliation Act (OBRA) in 1993, creating the Vaccines for Children (VFC) Program.[2] The VFC Program became operational in 1994 as a federally funded, state-operated program that supplies vaccines at no charge to enrolled public and private providers who serve VFC-eligible children. This entitlement program is required as part of each state's Medicaid Plan.

Goals. The national program offers an unprecedented approach to improving immunization rates and seeks to

- help raise childhood immunization levels,
- provide vaccines at no cost to children whose parents or guardians might not be able to afford them,
- increase the likelihood of children getting their vaccinations on schedule, and
- keep children in their medical home by reducing the practice of referring children from the private to the public sector for immunizations.

Provider Benefits

The VFC Program offers benefits to providers who serve VFC-eligible children from birth through 18 years of age who might not otherwise be vaccinated due to an inability to pay:

- reduced up-front provider costs through federally supplied vaccines
- comprehensive vaccine coverage that allows providers to offer all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)[3]
- reintegration of immunization and primary care to retain children who might otherwise be referred elsewhere
- enhanced provider services to support populations receiving Medi-Cal-funded preventive care

Patient Benefits

Patient benefits ensure VFC-eligible children from birth through 18 years of age are vaccinated:

- all routine vaccines administered at no cost (providers may charge administration fees)
- convenient immunizations administered by providers in private or public medical facilities
- a stable, patient-centered medical home for coordinated and comprehensive health-care services

How the VFC Program Works

The following steps outline how the federal VFC Program works:

- CDC awards federal funding to state health departments, which implement and oversee VFC Program activities.
- State health departments enroll providers to increase immunizations in vulnerable populations.
- CDC contracts with vaccine manufacturers to buy vaccines at reduced rates.
- Enrolled VFC providers order federally funded vaccines through their state VFC Program and receive routine vaccines (including influenza) at no cost.

California providers enroll online, and once the application is approved, a regional VFC Field Representative will conduct a site visit to ensure that key practice staff are trained and the practice or clinic is certified to store and manage VFC-supplied vaccines.

Program Administration

The VFC Program is administered at the federal level by the Centers for Disease Control and Prevention (CDC) and the National Center for Immunization and Respiratory Diseases (NCIRD). The California VFC Program is administered by the California Department of Public Health (CDPH) Immunization Branch.

The California VFC Program[4] was created in 1995 and has enrolled more than 4,000 public and private provider sites since its inception. The state-operated program accounts for nearly 10% of the total doses of vaccines distributed nationwide—equivalent to more than ten million doses of federally purchased vaccines. The success of the program is largely due to the commitment by participating providers to ensuring California's children are protected from vaccine-preventable diseases.

Regional offices. California's VFC Program is comprised of the VFC Call Center as well as five regional offices based in Northern California, the San Francisco Bay Area, the Central Valley, Los Angeles, and Southern California.

ACIP

The Advisory Committee on Immunization Practices (ACIP)[3] was founded in 1964 as a federal advisory committee to reduce the incidence of vaccine-preventable diseases and increase the safe use of vaccines. The committee of medical and public health experts develops and issues written statements advising on the use of routine vaccines for both pediatric and adult populations.

ACIP's role in the VFC Program. ACIP's congressional mandate includes the authority to make recommendations for the VFC Program (as well as the general population) regarding recommended vaccines, age for vaccination, vaccination schedules (including number and timing of doses in a series), precautions, and contraindications.

Key functions. ACIP acts as advisor for CDC and the Department of Health and Human Services to determine which vaccines should be recommended and covered. ACIP

- develops recommendations on vaccine use and immunization practices;
- approves vaccines to be included in the VFC Program; and
- harmonizes immunization schedules with the American Academy of Pediatrics (AAP), the American Academy of Family Practitioners (AAFP), and the American College of Obstetricians and Gynecologists (ACOG).

The VFC Program and Medi-Cal

The VFC Program is required as part of each state's Medicaid Plan. The majority of children eligible for VFC-supplied vaccines is enrolled in each state's Medicaid plan, which is implemented in California as Medi-Cal.

Notes

1. Walter A. Orenstein, "The Role of Measles Elimination in Development of a National Immunization Program," *The Pediatric Infectious Disease Journal* (2006), search for "medscape the role of measles elimination in development of a national immunization program".
2. "The Vaccines for Children (VFC) Program," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/programs/vfc/index.html.
3. "Advisory Committee on Immunization Practices (ACIP)," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/acip/index.html.
4. California VFC Program, California Department of Public Health Immunization Branch, http://EZIZ.org.

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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 *Haemophilus influenzae* type b
HepA	Hepatitis A
HepB	Hepatitis B
Hib	*Haemophilus influenzae* 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)

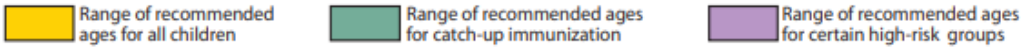
* ***Combination vaccines.*** In order to reduce the number of shots children must receive to stay current with ACIP-recommended immunizations, manufacturers combine two or more vaccines (that are available to be administered separately) into one shot. Refer to the "Immunization Schedule with Combination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

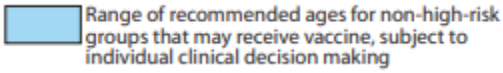
VFC providers agree to order and administer all ACIP-recommended vaccines to VFC-eligible children. Routine vaccine recommendations are identified on ACIP schedules with the following keys:



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 online order form. Vaccine status updates are posted on 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.

Key practice roles. Designation of key practice staff responsible for overseeing VFC-supplied vaccines is an important requirement that ensures successful compliance. Staff fulfilling key practice roles must be knowledgeable and trained in all VFC Program requirements. ***Important.*** Providers must report personnel changes to these roles through their MyVFCvaccines account or the VFC "Key Practice Staff Change Request Form."[6]

Provider of Record: The VFC Provider of Record is the physician-in-chief, medical director, or equivalent role that signs and agrees to the terms of the VFC "Provider Agreement" [3] and the California VFC Program "Provider Agreement Addendum" [4] and who is ultimately accountable for the practice's compliance. The Provider of Record must be a licensed MD, DO, NP, PA, pharmacist, or a Certified Nurse Midwife with prescription-writing privileges in California.

Provider of Record Designee: The VFC Provider of Record Designee is the on-site person that is designated by the Provider of Record to sign VFC documents on his/her behalf and assume responsibility for VFC-related matters in the absence of the Provider of Record.

Vaccine Coordinator: The VFC Vaccine Coordinator is an on-site employee who is fully trained and responsible for implementing and overseeing the provider's vaccine management plan. The Vaccine Coordinator might be responsible for all vaccine management activities, including training other (especially new) staff. In other practices, a different person might have one or more vaccine management responsibilities.

Backup Vaccine Coordinator: The VFC Backup Vaccine Coordinator is an on-site employee who is fully trained in the practice's vaccine management activities and fulfills the responsibilities of the Vaccine Coordinator if the Vaccine Coordinator is unavailable.

TABLE 3. Essential responsibilities for the Vaccine Coordinator and Backup

Responsibility	General Description
Receiving vaccines	Be present when vaccines are delivered, ensure acceptable temperatures were maintained during transport, and check for damage or shipping issues, which must be immediately reported
Storing vaccines	Prepare vaccine storage units to maintain stable temperatures, organize them for efficiency, configure data loggers with required settings, and store vaccines and diluents immediately upon receipt
Inventory management	Immediately add vaccines to inventory, rotate stock to ensure oldest vaccines are used first, remove all expired vaccines from storage units, and separate VFC-supplied vaccines from private stock
Monitoring temperatures	Use calibrated, compliant data loggers to record vaccine storage unit temperatures twice daily on VFC-supplied logs, take immediate action for out-of-range temperatures, and report temperature excursions immediately
Ordering vaccines	Conduct an inventory of VFC-supplied vaccines before ordering, account for vaccines returned/transferred since the previous order, and submit vaccine orders online

Attention providers. 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, practices and clinics must select for the roles of Vaccine Coordinator and its Backup those staff members who can consistently and accurately perform the responsibilities in **TABLE 3**. These roles might be filled by medical assistants, LVN, RN, office manager, or other trained staff.

Best Practices

Consider assigning the role of Immunization Champion to anyone on site who is passionate about immunizations. This is not an official role, but practices and clinics that assign an Immunization Champion often have better compliance rates. The Immunization Champion might

- Ensure staff know how to and are completing VFC eligibility screening and documentation consistently,
- Ensure vaccinators are consistently pulling from private or VFC stock as instructed in written orders,
- Ensure vaccinators are urging parent/guardian to schedule follow-up doses before leaving,
- Ensure vaccinators are educating patients and their parent/guardian about immunizations, and
- Research and collaborate with providers to implement essential immunization strategies practice-wide.

Notes

1. The "VFC Program Requirements" lesson can be found under the "EZIZ Training" menu at http://EZIZ.org.
2. The current "Program Participation Requirements at a Glance" document can be found by searching for "IMM-1240" at http://EZIZ.org.
3. The VFC "Provider Agreement" can be found by searching for "IMM-1241" at http://EZIZ.org.
4. The current California VFC Program "Provider Agreement Addendum" can be found by searching for "IMM-1242" at http://EZIZ.org.
5. The "Vaccine Management Plan" Word template can be found by clicking on "VFC Program" at http://EZIZ.org.
6. The VFC "Key Practice Staff Change Request Form" can be found by searching for "IMM-1166" at http://EZIZ.org.

Additional resources:

- The "Vaccine Coordinator" flyer can be found by searching for "IMM-968" at http://EZIZ.org.

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Training & Support

Overview

VFC providers and key practice staff must undergo annual training on key aspects of VFC Program requirements. To assist providers, the VFC Program offers convenient online training that fulfills federal education requirements. The VFC Call Center and regional VFC Field Representatives also train and support enrolled providers to ensure their success.

Program Requirements

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

- 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 (California VFC Program "Provider Agreement Addendum" #2A).
- Designate fully trained, on-site Vaccine Coordinator and Backup Vaccine Coordinator as detailed in "Vaccine Coordinator Roles & Responsibilities" (P.A.A. #2B).
- 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 (P.A.A. #2C).
- Ensure that staff are knowledgeable of and familiar with all ACIP-recommended immunizations including schedules, indications, dosages, and new products (P.A.A. #2D).
- 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 (P.A.A. #2E).
- Ensure staff authorized to accept packages are trained to immediately notify the Vaccine Coordinator when vaccines are delivered (P.A.A. #2F).
- Conduct regular vaccine transport drills to maintain competency and readiness for emergencies (P.A.A. #2G).
- 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" (P.A.A. #2H).

Best Practices

- All other staff (outside key practice roles) who are involved in immunizations, including front- and back-office staff, should be knowledgeable about VFC Program eligibility; they are encouraged to take the EZIZ training lessons.
- Clinic staff administering vaccines should demonstrate proficiency in administration techniques; provide refresher training as part of annual training or general staff meetings.

Importance of Vaccine Coordinator & Backup

The VFC Vaccine Coordinator and Backup are responsible for implementing the practice's vaccine management plan, which protects the viability of vaccines that might be worth from tens of thousands to more than $500,000 over the course of a year. Make sure staff filling these roles understand the impact they can have.

Staff must be properly trained on use of the practice's data loggers and the required corrective actions for out-of-range temperatures. Conduct regular vaccine transport drills to maintain staff competency and readiness for emergencies. Refer to "Responding to Vaccine-Related Emergencies" for details on drills. Encourage staff to consult with their supervisor or the VFC Call Center if they have questions about any vaccine-related tasks.

Other Vaccine-Related Training

Staff authorized to accept packages must be trained to immediately notify the Vaccine Coordinator when vaccines are delivered to ensure vaccines are stored promptly. Ensure that staff are knowledgeable of and familiar with all ACIP-recommended immunizations including schedules, indications, dosages, and new products.

Changes in Key Practice Staff

Report changes to key practice staff who have immunization responsibilities by updating the provider profile at MyVFCvaccines.org. Ensure staff assuming new immunization responsibilities complete all required EZIZ training lessons[1] and update the practice's vaccine management plan.[2]

EZIZ Training

All lessons can be found at EZIZ.org on the "EZIZ Training" page.[1] New providers and key practice staff will need to create an account to complete the required lessons.

TABLE 4. Online EZIZ training lessons required for key practice staff

Training	Learning Objectives	Roles
VFC Program Requirements lesson	Identify responsibilities of the Provider of Record and Vaccine Coordinator; comply with VFC Program requirements	Vaccine Coordinator & Backup, Provider of Record & Designee
Storing Vaccines lesson	Prepare refrigerators and freezers for vaccine storage; store vaccines in refrigerators and freezers; safeguard refrigerator and freezer power supplies	Vaccine Coordinator & Backup, Provider of Record & Designee
Monitoring Storage Unit Temperatures lesson	Read and record current, minimum, and maximum temperatures; identify temperatures that are too warm or too cold; take appropriate action	Vaccine Coordinator & Backup, Provider of Record & Designee
Conducting a Vaccine Inventory lesson	Conduct a physical inventory and record quantities on VFC Inventory Form for all VFC vaccines	Vaccine Coordinator & Backup

TABLE 5. Online EZIZ training recommended for key practice staff

Training	Learning Objectives	Roles
Preparing Vaccines lesson	Select vaccines based on physicians' orders; identify expired vaccines; mix, reconstitute, and draw up vaccines	Clinical staff
Administering Vaccines lesson	Identify correct needle lengths, insertion angles, and injection sites for intramuscular (IM) and subcutaneous (SC) injections; administer IM and SC injections	Clinical staff
"Immunization Techniques" video[3]	Best practices when administering vaccines to infants, children, and adults	Clinical staff

VFC Call Center

The VFC Call Center is an important resource for VFC providers. VFC Customer Service Representatives (CSRs) assist providers with a variety of issues:

- general program information and enrollment
- resolution of vaccine orders denied due to errors and omissions
- shipping discrepancies
- vaccine storage and handling issues
- vaccine returns or transfers

Contacting VFC. New VFC providers are assigned a unique six-digit PIN, which should be referenced when contacting the VFC Call Center or accessing MyVFCvaccines.org.

Hours of Operation	9:00 am to 5:00 pm, Monday through Friday
Telephone #	877-2GET-VFC or 877-243-8832
Fax #	877-329-9832
Mailing address	California Department of Public Health, Immunization Branch Vaccines for Children Program 850 Marina Bay Parkway, Building P, 2nd Floor Richmond, CA 94804-6403
Online provider account	MyVFCvaccines.org

FIGURE 1.2. VFC Program contact information.

VFC Field Representatives

VFC Field Representatives act as the primary liaisons between the VFC Program and California's prospective and enrolled providers. They work out of the California VFC Program's regional offices and perform a variety of support services for VFC providers:

- approve sites for enrollment
- conduct site visits
- assist with vaccine orders
- provide on-site training as learning gaps are identified
- provide answers for all things VFC

Providers can locate their regional Field Representative by clicking the "Find a VFC Field Representative in your area" link[4] on EZIZ.org.

Notes

1. Online EZIZ training lessons can be found under the "EZIZ Training" menu at http://EZIZ.org.
2. The "Vaccine Management Plan" Word template can be found by clicking on "VFC Program" at http://EZIZ.org.
3. *Immunization Techniques* video can be found under the "Resources" menu by clicking on "Vaccine Administration" at http://EZIZ.org.
4. "Find a VFC Field Representative in your area," EZIZ website, http://eziz.org/vfc/field-reps/.

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Provider Enrollment

Overview

Provider enrollment in the VFC Program begins online and concludes with an on-site visit by a regional VFC Field Representative. Enrollment requires estimating the number of VFC-eligible and non-VFC-eligible children to be immunized annually, ensuring vaccine storage units and temperature monitoring devices meet program requirements, and ensuring staff are properly trained to manage VFC-supplied vaccines. All program requirements must be met before the application is approved, the initial site visit is scheduled, and the initial vaccine order is submitted.

Target Audience

Provider of Record & Designee

Program Requirements

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

- VFC "Provider Agreement"[1] (federal agreement) and
- California VFC Program "Provider Agreement Addendum."[2]

Who May Enroll

Any provider who has a current California license with prescription-writing privileges and agrees to all terms of the VFC "Provider Agreement" [1] and the California VFC Program's "Provider Agreement Addendum"[2] may enroll.

Candidates for enrollment are typically licensed as a Medical Doctor (MD), Doctor of Osteopathy (DO), Nurse Practitioner (NP), Physician Assistant (PA), Pharmacist, or a Certified Nurse Midwife with prescription-writing privileges in the state of California.

Enrollment barriers. A provider may not enroll in the VFC Program if anyone in the practice or clinic

- has a complaint filed against him or her with the Office of Inspector General,
- is named on the "Medi-Cal Suspended and Ineligible Provider List", or
- has an invalid or non-active California license.

Notes on Medi-Cal and CHDP

Enrollment in Medi-Cal or Child Health and Disability Prevention (CHDP) is not required for enrollment; however, providers who wish to enroll in the Medi-Cal or the CHDP Program must enroll in the VFC Program first.

Facility Types

Table 6 identifies the types of facilities where VFC Providers of Record commonly work.

TABLE 6. Listing of common facility types

Public Types	
Public health department	American Indian/Tribal health clinic
Public health department/FQHC	Youth correctional facilities
Public hospital	School-based clinic
Federally Qualified Health Center (FQHC)	College/university
Rural Health Clinic (RHC)	Family planning/STD clinic
Other public health	Refugee health center
State-licensed community health center	Migrant health center
	Drug treatment center
Private Types	
Private practice (individual or group)	Pharmacy
Private hospital	Private other

Specialty or Specialty Practice Types	
Pediatrics	Multi-specialty
Family practice	OB/GYN
Internal medicine	Family planning
Adolescent health	American Indian/ Native American health clinic

Procedure

The enrollment process is detailed but straightforward, and the enrollment instructions and form are available online. Providers are walked through the steps listed in table 7. Note that completion of the online provider enrollment form is the last step.

TABLE 7. List of enrollment steps accessible from "VFC Program" – "Enrollment Steps and Forms" on EZIZ.org

Step	Description
1.	Ensure the Provider of Record and Designee have read the VFC "Provider Agreement"[1] and California VFC Program "Provider Agreement Addendum".[2]
2.	Designate key practice staff with VFC Program responsibilities—namely, Provider of Record (and Designee), Vaccine Coordinator (and Backup), Immunization Champion (optionally), and other staff with assigned vaccine management responsibilities.
3.	Ensure all required EZIZ training lessons[3] are completed by key practice staff.
4.	Download, complete, and sign the "Vaccine Management Plan."[4] (Refer to Chapter 3 "Vaccine Management Plan" for more details.) A. Download the recommended jobs aids and informational flyers.
5.	Ensure your practice is compliant with VFC Program vaccine storage unit and data logger specifications. ***Important.*** Some practices might need to purchase new vaccine refrigerators or freezers to meet VFC Program requirements.
6.	Download and complete the "Provider Enrollment Worksheet",[5] which will organize all required information in preparation for online enrollment: • Practice or clinic information/shipping • Facility type • Key practice staff (including current and valid medical license numbers and National Provider ID (NPI) numbers) • Completion of required EZIZ lessons (user ids and confirmation codes) • Vaccine storage units (brands/models for refrigerators and freezers) • Temperature monitoring equipment, backup devices, serial numbers, and calibration expiration dates; • Patient estimates (total VFC-eligible and non-VFC-eligible) • ACIP-recommended vaccines the practice or clinic will offer • List of health-care providers with prescription-writing privileges
7.	Complete, sign, and submit the online VFC "Provider Enrollment Form".[6] A. Ensure Provider of Record has reviewed the form before signing. B. For FQHC/RHC: Upload federal certificates (notice of FQHC designation issued by the Health Resources and Services Association (HRSA)), or alternatively fax to the VFC Call Center.

Final Steps

Representatives of the VFC Program review submitted enrollment forms, and if all required program elements are complete, the enrollment applications are approved and forwarded to the regional VFC Field Representative.

Initial site visit. All new providers must receive a VFC enrollment site visit—even if the provider has previously been enrolled. The purpose of this visit is to ensure that the provider and the key practice staff are educated on and have the appropriate resources to implement VFC Program requirements, including vaccine storage units and temperature monitoring devices that meet VFC Program requirements.

Initial vaccine order. Providers may not submit their initial vaccine order before the enrollment visit is successfully completed.

Provider Identification Number (PIN). Enrolled providers are assigned a unique six-digit Provider Identification Number (PIN). The PIN is to be used in all communications with the VFC Call Center and is required to order vaccines and access information at MyVFCvaccines.org. This number is different from a medical license, CHDP, or Medi-Cal provider number.

Changes in the Practice

To keep your provider profile current after enrollment, report immediately to VFC any changes in

- practice name, ownership, or affiliation (fax an official letter to the VFC Program);
- key practice staff who have completed all required EZIZ training lessons, practice address, and office hours (update account at MyVFCvaccines.org);
- Provider of Record (sign the VFC "Key Practice Staff Change Request Form"[7]);
- Provider of Record Designee (Provider of Record signs the VFC "Key Practice Staff Change Request Form"[7] to authorize that the Designee act on his/her behalf); and
- patient population (update account at MyVFCvaccines.org).

Notes

1. The VFC “Provider Agreement” can be found by searching for “IMM-1241” at http://EZIZ.org.
2. The current California VFC Program “Provider Agreement Addendum” can be found by searching for “IMM-1242” at http://EZIZ.org.
3. Online EZIZ training can be found under the “EZIZ Training” menu at http://EZIZ.org.
4. The “Vaccine Management Plan” Word template can be found by clicking on “VFC Program” at http://EZIZ.org.
5. VFC “Provider Enrollment Worksheet” can be found by searching for “IMM-1243” at http://EZIZ.org.
6. VFC “Provider Enrollment Form” can be found under the “VFC Program” menu at http://EZIZ.org.
7. The VFC “Key Practice Staff Change Request Form” can be found by searching for “IMM-1166” at http://EZIZ.org.

Additional resources:

- The “Vaccine Coordinator” flyer can be found by searching for “IMM-968” at http://EZIZ.org.

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Keeping You Informed

Overview

Because immunization is a dynamic field, the VFC Program communicates frequently with providers after enrollment to keep them current. Program communications are e-mailed to the site's Provider of Record, and any additional staff as requested.

EZIZ.org

The VFC Program is committed to being a green organization. The California VFC Program relies primarily on e-mail communications, so practices and clinics must maintain a current and valid e-mail account. Archived VFC Program communications[1] are posted on the home page at EZIZ.org.

Best Practices

All staff involved in immunizations are encouraged to sign up to receive EZIZ news and VFC letters via e-mail from the EZIZ.org home page. Providers are strongly encouraged to share and discuss all VFC-related information with staff.

Communication Methods

The VFC Program communicates with providers via the methods listed in table 8.

Table 8. Categories of VFC Program communication methods

Method	Description
VFC Program letters	Official VFC communications containing program information like vaccine recommendations and schedules, new requirements, recertification timelines, and timely information on vaccine shortages and delays.
Order information	E-mails sent when vaccine requests are submitted, approved, or denied and forwarded to the distributor(s) for fulfillment; confirmations are e-mailed directly to the Vaccine Coordinator.
Compliance reports	Communications generated by VFC Field Representatives following site visits are tailored to each practice and describe necessary actions to achieve compliance; reports are sent to the Provider of Record and additional staff as requested.
E-mail blasts	Brief messages alerting providers about vaccine supply issues (e.g., temporary vaccine recalls and temporary suspension) and reminders (e.g., upcoming deadlines); messages are sent to key practice staff who have signed up to receive notifications.
Vaccine tips	One-page flyers (generated about once a month) with helpful reminders about successful immunization practices.
EZIZ.org alerts	Communications with information about trainings, new projects, campaigns, and other helpful resources.

Notes

1. Archived communications can be found by clicking the "VFC Memos" and "From CDPH" links at http://EZIZ.org.

Quick Start Guide

Initial Storage Unit & Device Setup	• Use vaccine storage units and digital data loggers that meet VFC Program requirements. (Refer to "Vaccine Storage Unit Specifications" and "Data Logger Specifications.") • Configure all storage units and digital data loggers to meet VFC Program requirements. (Refer to "Configuring Vaccine Storage Units" and "Configuring Data Loggers.") • Post VFC-supplied temperature logs on vaccine storage unit doors, or nearby in an accessible location. • Do not store vaccines in storage units until temperatures are stable (refrigerators at around 40.0°F and freezers below 0.0°F) for 3–5 days.
Daily Tasks	• Read and record storage unit temperatures accurately, neatly, and twice a day, when the clinic opens and before it closes. (Refer to "Monitoring Storage Unit Temperatures.") • Document temperatures on VFC refrigerator (Fahrenheit | Celsius) and freezer (Fahrenheit | Celsius) temperature logs. (Refer to "Monitoring Storage Unit Temperatures.") • Take immediate action for temperature excursions, if any, to protect vaccines. (Refer to "Taking Action for Temperature Excursions.")
Bi-Weekly Tasks	• Supervisor: Certify and sign that temperatures were recorded twice daily, staff printed names and initials, and corrective actions were taken—for each two-week reporting period. (Refer to "Monitoring Storage Unit Temperatures.") • Download and review data files at the end of every two-week reporting period to look for missed excursions or temperature trends that might indicate performance issues with vaccine storage units. (Refer to "Monitoring Storage Unit Temperatures.")
Monthly Tasks	• Conduct a careful and accurate physical vaccine inventory and complete the VFC "Vaccine Physical Inventory Form" or electronic equivalent. (Refer to "Conducting a Physical Vaccine Inventory.") • Check vaccine expiration dates and rotate stock to place vaccines that will expire soonest in front of those with later expiration dates. • Transfer vaccines that will expire within six months to other VFC providers. (Refer to "Transferring Vaccines between Providers.")
Annual	• Allocate time for and complete VFC recertification. • Calibrate primary and backup temperature monitoring devices annually (or every other year if the manufacturer's recommendation is for a longer period) following VFC Program requirements. (Refer to "Configuring Data Loggers" for routine maintenance.) • Review and update the practice's vaccine management plan. (Refer to "Vaccine Management Plan.") • Review with key practice staff the vaccine management plan's section on preparing for and responding to vaccine-related emergencies and conduct regular vaccine transport drills to maintain competency.
At Each Immunization Visit	• Conduct eligibility screening for all children through 18 years of age. (Refer to "Conducting Eligibility Screening.") • Review immunization records and recommend all age-appropriate ACIP-recommended vaccines. (Refer to "Reviewing Immunization Records.")

- Administer vaccines and update VFC daily usage logs with doses used. (Refer to "Administering Vaccines.")

When Ordering Routine Vaccines

- Return any spoiled and expired vaccines. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines.")
- Complete any transfers between providers. (Refer to "Transferring Vaccines between Providers.")
- Determine total doses administered since previous order using VFC daily usage logs or equivalent. (Refer to "Administering Vaccines.")
- Conduct a careful and accurate physical vaccine inventory to determine total doses on hand by vaccine. (Refer to "Conducting a Physical Vaccine Inventory.")
- Calculate the doses to order using the VFC "Vaccine Ordering Worksheet" (IMM-1246). (Refer to "Submitting Routine Vaccine Orders.")
- Submit routine vaccine orders according to provider category and order frequency. (Refer to "Submitting Routine Vaccine Orders.")

When Receiving Vaccine Deliveries

- Inspect packages carefully and complete the VFC "Vaccine Receiving Log and Checklist" to report damage or discrepancies immediately. (Refer to "Receiving Vaccine Deliveries.")
- Store vaccines and diluent immediately and rotate stock. (Refer to "Storing Vaccines.")

To Minimize Loss

- Transfer to other VFC providers vaccines that will expire within six months. (Refer to "Transferring Vaccines between Providers.")
- Respond to planned or sudden vaccine-related emergencies following practice or clinic vaccine management plan. (Refer to "Responding to Vaccine-Related Emergencies.")
- Confirm clinic delivery hours when submitting routine vaccine orders are available to receive vaccines.

Spoiled, Expired & Wasted Vaccines

- Return any spoiled and expired vaccines (within six months of expiration) for excise tax credit. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines.")
- Properly dispose of wasted vaccines. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines.")

Changes in Key Practice Staff

- 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).
- Ensure new key practice staff complete EZIZ lessons, demonstrate competency in their assigned VFC responsibilities, and are knowledgeable of and familiar with ACIP-recommended immunizations, including schedules, indications, dosages, and new products.

Routine Maintenance

- Establish regular routine for cleaning vaccine storage units and defrosting manual-defrost freezers. (Refer to "Configuring Vaccine Storage Units.")
- Replace batteries in data loggers every six months. (Refer to "Configuring Data Loggers" for routine maintenance.)

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Patient Vaccinations

Chapter Two
clickable topics

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Introduction

In California, VFC providers vaccinate over 50% of children from birth through 18 years. By offering vaccines at no cost to VFC-eligible children and reintegrating vaccinations with primary care, providers are uniquely positioned to influence healthy immunization levels in their local communities. Why?

- Parents are likely to follow vaccine recommendations of their child's doctor—even when the adults were initially reluctant.[1]
- Adolescent immunizations are lagging behind childhood immunizations in California, which means missed immunization opportunities.
- Fewer than 70% of health-care providers typically receive influenza vaccine,[1] creating an opportunity for increased expansion of health-care prevention and maintenance.

Figure 2.1 highlights the key topics covered in chapter two.

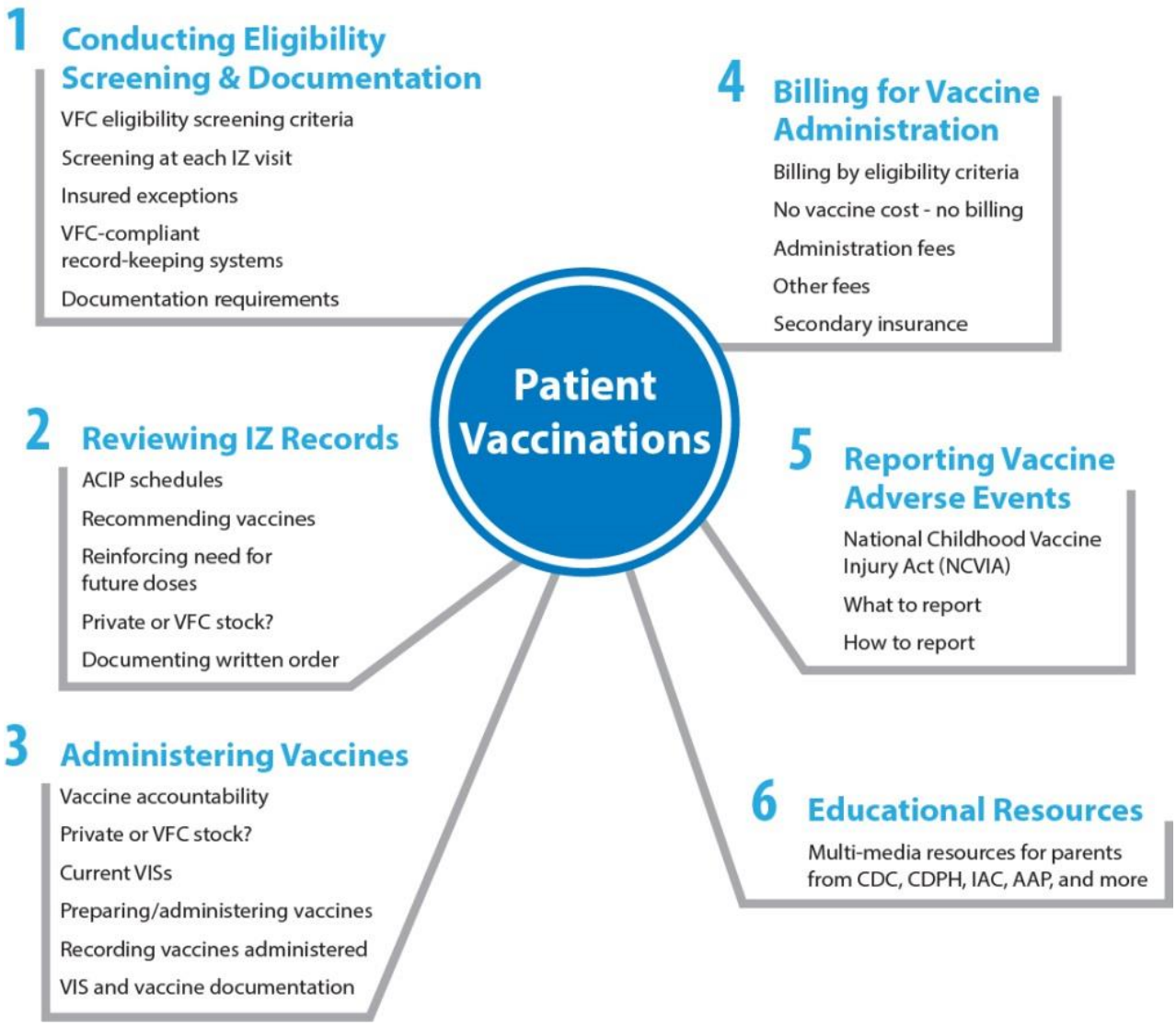

FIGURE 2.1. Overview of the key topics of patient vaccinations.

Conducting Eligibility Screening & Documentation

Overview

Eligibility screening and documentation is a key procedure that impacts downstream vaccine administration and accurate billing of the appropriate party. It's typically conducted when the immunization visit is scheduled. 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.

Target Audience

Typically front-office staff; office managers and 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).
- Federally funded vaccine-eligible children include American Indian or Alaskan Native, Medicaid-eligible, uninsured, or underinsured and served in Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHC) (P.A. #2).
- No other factor(s) may be considered when screening for eligibility (P.A. #2).
- Document the eligibility criterion (or status) that was met in the child's permanent medical record for each immunization visit (P.A. #2).
- Providers must maintain all records related to the VFC Program (including VFC screening and eligibility documentation) for a minimum of three years and upon request make these records available for review (P.A. #4).
- Pharmacies, urgent care, and school-located vaccine clinics must agree to vaccinate all "walk-in" (not just established) VFC-eligible children and must never refuse to vaccinate VFC-eligible children because the child's parent or guardian is unable to pay the administration fee (P.A. #12).

Rationale

The VFC Program is an entitlement program. Children must meet federal VFC eligibility criteria to receive publicly funded vaccines. Providers must document the screenings and retain eligibility documentation to prove compliance and ensure vaccines are going to the intended populations. Failure to comply is grounds for immediate suspension and a site visit, and might lead to termination if compliance issues are not resolved.

VFC Eligibility Criteria

Children from birth through 18 years of age must meet at least one of the criteria in table 1 *at each immunization visit* to be eligible to receive VFC-supplied vaccines. Verification of a parent's response or self-identification of eligibility criterion (or criteria) is not required.

TABLE 1. VFC-approved eligibility criteria (or status)

Criterion	Description
Medicaid eligible (or enrolled)	Has Medi-Cal or California's Child Health and Disability Prevention (CHDP) as primary or secondary coverage
American Indian (AI) or Alaskan Native (AN)	As defined by the Indian Health Care Improvement Act[1]
Uninsured	No health insurance coverage
Underinsured	Health insurance doesn't cover vaccines, doesn't cover all ACIP-recommended vaccines, or covers vaccines but with a fixed dollar limit (or cap); underinsured patients are only eligible to receive VFC vaccines at FQHC or RHC facilities.

Important. No other factor(s) may be considered when screening children for eligibility.

Examples of Children *Not* Eligible

- Children whose health insurance covers the cost of vaccinations are not eligible for VFC vaccines—even when a claim would be denied for payment because the plan's deductible has not been met.
- Children covered by medical savings or health savings accounts are not eligible.

If Multiple Eligibility Criteria Apply

Providers should select the eligibility criterion (or criteria) that requires the least amount of out-of-pocket expenses for the parent or guardian. Refer to table 2 for examples of how to record multiple eligibility criteria in screening systems.

TABLE 2. Sample entries for children with multiple eligibility criteria

Eligibility criteria	Screening-system entry
AI/AN & on Medi-Cal	Select "Medi-Cal" (and "AI/AN" if system allows two). Why? Medi-Cal will be responsible for administration fee.
AI/AN & Uninsured	Select "AI/AN" (and "Uninsured" if the system allows two). Why? "AI/AN" is the permanent eligibility criterion. Parent or guardian will be billed for the administration fee, which must be waived if due to inability to pay.
AI/AN & Underinsured	Select "AI/AN" (and "Underinsured" if the system allows two). Why? "AI/AN" is the permanent eligibility criterion and allows vaccination at any provider facility—not just FQHC/RHC. Parent or guardian will be billed for the administration fee, which must be waived if due to inability to pay. (Refer to "Billing for Vaccine Administration" for more details.)
Underinsured & Medi-Cal (as secondary)	Select "Medi-Cal" (and "Underinsured" if system allows two). Why? Medi-Cal will be responsible for administration fee, and the child will be covered in all provider settings—not just FQHC/RHC. (Refer to "Billing for Vaccine Administration" for more details.)

Insured Exceptions

In limited situations, insured children might be eligible to receive VFC vaccines:

- *AI/AN children with private health insurance that covers immunizations:* Insured American Indian and Alaskan Native children may be screened as "AI/AN" and are always eligible.
- *Insured with Medi-Cal as secondary insurance:* These children may be screened as "Medicaid eligible" because they are enrolled in Medi-Cal. (Refer to "Billing for Vaccine Administration" for more details.)
- Persons under 19 years of age who are incarcerated in detention centers and lost access to their parent's insurance benefits as a result of incarceration may be screened as "uninsured."

Refer to **TABLE 4** for a summary of other eligibility screening scenarios.

Exceptions for Family Planning Clinics

Persons under 19 years of age who have insurance, but because of the confidential circumstances of seeking services in a family planning clinic* do not have access to that insurance, may be screened as "uninsured."

* CDC defines a family planning clinic as a clinic or provider whose purpose is to prescribe contraceptives and/or treat sexually transmitted diseases. School-based clinics or any VFC-enrolled provider whose main services are primary or acute care services do not meet CDC's definition of a family planning clinic and may not use this VFC eligibility criterion.

Pharmacies, Urgent Care, and School-Located Vaccination Clinics

Every patient seeking immunization services in pharmacy settings is considered an established patient. Therefore, pharmacies, urgent care, and school-located vaccine clinics agree to vaccinate all walk-in, VFC-eligible children. In these settings, vaccination of VFC-eligible children may not be denied due to a parent's inability to pay the administration fee.

VFC-Compliant Record Keeping Systems

Providers must document the results of the eligibility screening in the child's permanent medical record using any of these VFC-compliant record keeping systems:

- Electronic Medical Record (EMR)/Electronic Health Record (EHR) system
- Electronic immunization registry
- VFC "Patient Eligibility Screening Record"[2] or other paper chart

By federal law, the child's permanent medical record (electronic or paper) must reflect the following VFC eligibility data:

- screening date
- VFC eligibility (Y/N)
- eligibility criterion (or criteria) that was met

Important. If the electronic system does not store the federally required VFC eligibility data, providers must supplement the permanent record (e.g., by using VFC "Patient Eligibility Screening Record" [2] or equivalent) to store the required data.

Procedure

Incorporate these instructions into practice protocols to conduct eligibility screening and documentation in compliance with VFC Program requirements and best practices.

TABLE 3. Instructions for conducting eligibility screening & documentation

Step	Description
1.	Conduct insurance verification per office protocol.
2.	Screen for VFC eligibility at every immunization visit: A. Verify children are through 18 years of age. B. Verify children meet at least one of the four VFC eligibility criteria: Self-reported **Eligibility Criteria** Medi-Cal Eligible American Indian/AK Native Uninsured Underinsured (FQHC/RHC) ***Important.*** Do not use any other factor(s) when screening children for eligibility.
3.	Ensure the child may be vaccinated in your facility; namely, underinsured children are eligible to receive VFC-supplied vaccines only through a FQHC or RHC.
4.	Document VFC eligibility in the child's permanent medical record, using any VFC-compliant record keeping system, including • screening date, • VFC eligibility (Y/N), and • eligibility criterion (or criteria) that was met. ***No access to an immunization registry or EHR/EMR?*** Consider using the VFC "Patient Eligibility Screening Record for VFC Program".[2]

TABLE 4. Summary of VFC eligibility scenarios, insurance status, and eligibility outcomes

VFC eligibility scenario	Insurance status	Is child VFC-eligible?
Medi-Cal eligible	Active at the time of the immunization visit	Yes
American Indian/Alaskan Native	Any or no insurance	Yes
Uninsured	No	Yes
Underinsured	Yes but health insurance doesn't cover vaccines, doesn't cover all ACIP-recommended vaccines, or covers vaccines but with a fixed dollar limit	Yes, but underinsured patients are only eligible to receive VFC vaccines at FQHC or RHC facilities.
Child has insurance, but plan limits coverage to a specific number of provider visits annually	Underinsured (once the limited number of visits has been reached during the year)	Yes, once the limited number of visits has been reached and only if administered by a FQHCs or RHCs
Child is seeking contraceptive or STD services at family planning or STD clinic and wants to be immunized but does not want to access insurance or doesn't know status	Uninsured	Yes
Child has Medi-Cal as secondary insurance	Medi-Cal eligible	Yes
Plan covers only a portion of the vaccine cost and has Medi-Cal as secondary insurance	Medi-Cal eligible	Yes
Child has not yet met plan's deductible and has Medi-Cal as secondary insurance	Medi-Cal eligible	Yes
Child cannot access health insurance due to being incarcerated	Uninsured	Yes
Child has not met plan's deductible	Insured	No
Plan covers all ACIP-recommended vaccines but excludes certain products/combination vaccines	Insured	No
Plan covers only a portion of the vaccine cost and does not have Medi-Cal as secondary insurance	Insured	No
Child is seeking contraceptive or STD services at a school-based clinic or facility whose main services are primary or acute care; child wants to be immunized but does not want to access insurance	Insured	No

Child is enrolled in a Health-Care Sharing Ministry (HCSM), nonprofit alternatives to purchasing health insurance from private, for-profit insurers. Generally, HCSMs are organizations whose members share a common belief system and collectively share the cost of their members' medical care.	Uninsured, as health-care sharing ministries are not recognized as insurance by the state of California	Yes

Notes

1. "Indian Health Care Improvement Act," Indian Health Service website, https://www.ihs.gov/ihcia/.
2. VFC "Patient Eligibility Screening Record" can be found by searching for "IMM-1111" at http://EZIZ.org.

Additional resources:

- VFC "Eligibility Screening & Documentation Requirements" can be found by searching for "IMM-1161" at http://EZIZ.org.
- VFC "Who's Eligible" can be found by searching for "IMM-1088" at http://EZIZ.org.
- VFC "Eligibility Table Tent" (IMM-1221) can be obtained by contacting a VFC Field Representative.

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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" form[1] (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 rates[2] 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. ***No access to an immunization registry or EHR/EMR?*** 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. Do not refer patients to other facilities where they might be charged for vaccine administration. B. 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.

Transcribing Immunizations

Immunization records from other providers must be transcribed into the child's permanent medical record (electronic or paper) to reflect a complete immunization history. When transcribing immunization records, document the date the vaccine was given, the full name of the practice, and write "transcribed" to clearly identify that the vaccine was given elsewhere.

Administering 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. Vaccinating patients in this scenario might be done two ways, as determined by the provider:

- Pull from private stock (the patient's primary insurance should be billed for vaccine cost and administration), or
- Pull from VFC-supplied doses (Medi-Cal should be billed for the vaccine administration fee). There is no out-of-pocket expense for the parent or guardian with this option.

(Refer to "Billing for Vaccine Administration" for more details.)

IMPORTANT. Providers should select the vaccine inventory that is most cost-efficient for the family and train their staff accordingly. Be sure to provide clear instructions to those responsible for vaccine administration.

Vaccine Information Statements (VISs)

Providers are required to distribute the current Vaccine Information Statements (VISs) each time a vaccine is administered—including each dose in a series—and document and maintain records in accordance with the National Childhood Vaccine Injury Act (NCVIA). Vaccine Information Statements (VISs) are produced by CDC, in consultation with panels of experts and parents, to educate the public about the benefits and risks of vaccines. For a list of current VISs, visit http://www.cdc.gov/vaccines/hcp/vis/.[1] Key points:

- VISs must be distributed to all patients *before* vaccine administration—in both private and public settings.
- Providers must distribute the most current version, in either paper or electronic formats. (Some EMR/EHR systems don't update VISs automatically.)
- VISs must be distributed for each dose administered—including combination vaccines.
- VISs should be given in the language that the recipient can easily understand, and they are available in multiple languages under "Vaccine Information Statements"[1]
- Signed consent is not required for a person to be vaccinated.
- VISs must not be altered before distribution to the patient, parent, or guardian.

Vaccine Dose Documentation

In accordance with federal law, all providers must maintain immunization records that include all of the following elements:

- VIS edition date
- Date the VIS is distributed
- Practice address and name/title of the person who administered vaccine(s)
- Vaccine and date administered
- Vaccine manufacturer and lot number

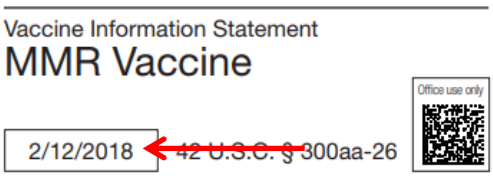

FIGURE 2.2. Edition date found on the back of the VIS in the right bottom corner.

Minimum Intervals

CDC encourages using the shortest interval to complete immunizations. For example, when a VFC-eligible child is in the four- to five-month interval between doses of DTaP, target the four-month date for receiving the next dose rather than waiting the maximum five months. Encourage the parent or guardian to schedule the next dose but caution them not to get the dose before the minimum interval is reached.

Birth to 15 Months

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos
Hepatitis B[1] (HepB)	1st dose	←2nd dose→			←3rd dose→			
Rotavirus[2] (RV) RV1 (2-dose series); RV5 (3-doses series)			1st dose	2nd dose	See footnote 2			
Diphtheria, tetanus, & acellular pertussis[3] (DTaP: <7 yrs)			1st dose	2nd dose	3rd dose			←4th dose→

IMAGE 2.3. Screenshot from CDC's "Recommended Immunization Schedule for Persons Aged 0 through 18 Years".[2]

Vaccine Preparation

CDC recommends preparing vaccines immediately prior to administration in order to assure vaccine viability and prevent waste. Vaccines that are not administered immediately are at risk of exposure to temperatures outside of the required range, which can affect viability and, ultimately, might leave children unprotected against vaccine-preventable diseases.

Vaccine Accountability

All doses removed from the storage unit and administered must be totaled by vaccine type and recorded—either electronically through an EMR/EHR or immunization registry, or on a daily usage log. Accurate accounting of doses administered helps ensure that future orders meet actual need and reduces the likelihood of vaccine orders being denied due to accountability issues.

How do practices benefit? Accurately logging doses administered helps practices assess immunization rates in their patient populations. It also helps identify non-vaccinated children who might need to be quarantined in the event of a public health intervention in response to outbreaks and epidemics.

Additionally, in the event of a vaccine recall, practices can easily determine which patients received a specific vaccine and how many must be recalled to ensure protection against vaccine-preventable diseases.

Vaccines & Administration Routes

Refer to table 6 to identify correct anatomic sites before vaccine administration.

TABLE 6. Vaccines and correct administration routes

Vaccine	Administration route
DTaP	intramuscular
DTaP-HepB-IPV	intramuscular
DTaP-IPV	intramuscular
DTaP-IPV/Hib	intramuscular
HepA	intramuscular
HepB	intramuscular
Hib	intramuscular
HPV	intramuscular
Influenza	intramuscular
IPV	intramuscular or subcutaneous
MCV4 or MenB	intramuscular
MMR	subcutaneous
MMRV	subcutaneous
PCV13 or PPSV23	intramuscular
RV	oral
Td	intramuscular
Tdap	intramuscular
VAR	subcutaneous

Procedure

Incorporate these instructions into existing practice protocols to administer vaccines in compliance with federal and VFC Program requirements and best practices.

TABLE 7. Instructions for administering VFC-supplied vaccines

Step	Description
1.	Review the physician's written order to determine vaccines to administer.
2.	Distribute the Vaccine Information Statement (VIS) for each vaccine *before* vaccine administration and educate the family as necessary. • ***Tip.*** The current VIS must be given with every vaccination—including each dose in a multi-dose series and combination vaccines.
3.	Pull from VFC-supplied or private stock as instructed or based on eligibility. • Never borrow from VFC-supplied vaccines for private use. • Check with supervisor if instructions are not clear or complete.
4.	Double check the selected vaccines for accuracy and expiration. A. Double check each vaccine against physician's written order to prevent vaccination with the wrong vaccine. B. Use vaccines with the earliest expiration dates first. ***Do NOT use expired vaccines.***
5.	Sort vaccines by administration route to quickly determine the number of needles to select. (Refer to **TABLE 6** for assistance.)
6.	Before you start: A. Wash your hands. B. Gather alcohol, syringe, and appropriate needles as needed. C. Intramuscular route: Vaccines require 1-inch, 23- or 25- gauge needle. For heavier or larger patients, consider a 1-1/2" needle. D. Subcutaneous route: Vaccines require 5/8-inch, 25-gauge needle.
7.	Prepare vaccines according to practice protocols. ***Tips:*** • Refer to "Preparing Liquid Vaccines"[3] for more details. • Refer to "Preparing Reconstituted Vaccines"[4] for more details. • Use only the diluent that comes with the vaccine for reconstitution.
8.	Administer vaccine(s) in the correct anatomic site per practice protocol.

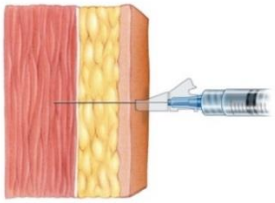

FIGURE 2.4. Proper 90° angle for intramuscular injection.

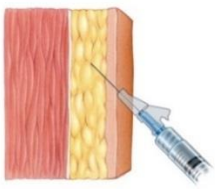

FIGURE 2.5. Proper 45° angle for subcutaneous injection.

- Refer to "Anatomic Sites for Immunization" poster[5] for assistance with infant/toddler or child/adult injections.
- Refer to "Administering Injectable Vaccines"[6] for more details.

9. Allow the patient to sit for at least a few minutes following vaccination.
   - ***Tip.*** Consider observing vaccinated adolescents (with patients seated or lying down) for 15 minutes after vaccination to decrease the risk of fainting.

10. Document the following information in the patient's permanent medical record:

    - VIS edition date
    - date VIS is distributed
    - practice name and address
    - date vaccine administered
    - trade name/manufacturer and lot number
    - administration site (e.g., left deltoid, etc.)
    - vaccinator name and title
    - vaccine administered

    No access to an immunization registry or EHR/EMR?

    Update the child's permanent medical record using the CDPH "Immunization Record and History"[7] or other chart.

    Document each dose administered to ensure all vaccines are accounted for using VFC (or equivalent)
    - "Daily Usage Log"[8] accountability form,
    - "Flu Usage Log" [9] accountability form, or
    - "Daily Usage Log - Private Vaccine"[10] accountability form.

11. Request that the parent/guardian complete the AAP "Refusal to Vaccinate" form[1] (or equivalent) if appropriate.

12. Print a copy of the immunization history for parent or guardian.

    No access to an immunization registry or EHR/EMR?

    Complete the child's "Immunization Record"[11] (or equivalent).

Reporting Vaccination Errors

Always double check each vaccine against the physician's written order to prevent vaccination with the wrong vaccine. In the event of accidents, report errors to the national Vaccine Errors Reporting Program (VERP) website,[12] including incorrect doses, wrong or expired vaccines, and wrong administration sites.

Notes

1. "Vaccine Information Statements," Immunization Action Coalition, http://www.immunize.org/vis/.
2. "Birth-18 Years Recommended Immunization Schedule," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html.
3. VFC "Preparing Liquid Vaccines" can be found by searching for "IMM-896" at http://EZIZ.org.
4. VFC "Preparing Reconstituted Vaccines" can be found by searching for "IMM-897" at http://EZIZ.org.
5. "Anatomic Sites for Immunization" poster can be found by searching for "IMM-685" at http://EZIZ.org.
6. VFC "Administering Injectable Vaccines" can be found by searching for "IMM-898" at http://EZIZ.org.

7. CDPH "Immunization Record and History" form can be found by searching for "IMM-542P" at http://EZIZ.org.
8. VFC "Daily Usage Log" can be found by searching for "IMM-1053" at http://EZIZ.org.
9. VFC "Flu Usage Log" can be found by searching for "IMM-1053F" at http://EZIZ.org.
10. VFC "Daily Usage Log – Private Vaccine" can be found by searching for "IMM-1053P" at http://EZIZ.org.
11. The California "Immunization Record" can be found by searching for "IMM-75LK" at http://EZIZ.org.
12. ISMP National Vaccine Errors Reporting Program, http://verp.ismp.org/.

Additional resources:

- The "Preparing Vaccines" lesson can be found under the "EZIZ Training" menu at http://EZIZ.org.
- The "Administering Vaccines" lesson can be found under the "EZIZ Training" menu at http://EZIZ.org.
- Job aids and other resources can be found under the "Resources" menu by clicking on "Vaccine Administration" at http://EZIZ.org.
- "Top 10 Facts about VISs," Immunization Action Coalition, http://www.immunize.org/catg.d/p2027.pdf.
- "Skills Checklist for Pediatric Immunization" can be found by searching for "IMM-694" at http://EZIZ.org.
- *Immunization Techniques Video* can be found under the "Resources" menu by clicking on "Vaccine Administration" at http://EZIZ.org.
- VFC "Immunization Site Map" can be found by searching for "IMM-718" at http://EZIZ.org.

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Reporting Vaccine Adverse Events

Overview

In 1986, Congress passed the National Childhood Vaccine Injury Act (NCVIA), which mandates that all health-care providers report adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).[1] VAERS is a safety surveillance program through which vaccine safety-related information is analyzed and disseminated to the public.

Target Audience

Typically front-office staff and medical assistants; Immunization Champion

Program Requirements

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

- 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) (VFC "Provider Agreement" #8).

What is VAERS?

The Vaccine Adverse Event Reporting System is a national vaccine safety program co-sponsored by CDC and the Food and Drug Administration (FDA).

According to CDC, while clinical trials provide important information on vaccine safety, rare side effects and delayed reactions might not be evident until the vaccine is administered to millions of people. Therefore, the federal government established the Vaccine Adverse Event Reporting System to monitor adverse events following vaccination.[2]

According to the VAERS website, "VAERS provides a nationwide mechanism by which adverse events following immunization may be reported, analyzed, and made available to the public. VAERS also provides a vehicle for disseminating vaccine safety-related information to parents and guardians, health care providers, vaccine manufacturers, state vaccine programs, and other constituencies."[3]

Procedure

To report vaccine adverse effects in compliance with federal and VFC Program requirements, go to https://vaers.hhs.gov/ and follow the instructions on the website.

Notes

1. "Vaccine Adverse Event Reporting System," Centers for Disease Control and Prevention, website, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html.
2. "History of Vaccine Safety," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html.
3. "Vaccine Adverse Event Reporting System (VAERS)," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html.

Additional resources:

- "VAERS and VERP" can be found by searching for "IMM-1153" at http://EZIZ.org.

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Billing for Vaccine Administration

Overview

Providers must use screening results to ensure that only VFC-eligible children receive VFC-supplied vaccines and that administration fees are billed as appropriate. Established patients cannot be turned away or reported to collections for inability to pay the administration fee.

Target Audience

Typically medical billing and coding specialists or office managers; Immunization Champion

Program Requirements

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

- Maintain all records related to the VFC Program (including billing records) for a minimum of three years and upon request make these records available for review (VFC "Provider Agreement" #4).
- Agree to immunize VFC-eligible children with publicly supplied vaccine at no charge to the patient for the vaccine (P.A. #5).
- For Medi-Cal children, agree to accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans (P.A. #6).
- For non-Medi-Cal VFC-eligible children, agree not to charge a vaccine administration fee that exceeds the administration fee cap of $26.03 per vaccine dose (P.A. #6).
- 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).
- For pharmacies, urgent care, or school located vaccine clinics, I agree to:
- Vaccinate all "walk-in" VFC-eligible children and
- Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee (P.A. #12).
- 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 (California VFC Program "Provider Agreement Addendum" #14F).
- For Medi-Cal children, never bill the difference between Medi-Cal's administration fee and the administration fee cap to the parent/guardian (P.A.A. #14G).

Rationale

VFC-supplied vaccines are provided at no cost to both the VFC provider and VFC-eligible children. At no time should billing occur for the cost of VFC vaccines. Billing for the cost of vaccines is prohibited by federal law, and billing constitutes fraud or abuse and might lead to termination from the VFC Program. Providers must never bill two different payers (i.e., patient, Medi-Cal, insurance) for the same vaccine administration fee.

Best Practices

- Ensure clinic billing staff are familiar with VFC eligibility categories and maximum vaccine administrative fees.
- Providers are encouraged to clearly outline the breakdown of fees associated with vaccine administration and office visits to prevent patient confusion.

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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Educational Resources for Families

Overview

While occurrence of vaccine-preventable disease is rare within the United States, the resurgence of pertussis, expanded immunization recommendations for seasonal flu and HPV, and the rise of unvaccinated travelers returning infected from other countries have raised awareness of gaps in immunization efforts:

- 2015: Large multi-state measles outbreak linked to a California amusement park[1]
- 2014: 23 measles outbreaks with many US cases linked to cases brought in from the Philippines[2]
- 2014: Pertussis epidemic declared in CA; incidence of pertussis peaks every 3- 5 years[3]
- 2011: More than 30 countries reported increase in measles [1]
- 2010: Everyone 6 months of age and older should now get a flu vaccine every season[1]

Target Audience

Immunization Champion

Best Practices

Refer parents and guardians to these resources to educate them about vaccine benefits:

TABLE 9. Immunization resources for parents and guardians

Topic	Resource	Source
General Vaccines	"Parents' Guide to Childhood Immunizations"[4]	CDC
	"For Parents: Vaccines for Your Children"[5]	CDC
	"Instant Childhood Immunization Schedule"[6]	CDC
	"Immunization Promotional Materials for Staff and Patients"[7]	CDPH (EZIZ)
	"Educating Patients & Parents"[8]	CDPH (EZIZ)
	"Be there for your child during shots"[9]	CDPH (EZIZ)
	"Handouts: Clinic Resources"[10]	Immunization Action Coalition
Vaccine Hesitancy	"Vaccine-Hesitant Parents"[11]	AAP
	"Responding to Parents"[12]	Immunization Action Coalition
Vaccine Safety	"Vaccine Safety: Answers to Parents' Top Questions"[13]	CDPH (EZIZ)
	"Parent Education (Vaccine Safety)" [14]	CDPH (EZIZ)
Autism	"MMR Vaccine and Autism"[15]	CDPH (EZIZ)
	"MMR Vaccine Does Not Cause Autism"[16]	Immunization Action Coalition
Flu	"Flu & Respiratory Disease Prevention Promotional Materials"[17]	CDPH (EZIZ)
Vaccine Information Statements	"Vaccine Information Statements"[18]	Immunization Action Coalition

Schedules & Recommendations	"Schedules and Recommendations"[19]	CDPH (EZIZ)
	"Immunizations: Immunization Schedule"[20] | Spanish[21]	CDPH (EZIZ)
	"Immunization Schedules for Infants and Children"[22]	CDPH (EZIZ)
Child Care & School Immunization Requirements	ShotsforSchool.org[23]	CDPH
	"Parents' Guide to Immunizations Required for Child Care or Preschool" | Spanish | Chinese | Russian[24]	CDPH (EZIZ)
	"Parents' Guide to Immunizations Required for School Entry" | Spanish | Chinese | Russian[25]	CDPH (EZIZ)
Personal Stories	ShotByShot.org[26]	

Notes

1. Centers for Disease Control and Prevention; 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.
2. "Measles Cases and Outbreaks," Centers for Disease Control and Prevention, http://www.cdc.gov/measles/cases-outbreaks.html.
3. "Pertussis Epidemic – California, 2014," Centers for Disease Control and Prevention, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6348a2.htm.
4. "Parents' Guide to Childhood Immunizations," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/pubs/parents-guide/default.htm.
5. "For Parents: Vaccines for Your Children," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/parents/index.html.
6. "Instant Childhood Immunization Schedule," Centers for Disease Control and Prevention, http://www2a.cdc.gov/nip/kidstuff/newscheduler_le/.
7. "Immunization Promotional Materials for Staff and Patients,"EZIZ.org, http://eziz.org/resources/immunization-promo-materials/.
8. "Educating Patients & Parents" can be found under the "Resources" menu by clicking on "Vaccine Administration" at http://EZIZ.org.
9. "Be there for your child during shots" can be found by searching for "IMM-686" at http://EZIZ.org.
10. "Handouts: Clinic Resources," Immunization Action Coalition, http://immunize.org/handouts/discussing-vaccines-parents.asp.
11. "Vaccine-Hesitant Parents," American Academy of Pediatrics, can be found by searching for "AAP Vaccine-Hesitant Parents."
12. "Responding to Parents," Immunization Action Coalition, http://www.immunize.org/talking-about-vaccines/responding-to-parents.asp.
13. "Vaccine Safety: Answers to Parents' Top Questions" can be found by searching for "IMM-916 at http://EZIZ.org.
14. "Parent Education (Vaccine Safety)," EZIZ.org, http://eziz.org/resources/parented/.
15. "MMR and Autism," EZIZ.org, http://eziz.org/resources/parented/studies/#T3.
16. "MMR Vaccine Does Not Cause Autism," Immunization Action Coalition, http://immunize.org/catg.d/p4026.pdf.

17. "Flu & Respiratory Disease Prevention Promotional Materials," EZIZ.org, http://eziz.org/resources/flu-promo-materials/.
18. "Vaccine Information Statements, Immunization Action Coalition, http://www.immunize.org/vis/.
19. "Schedules and Recommendations," EZIZ.org, http://eziz.org/administration/schedules-recs/.
20. "Immunizations: Immunization Schedule" can be found by searching for “IMM-234” at http://EZIZ.org.
21. "Immunizations: Immunization Schedule (Spanish)" can be found by searching for “IMM-234S at http://EZIZ.org.
22. "Immunization Schedules for Infants and Children," Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/schedules/easy-to-read/child.html.
23. Refer parents to ShotsforSchool.org to see how their schools rank at http://www.shotsforschool.org/.
24. "Parents' Guide to Immunizations Required for Child Care or Preschool" can be found in multiple languages under the “Child Care” menu at http://www.shotsforschool.org/.
25. "Parents' Guide to Immunizations Required for School Entry" can be found in multiple languages under the “K-12” menu at http://www.shotsforschool.org/.
26. Print and video stories can be found on the ShotbyShot.org website at http://www.shotsforschool.org/.

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Essential Immunization Strategies

Target Audience

Immunization Champion

Assessment, Feedback, Incentives, and eXchange (AFIX)

Studies show that providers do not have an accurate perception of their own practice or clinic immunization rates.[1] To assist, VFC Field Representatives conduct site visits to assess provider immunization coverage and identify missed opportunities, provide feedback to improve immunization practices and coverage levels, motivate key practice staff to incorporate improvements into their practices, and follow up to monitor and support progress towards improving coverage levels.

Summary

Both the National Vaccine Advisory Committee (NVAC) [2] Standards for Child and Adolescent Immunization Practices and Standards for Adult Immunization Practices are calling on providers to track immunizations so they can remind parents when vaccinations are due and recall children who are past due. The following strategies are recommended in CDC's *Pink Book* to help providers raise immunization levels in their patient populations:[3]

- Recordkeeping
  a. Immunization records must be accurate and up to date; active medical records should reflect current patient population.
  b. Ensure immunization record is up to date and tied to the child's permanent medical record.
- Immunization Information Systems
  a. Maximize use of population-based IISs (including immunization registries), which are proven to increase immunization levels:
     i. Client reminder/recall systems
     ii. Provider reminder systems
     iii. Identification of missed vaccination opportunities
     iv. Vaccine management and accountability
- Best Practices with Parents and Reinforcement of Immunization's Importance
  a. Strong provider recommendation for immunizations.
  b. Recommend age-appropriate vaccines.
  c. Reinforce the need to return for subsequent doses.
  d. Use verbal and written reminders tied to calendar events.
- Reminder and Recall Messages to Patients
  a. Issue reminder calls notifying parents that vaccines are soon due.
  b. Issue recalls notifying parents that vaccines are past due.
- Reminder and Recall Messages to Providers
  a. Use internal tracking systems to remind providers of patient immunizations and raise staff awareness of the importance of checking immunization status:
     i. Computer-generated lists
     ii. Stamped note in patient charts
     iii. "Immunization Due" clip or Post-It on patient chart
     iv. Electronic reminders
- Reduction of Missed Opportunities to Vaccinate
  a. Reintegrate immunization and primary care to eliminate referrals.
  b. Consider standing orders that enable non-physician immunization personnel to vaccinate clients without direct physician involvement.
  c. Educate staff that concern about multiple vaccinations in the same patient visit is not supported by scientific data; prevent unnecessary additional visits that might be a barrier for families.

   d. Ensure staff members responsible for vaccine administration are knowledgeable about the principles of vaccines and immunization schedules so they can educate families who might have concerns.
   e. Use reminder and recall systems.
- Reduction of Barriers to Immunization within the Practice
   a. Provide a walk-in vaccination clinic at least once a week to reduce patient barriers to immunization.
   b. Ensure staff are knowledgeable about VFC eligibility requirements to reduce cost as a barrier.
   c. Educate parents to ensure concerns about vaccine safety are not creating psychological barriers to immunization.

Notes

1. Centers for Disease Control and Prevention; "Immunization Strategies for Healthcare Practices and Providers," 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.
2. National Vaccine Advisory Committee, US Department of Health and Human Services, https://www.hhs.gov/nvpo/nvac/index.html.
3. Centers for Disease Control and Prevention; "Immunization Strategies for Healthcare Practices and Providers", 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.

Additional resources:

- "AFIX (Assessment, Feedback, Incentive and eXchange)", CDC's website, https://www.cdc.gov/vaccines/programs/afix/about/overview.html.

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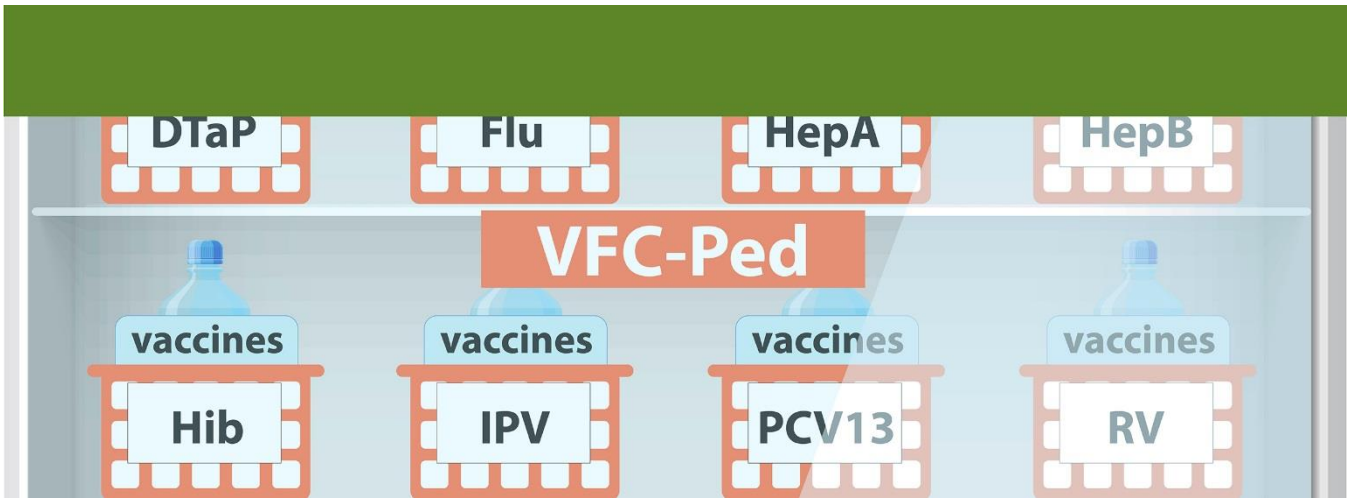

Vaccine Management

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Introduction

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 due to temperature excursions.

Success is dependent on five key factors: 1) a complete and up-to-date vaccine management plan, 2) properly trained staff, 3) reliable vaccine storage units with sufficient capacity, 4) proper temperature monitoring with calibrated, accurate devices, and 5) careful and consistent adherence to routine tasks that protect vaccine viability.

Figure 3.1 highlights key topics covered in chapter three to help practices and clinics comply with VFC Program requirements and best practices that protect vaccine viability and minimize loss.

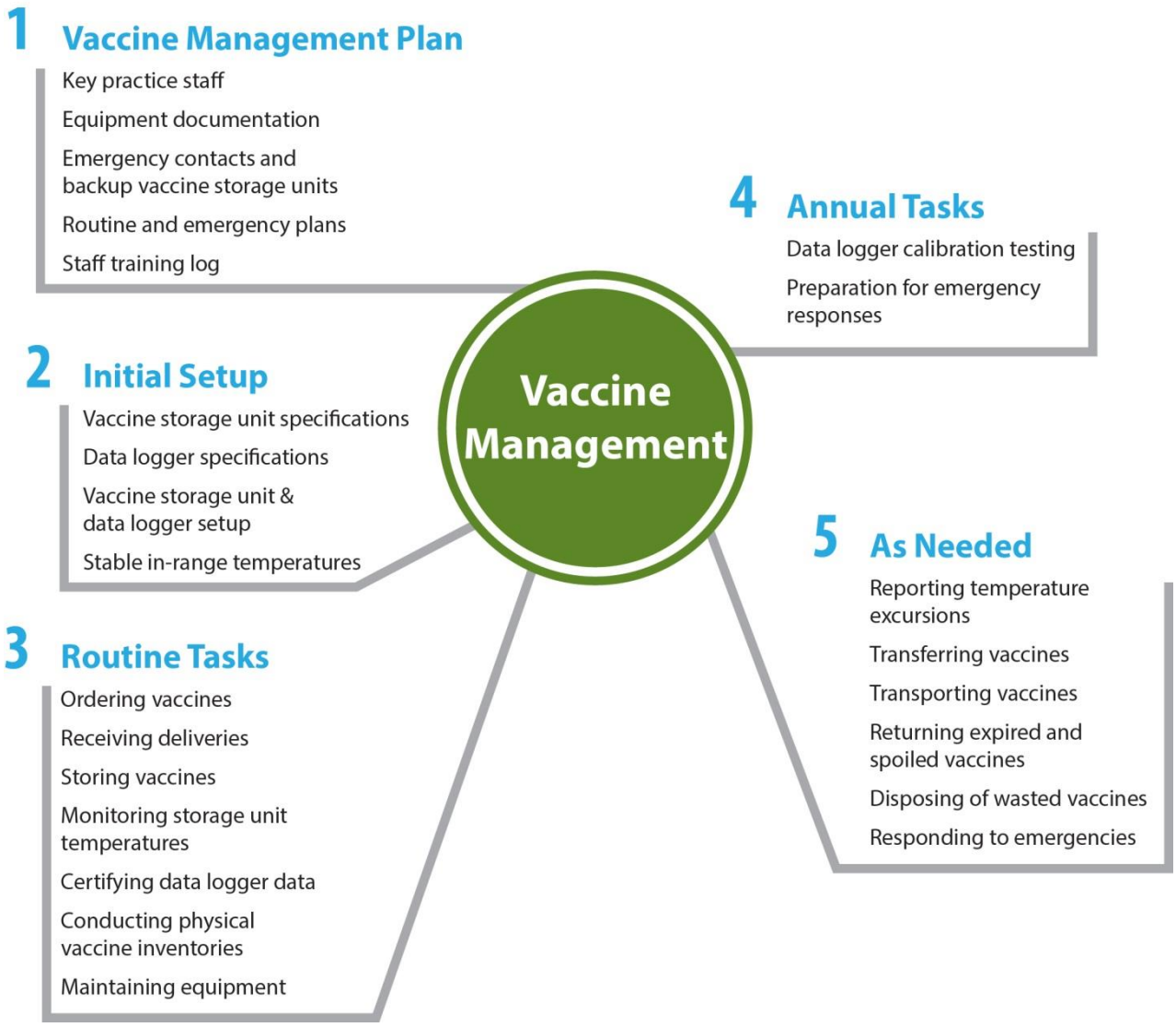

FIGURE 3.1. Overview of the topics of vaccine management.

Vaccine Management Plan

Overview

Providers agree to complete and maintain a vaccine management plan that covers routine and emergency situations. The plan details proactive responses providers and staff must take to protect vaccines and minimize vaccine loss due to negligence. Vaccine Coordinators (and Backups) are responsible for implementing the plan, and the Provider of Record is ultimately accountable for practice or clinic compliance. The vaccine management plan covers the topics detailed in chapters three (Vaccine Management) and four (Vaccine Orders).

Target Audience

Provider of Record and Designee, Vaccine Coordinator and Backup

Program Requirements

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

- 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).
- Review and update the plan at least annually, when VFC Program requirements change, and when staff with designated vaccine-management responsibilities change (P.A.A. #1B).
- Designate a staff member responsible for updating the practice's management plan (P.A.A. #1C).
- Ensure staff with assigned vaccine-management responsibilities review, sign, and date the vaccine management plan annually and each time it is updated (P.A.A. #1D).
- Store the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units (P.A.A. #1E).

Rational

Because federally purchased vaccines are supplied to providers at no cost, providers must manage their vaccine inventory to prevent negligent loss. Providers are required to compensate the VFC Program for loss that could have been prevented—on a dose-for-dose basis.

Practice-Specific Protocols

The VFC Program provides a template to assist providers with most vaccine-management tasks. However, practice-specific protocols will be required to direct staff to respond to common situations, such as responding to temperature excursions after hours. Document the steps staff are expected to follow and ensure new staff are familiar with practice protocols.

Updates to Vaccine Management Plan

Review and update your plan at least once a year. Ensure that all content in each section (including emergency contact information and alternate vaccine storage location) is up to date. Key practice staff must sign and acknowledge the signature log whenever your plan is revised.

Providers must assign someone responsible for ensuring their plan is updated and ready to be executed. Keep the plan in a location easily accessible to all staff, ideally near the vaccine storage units.

Key Practice Staff

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, key practice staff must be knowledgeable about the plan's content and be able to respond to emergency situations.

Provider of Record.

- Oversee key practice staff to ensure VFC Program requirements are met.
- Comply with all federal vaccine management requirements, including key areas outlined in this plan.
- Complete required EZIZ training lessons for Provider of Record.
- Designate one provider as the VFC Provider of Record Designee responsible for ensuring all VFC Program requirements are met when the Provider of Record is not available.
- Designate the VFC Vaccine Coordinator responsible for implementing and overseeing the vaccine management plan.
- Designate one employee as the VFC Backup Vaccine Coordinator responsible for vaccine management when the Vaccine Coordinator is not available.
- Report to the VFC Call Center any staffing changes for the Vaccine Coordinator, Backup Vaccine Coordinator, Provider of Record, and Provider of Record Designee.
- Meet and document required annual EZIZ training lessons for the practice's vaccine management staff.
- Ensure that vaccine management staff are knowledgeable of VFC Program requirements for temperature monitoring and vaccine storage.
- Ensure that the practice's vaccine inventory management is consistent with VFC Program requirements.
- Ensure that the practice's vaccine storage units and temperature monitoring devices meet VFC Program requirements.
- Update and revise vaccine management plan at least annually and when necessary.
- Review VFC Program requirements and management plan with staff at least annually and when necessary.
- The Provider of Record or Designee must be present for site visits—especially during the feedback portion of the visit—and sign the acknowledgement form.

Provider of Record Designee.

- Complete required EZIZ training lessons.
- Meet responsibilities listed above for the Provider of Record.

Vaccine Coordinator.

- Complete required EZIZ training lessons.
- Oversee the practice's vaccine management plan for routine and emergency situations.
- Maintain VFC-related documentation in an accessible location.

Backup Vaccine Coordinator.

- Complete required EZIZ training lessons.
- Meet responsibilities listed above for the Vaccine Coordinator.

Procedure

Follow these instructions to complete the practice's vaccine management plan.

TABLE 1. Instructions for completing provider vaccine management plan

Step	Description
1.	Go to EZIZ.org and click the "VFC Program" menu.
2.	Scroll down to "VFC Provider Requirements."
3.	Click the link to the "Vaccine Management Plan - Word template."[1]
4.	Open the document and complete the plan by providing the required information.
5.	Print and review with staff the designated responsibilities in the vaccine management plan to ensure they understand their assigned responsibilities. ***Important.*** Refer staff to the California VFC Program's *Provider Operations Manual* (POM) for instructions for any assigned tasks. Instruct them to ask their supervisor or call the VFC Call Center with any vaccine-related questions.
6.	Ensure that the VFC Provider of Record and Designee, Vaccine Coordinator and Backup, and other staff with assigned vaccine management responsibilities sign and date the signature log.
7.	Store the printed plan in a location easily accessible by all staff with vaccine management responsibilities (ideally near vaccine storage units) in case of emergencies or VFC site visits.

Notes

1. The "Vaccine Management Plan" MS Word template can be found by clicking "VFC Program" at http:/EZIZ.org.

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VFC Temperature Logs

Overview

Temperature logs are official VFC Program documents. Providers must use the most current VFC temperature logs to record temperatures for VFC-supplied vaccines. Completed logs must remain on-site and may not be falsified. Logs include a section for supervisors to review and certify completeness; through this process, supervisors can identify staff training issues.

Target Audience

Typically Vaccine Coordinator & Backup

Program Requirements

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

- Ensure vaccine storage unit temperatures are recorded on VFC temperature logs (California VFC Program "Provider Agreement Addendum" #10A).
- Retain paper logs and electronic files related to temperature monitoring for three years (P.A.A. #10I).
- Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted (P.A.A. #9J).

How to Get VFC Temperature Logs

The VFC temperature logs can be printed by accessing PDF versions from EZIZ for refrigerators (Fahrenheit[1] | Celsius[2]) and freezers (Fahrenheit[3] | Celsius[4]).

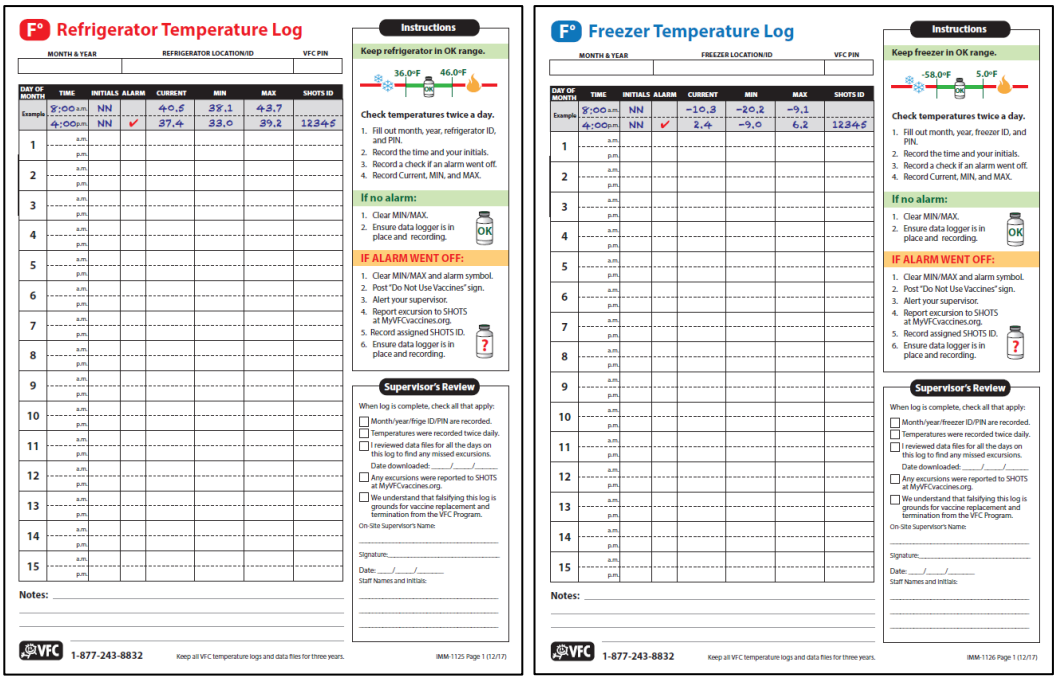

FIGURE 3.2. Illustration showing VFC refrigerator and freezer logs identically formatted except for OK temperature ranges.

Notes

1. Fahrenheit Refrigerator Temperature Logs can be found by searching for "IMM-1125" at http:/EZIZ.org.
2. Celsius Refrigerator Temperature Logs can be found by searching for "IMM-1127" at http:/EZIZ.org.
3. Fahrenheit Freezer Temperature Logs can be found by searching for "IMM-1126" at http:/EZIZ.org.
4. Celsius Freezer Temperature Logs can be found by searching for "IMM-1128" at http:/EZIZ.org.

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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

- 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

- 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

Providers must purchase a new vaccine refrigerator or freezer if

- vaccine storage units do not meet VFC Program specifications, or
- the practice has had storage incidents resulting in spoiled vaccines.

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.

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 36.0ºF and 46.0ºF (between 2.0ºC and 8.0ºC);
- 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 +5.0ºF (between -50.0°C and -15.0ºC);
- 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) *Best*	Purpose-built to maintain consistent temperatures for storage of fragile vaccines or biologics. They come in stand-alone and combination units, including auto-dispensing units without doors.	Very high (required) Others: preferred
Compact pharmacy-, biologic-, or laboratory-grade (stand-alone) *Best*	Purpose-built, under-the-counter storage units suitable for smaller practices with limited space.	Low, Medium, High
Commercial units (stand-alone) *Good*	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) *Discouraged*	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) *Good*	Purpose-built to maintain consistent temperatures for storage of fragile vaccines or biologics. Purpose-built combination units, including auto-dispensing units without doors, are allowed.	Any practice
Pharmacy-, biologic-, or laboratory-grade (combination) *Good*	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) *Good*	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) *Good*	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)	Small, under-the-counter, stand-alone refrigerators with a capacity of 11 cubic feet or less are not allowed. Compact household refrigerator
Household combination refrigerator/freezer	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. Household combination unit
Dormitory-style and bar-style combined refrigerator/freezers	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. Dormitory-style unit
Manual-defrost refrigerators	These models have a vertical cooling plate at the back of the refrigerator, which poses potential risk of significant temperature variation and freezing vaccines.
Convertible units	These units have an internal switch that converts an all-refrigerator unit to an all-freezer unit.
Cryogenic freezers	These units reach temperatures well below -58.0°F.
Transport units	Coolers and battery-operated units may not be used for routine vaccine storage.

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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Configuring Vaccine Storage Units

Overview

Vaccine storage units should be organized for efficiency and with preparations to stabilize interior temperatures. Carefully grouping and labeling vaccines reduces time spent searching for vaccines, administration errors, and vaccine exposure to room temperatures. Filling empty interior spaces with water bottles or cold packs also preserves cold mass and helps reduce the frequency of temperature excursions.

Target Audience

Typically Vaccine Coordinator and Backup

Program Requirements

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

- Prepare vaccine refrigerators (IMM-962) and vaccine freezers (IMM-965) following VFC Program requirements (California VFC Program "Provider Agreement Addendum" #4A).
- Place water bottles (in refrigerators) and ice packs (in freezers only) to stabilize temperatures. (Exception for purpose-built, auto-dispensing units without doors.) (P.A.A. #4B).
- Place buffered probes in the center of the refrigerator and freezer near vaccines. (Exception for purpose-built, auto-dispensing units without doors.) (P.A.A. #4C).
- 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.) (P.A.A. #4D).
- 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. (P.A.A. #4E).
- Post "Do Not Unplug" (IMM-744) signs on the electrical outlets and circuit breakers to prevent interruption of power (P.A.A. #4F).
- Set up vaccine refrigerators (IMM-963) and vaccine freezers (IMM-966) following VFC Program requirements (P.A.A. #4G).
- Clearly identify VFC-supplied and privately purchased vaccines. Designate and label separate shelf space or mesh baskets (P.A.A. #4H).
- Clearly label shelves or baskets to group vaccines by pediatric, adolescent, and adult types (P.A.A. #4I).
- 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.) (P.A.A. #4J).
- Post VFC temperature logs on vaccine storage unit doors or in an easily accessible location (P.A.A. #4K).

Rationale

Careful preparation and setup of vaccine storage units is the first step of a well-organized vaccine management plan designed to minimize preventable vaccine loss.

Best Practices

- Store vaccines with similar packaging or names on different shelves to lessen risk of administration errors.
- Never store refrigerated vaccines near cooling vents, which can result in freezing of these vaccines.
- Purchase plastic mesh baskets for all vaccines identified in the practice's provider profile to organize vaccines for easy access.
- If the practice is in an area that experiences frequent power outages, consider an emergency power generator and then test it regularly with staff.

- Large hospitals and health-care systems can demonstrate their power source is protected by providing comprehensive policies and standard operating procedures to prevent vaccine storage units from being physically disconnected from the power supply.

Placement Considerations

- Locate vaccine storage units away from public spaces, direct sunlight, and any heat sources.
- Ensure each storage unit has its own dedicated wall outlet to ensure all vaccines aren't at risk if a breaker is tripped.
- Do not use outlets controlled by wall switches or outlets with built-in circuit breakers because power can easily be interrupted.
- Position storage units to allow good air circulation around the top, sides, and back.

Procedure: Preparing Storage Units

Storage units must be prepared to maintain stable temperatures before storing vaccines. The concepts are identical for both refrigerators and freezers.

Follow these instructions to prepare vaccine storage units in compliance with VFC Program requirements and best practices.

TABLE 5. Instructions for preparation of vaccine storage units

Step	Description
1.	Protect the power supply. A. Plug each storage unit into its dedicated wall outlet. B. Do NOT use multi-outlet power strips or extension cords, or outlets with GFI circuit switches (have reset buttons between plugs). C. Protect the power supply by securing the plug with a guard or cover and posting "Do Not Unplug" signs[1] near the outlet. D. Label fuses and circuit breakers so the Vaccine Coordinator is alerted if power goes off.
2.	Add plenty of water bottles (refrigerators) or cold packs (freezers only) in unstable areas to help maintain recommended temperatures during busy days and power outages. Add them: A. On the top shelf, but don't block the air vents. B. On the unit's floor. (For household stand-alone units, remove drawers and bins before adding water bottles.) C. In any door shelves.

Tip: Also add them along the back wall to prevent vaccines from touching the back of the storage unit. (For purpose-built, auto-dispensing units without doors, water bottles and cold packs are not needed.)

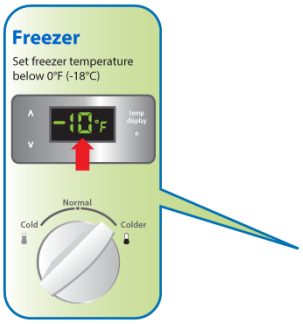
3. Set up a data logger for each storage unit.
   A. Place the buffered probe in the center of the storage unit near the vaccines.
   B. Place or mount the digital display so temperatures can be read without opening the storage unit door.
   C. Thread the probe's cable through the side of the door and attach it to the digital display.

(For purpose-built, auto-dispensing units without doors, internal data loggers must meet VFC Program requirements. Refer to "Data Logger Specifications" for details.)

4. Ensure the data logger is recording storage unit temperatures—not room temperature.

   Tip: Some devices might display "REC" or "RECORDING" if recording internal storage unit temperatures.

5. Set storage unit temperatures.
   For refrigerators. If the thermostat is set to Fahrenheit, set it at 40°F. If it has a dial with a range of settings, adjust the temperature dial as needed.



For freezers. If the thermostat is set to Fahrenheit, set it below 0°F. If it has a dial, set it to the coldest.

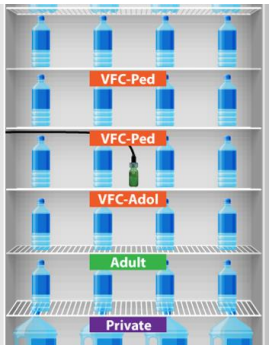
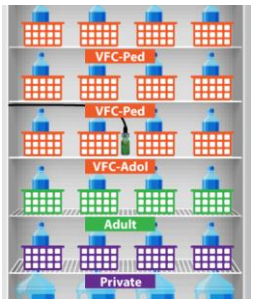
6. Post VFC-supplied temperature logs on the corresponding refrigerator or freezer door to prevent recording temperatures on the wrong logs.
7. Configure the data logger to meet VFC Program requirements. (Refer to "Configuring Data Loggers.")
8. Follow the instructions in **TABLE 6** to set up vaccine storage units while waiting for temperatures to stabilize.

Procedure: Setting Up Vaccine Storage Units

Proper setup involves organizing the storage unit interiors for efficiency. It also reduces time spent with doors open searching for vaccines. The concepts are identical for both refrigerators and freezers. ***For purpose-built, auto-dispensing units without doors:*** Follow manufacturer's instructions for setup of vaccine storage units.

Follow these step-by-step instructions to set up storage unit interior spaces to comply with VFC Program requirements and best practices.

TABLE 6. Instructions for setup of vaccine storage units

Step	Description
1.	Clearly identify VFC-supplied and privately purchased vaccines. Consider designating separate shelf space (or breathable mesh baskets). 
2.	Designate separate shelf space or baskets to group vaccines (such as by pediatric, adolescent, and adult types) to prevent administration errors.
3.	Position vaccines or baskets 2-3 inches away from walls, floor, and other baskets to allow space for air circulation. ***Tip:*** Do not stack baskets on top of each other as this reduces air circulation around the vaccines. 

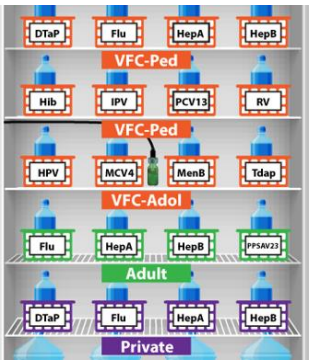
4. Set up space for diluents in the refrigerator or at room temperature according to manufacturer recommendations.

   Tips:
   - When diluents are packaged with vaccines, store them together.
   - Store diluents with similar packaging or names on different shelves to lessen risk of administration errors.
   - Otherwise, clearly label diluents and store where they can be easily identified and retrieved.

5. If storage of medications or biologics is necessary, store them below the vaccines and on a different shelf to prevent contamination of vaccines due to spills.

6. Label your baskets or shelf space to make vaccines easy to find for administration.

   Tip: Plan to store vaccines with similar packaging or names on different shelves to lessen risk of administration errors.



7. Once storage unit temperatures have stabilized, record CURRENT, MIN, and MAX temperatures on the appropriate VFC temperature log twice a day—until all three temperatures remain in the OK range for three to five days. (Refer to "Monitoring Storage Unit Temperatures.")

   Important. OK range for refrigerated vaccines is between 36.0ºF and 46.0ºF (between 2.0ºC and 8.0ºC).

   OK range for frozen vaccines is between -58.0ºF and +5.0ºF (between -50.0ºC and -15.0ºC).

8. Store vaccines in the storage units following VFC Program requirements and best practices. (Refer to "Storing Vaccines.")

Routine Maintenance

Regular care helps ensure that vaccine refrigerators and freezers work properly. Follow these step-by-step instructions to maintain vaccine storage units.

TABLE 7. Instructions for cleaning vaccine storage units

Step	Description
1.	Do not unplug the storage unit.
2.	• Wipe the inside of compartments and shelves with disinfectant or antibacterial wipes. Do not remove vaccines from the storage unit to clean it. • Move the trays of vaccines as shelves are wiped. • Return vaccines to their designated location.
3.	• Check door seals to ensure no gaps allow cool air to escape. Locate and examine door seals. • Ensure seals are not torn or brittle. • Ensure there are no gaps when the door is shut. • Report any issues to the supervisor.
4.	Clean outside coils and motor. Use a duster to remove dust from coils.

Plan to defrost manual-defrost vaccine freezers if about one inch of ice has built up.

TABLE 8. Instructions for defrosting manual-defrost vaccine freezers

Step	Description
	Plan Ahead
1.	Ensure there is enough space to accommodate vaccines in an alternate on-site freezer (e.g., the breakroom freezer). • Remove any food. • If the freezer cannot accommodate the practice's vaccines, make plans to transport vaccines to the alternate storage location identified in the practice's vaccine management plan. • Do not store vaccines in coolers while defrosting the freezer.
2.	Install the backup data logger in the alternate freezer. • Check device settings to ensure LO/HI temperature alarm alerts are set between -58.1°F (-50.1°C) and +5.1°F (-14.9°C). • Ensure the device is set to begin recording storage unit temperatures.
3.	Wait for the device to register the internal freezer temperature.
4.	Adjust freezer thermostat if temperatures are outside the required range. • Do not transfer VFC vaccines until temperatures have stabilized within the required range.
5.	Defrosting of the freezer should start at the beginning of the workday so vaccines can be returned to their original unit before the practice closes.

Defrost Your Freezer

1. Transfer frozen vaccines to the alternate on-site freezer and close the door.
2. Defrost the freezer following the practice's preferred method identified in the practice's vaccine management plan—if different from steps below.
   - Unplug the storage unit.
   - Open the freezer door.
   - Place shallow pans, towels, or paper towels to absorb melting ice.
   - Heat a bowl of water and place it in the freezer to speed up the melting process; reheat the water every 15 minutes or so.
   - Use an ice scraper and carefully remove melting ice to speed up the process; be careful not to puncture freezer walls.

Final Steps

1. After the freezer has defrosted, clean interior surfaces with soap and water.
   - Rinse the soap off and wipe down thoroughly.
   - Dry interior thoroughly.
   - Wipe down the door seals.
2. Plug in the freezer.
3. Allow the internal temperature to stabilize between -58.1°F (-50.1°C) and +5.1°F (-14.9°C).
4. Once temperatures have stabilized, return vaccines to the freezer and close the door.
5. Return the backup data logger to the location documented in the practice's vaccine management plan.

Notes

1. "Do Not Unplug" sign can be found by searching for "IMM-744" at http://EZIZ.org.

Additional resources:

- The "Storing Vaccines" lesson can be found on the EZIZ.org website under the "EZIZ Training" menu at http://EZIZ.org.
- "Preparing Refrigerators for Vaccine Storage" can be found by searching for "IMM-962" at http://EZIZ.org.
- "Refrigerator Setup for Vaccine Storage" can be found by searching for "IMM-963" at http://EZIZ.org.
- "Preparing Freezers for Vaccine Storage" can be found by searching for "IMM-965" at http://EZIZ.org.
- "Freezer Setup for Vaccine Storage" can be found by searching for "IMM-966" at http://EZIZ.org.
- "Safeguard Your Power Supply" can be found by searching for "IMM-967" at http://EZIZ.org.
- "Monthly Care of Vaccine Storage Units" can be found by searching for "IMM-970" at http://EZIZ.org.

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Data Logger Specifications

Overview

Continuous temperature monitoring is an essential component of each provider's vaccine management plan, but data logger reliability is the critical factor that helps to ensure vaccine viability. VFC Program specifications ensure vaccines will be accurately and reliably monitored if providers used compliant devices.

Target Audience

Provider of Record and Designee, Vaccine Coordinator & Backup

Program Requirements

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

- Temperature monitoring devices must meet CDPH VFC storage and handling requirements (VFC "Provider Agreement" #9).
- 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.) (California VFC Program "Provider Agreement Addendum" #5A).
- 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 (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 (P.A.A. #5C).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.) (P.A.A. #5B)
- 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.) (P.A.A. #5C)

Rationale

Investing in reliable, VFC-compliant temperature monitoring devices is less expensive than replacing vaccines spoiled due to inaccurate temperature readings.

Best Practices

- Providers should choose Fahrenheit (F) or Celsius (C) scale for all storage units.
- "2-point"temperature calibration testing satisfies VFC Program requirements. ("Calibration test points" refer to the number of points used to test the accuracy of data loggers across the temperature spectrum.)

Purpose-Built, Auto-Dispensing Units without Doors

These storage units might contain multiple built-in, digital data loggers to accurately monitor temperatures throughout the storage unit. These internal devices must meet VFC Program requirements. Contact a VFC Program Field Representative with concerns or questions.

Backup Devices

Practices are required to keep on hand at least one backup, battery-operated digital data logger for use if the primary device breaks or does not meet calibration requirements, or for use during emergency vaccine transport. Depending on the size of the practice, additional devices might be needed.

Key Terms

Digital Data Logger (DDL). Also known as a "continuous temperature monitoring device" or just a "data logger." Reads and records storage unit temperatures, which can then be downloaded and saved as an electronic file on a computer.

Buffered probe. Measures internal storage unit temperatures. Probes might be detachable or permanently embedded in buffered material.

Digital display. Displays temperature readings and other settings, often with a menu.

Cable. Connects the digital display (placed or mounted outside the storage unit) and the buffered probe (remains inside the storage unit at all times).

FIGURE 3.7. Illustration of typical data logger components connected for use.

Data Logger Specifications

The minimum features and specifications for data loggers or other continuous temperature monitoring devices used for vaccine management are listed below.

TABLE 9. Minimum data logger specifications

Feature	Description
Accuracy	+/-1.0°F (+/-0.5°C)
Logging interval	Programmable (at least every 30 minutes)
Memory storage	4,000 readings or more
Buffered temperature probe	• Only use the buffered probe bundled with the device • Detachable from unit, or permanently embedded in a buffered material as long as the temperature monitoring system can be calibrated • Immersed in a vial filled with thermal buffer material, including liquid up to 60 mL (e.g., glycol, ethanol, or glycerin), loose media (e.g., sand or glass beads), or a solid block of material (e.g., Teflon® or aluminum)
Digital display	• Active external display • Must include current, MIN, and MAX temperatures • Must be in close proximity to storage units and VFC-supplied temperature logs • Low-battery indicator
Alarm capabilities	• Programmable • Visual or audible alarm to signal out-of-range temperatures
Battery backup	• Necessary in case of loss of power, and for transport of vaccines during emergencies

Unacceptable Devices and Features

Any devices that don't provide continuous temperature monitoring, don't have the acceptable accuracy for monitoring storage unit temperatures, or don't meet the other VFC Program requirements identified above are prohibited, including but not limited to

- thermometers (for example, round dial thermometers, fluid-filled and/or min-max bar thermometers, household-use and kitchen thermometers, infrared temperature guns, alcohol or mercury thermometers, and bi-metal stem thermometers);
- chart recorders, which are units that plot temperatures on printed graphs;
- data loggers that do not have probes immersed in a vial filled with liquid, loose media, or a solid block of material; and
- any temperature alarm system that does not meet VFC Program device specifications.
- ***Virtual or simulated technologies.*** Digital data loggers with bullet probes, solid vial simulators, modified simulators, or virtual buffering technology do not meet requirements at this time.

Calibration Specifications

Each data logger must have a valid certificate of calibration testing (also known as report of calibration). "2-point"temperature testing is sufficient to meet VFC Program calibration requirements. New temperature monitoring devices typically come with a certificate of calibration. Certificates must include specifications listed in table 10.

TABLE 10. Calibration specifications for accredited and non-accredited laboratories

Item	Comments
Laboratory name and address	
Device name	Optional
Model number	Enables product identification
Serial number	Enables product identification
Calibration date	Report or issue date
Measurement results for devices	• Instrument *pass* or *in tolerance* testing result, or documented uncertainty [must be within ±1°F (±0.5°C)]
Credentials	• *Non-accredited laboratories* must provide a statement that calibration testing conforms to ISO/IEC 17025 standards. • *Accredited laboratories* must have one of the following logos on the certificate:

Before Purchasing Data Loggers

Data loggers are available online and from many medical supply companies. Read the specifications carefully and contact the manufacturer if you have questions. Do not purchase a device based solely on its picture.

Notes

Additional resources:

- "Certificate of Calibration Quick Guide" can be found by searching for "IMM-1119" at http://EZIZ.org.
- "Digital Data Logger Pre-Purchase Worksheet" can be found by searching for "IMM-1236" at http://EZIZ.org.
- "Data Logger Feature Comparison Guide" can be found by searching for "data logger feature comparison guide" at http://EZIZ.org.
- VFC "Introduction to Digital Data Loggers" video can be accessed from the "Storage and Handling" menu by clicking "Digital Data Loggers" under additional resources.

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Configuring Data Loggers

Overview

There are many data loggers on the market today, each with their own setup guides and instructions. Practices and clinics must get familiar with their temperature monitoring device and then configure the settings for use according to VFC Program requirements and best practices. Refer to manufacturer's product guide (or video if available) to learn how to use the device. Call the vendor's support contact number for all questions regarding setup, functionality, or configuration.

Target Audience

Typically Vaccine Coordinator and Backup

Requirements

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

- 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 (California VFC Program "Provider Agreement Addendum" #6A).
- 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.) (P.A.A. #6B).
- 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 (P.A.A. #6C).
- Ensure certificates issued by non-accredited laboratories are valid certificates of calibration (IMM-1119) (P.A.A. #6D).
- Keep certificates of calibration on file and make them available to the VFC Program upon request (P.A.A. #6E).
- If any data logger or probe is damaged, replace the entire device (P.A.A. #6F).
- 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 (P.A.A. #10D).

Best Practices

- For setup and configuration of new data loggers, continue using existing devices to monitor storage unit temperatures until new devices acclimate to internal storage unit temperatures and staff have demonstrated proficiency in their use.
- Label device components (primary and backup devices) to keep components for the same device linked together.
- Calibrate primary and backup devices on different schedules to prevent expiration of certificates of calibration at the same time.
- Place buffered probes in vaccine storage units for two to three hours before configuring devices and connecting for use.

Purpose-Built, Auto-Dispensing Units without Doors

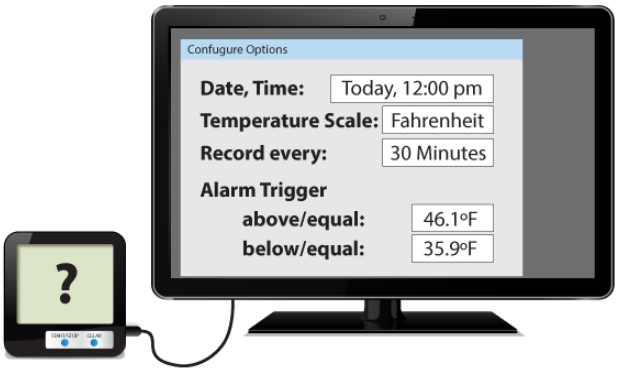
Consult the manufacturer's documentation to ensure devices are set up correctly—including device name, low and high temperature alarm limits, and a 30-minute logging interval—according to VFC Program requirements.

Procedure

Important. Providers must 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. Settings might be programmed using the menu on the data logger or using the software installed on the computer, depending on your device. Adjust the instructions provided in table 11 based on device make and model and the manufacturer instructions.

TABLE 11. General instructions for data logger setup

Step	Description
1.	Open the box and retrieve its contents. A. Store the certificate of calibration in the practice's VFC Program binder. B. Locate vendor's support number for assistance with setup. C. Review any training video or resources. D. Review the manufacturer's product guide.
2.	Place the buffered probe in the center of the vaccine storage unit. A. Slide the attached cable through the hinge side of the door and close the storage unit door.
3.	Set up and prepare your device—including all required settings—following any configuration prompts. A. Install software, if necessary based on device make and model. Data download might require a flash drive or setup of a cloud account. B. Assign a **device name** (for example, Injection_Room_Unit_01). C. Set the device to the **current date/time**. D. Set the **temperature scale** to Fahrenheit or Celsius. E. Set the logging interval to record at least every 30 minutes. F. Set the **LO/HI temperature alarm limits** for refrigerators and freezers.



In the example below, settings are programmed for data loggers whose settings trigger alerts at or below the listed value. Refer to your manufacturer instructions for more assistance.

Settings	Refrigerator	Freezer
LO	35.9°F (1.9°C)	-58.1°F (-50.1°C)
HI	46.1°F (8.1°C)	+5.1°F (-14.9°C)

4. Place or mount the digital display outside the storage unit so temperatures can be read without opening the door.
   A. Attach the digital display to the probe's cable.

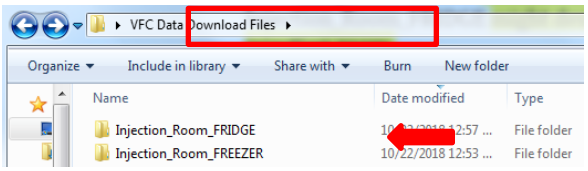
5. Ensure the device is set to begin recording storage unit temperatures.

   Tip. Some devices display "REC" or "RECORDING" on the digital display when recording storage unit temperatures.

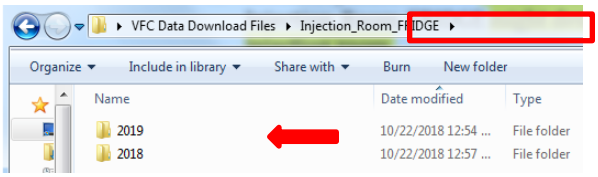
6. Get familiar with the device using the manufacturer's training materials.
   A. Locate CURRENT, MIN, and MAX readings. These readings might appear on the digital display or be accessed by menu buttons (e.g., REVIEW, START, or DISPLAY).
   B. Determine how the device will communicate temperature alarms (e.g., audible alarms, visual icon, or text/e-mail alerts).

7. Practice downloading temperature data files.
   A. Ensure the probe remains in the vaccine storage unit at all times.

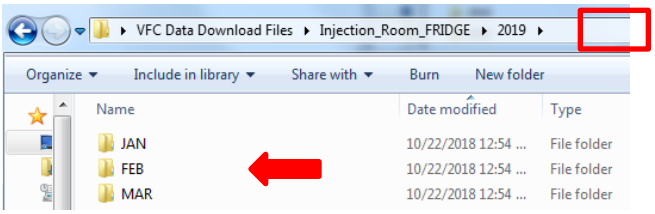
8. Save downloaded temperature data files to the computer or cloud.
   A. Create a folder **for each storage unit by location**. For example, Injection_Room_FRIDGE might designate the vaccine refrigerator in the injection room.



   B. Create a folder for each storage unit **for the calendar year**.



C. Create additional folders for each storage unit **for all twelve months.**

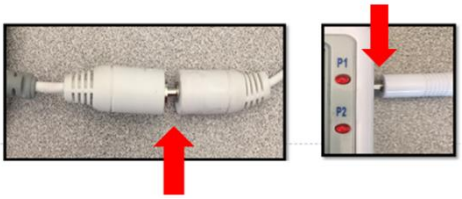


D. Save the data file in the folder **for the current date** using a file name that makes it easy to identify later.

Tip. Include VFC PIN, storage unit ID, and date. For example, 012345_FRIDGE_01162019.

9. Resume temperature recording after data downloads, if necessary based on device make and model.

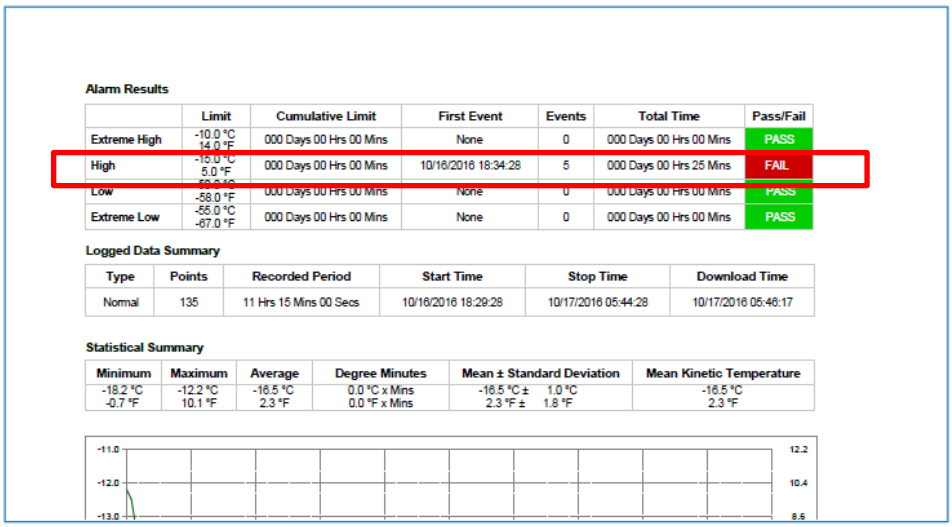
A. If the device was stopped and disconnected, carefully reconnect and restart the device.



Tip. Ensure there are no gaps in the connectors.

10. Get familiar with downloaded temperature data files.

A. Locate excursion time/date, MIN/MAX temperatures, and total time above/below alarm limits. ***Tip.*** Some devices might have a one-page summary that easily identifies any temperature excursions.



Alarm Results

	Limit	Cumulative Limit	First Event	Events	Total Time	Pass/Fail
Extreme High	-10.0 °C 14.0 °F	000 Days 00 Hrs 00 Mins	None	0	000 Days 00 Hrs 00 Mins	PASS
High	-15.0 °C 5.0 °F	000 Days 00 Hrs 00 Mins	10/16/2016 18:34:28	5	000 Days 00 Hrs 25 Mins	FAIL
Low	-58.0 °F	000 Days 00 Hrs 00 Mins	None	0	000 Days 00 Hrs 00 Mins	PASS
Extreme Low	-55.0 °C -67.0 °F	000 Days 00 Hrs 00 Mins	None	0	000 Days 00 Hrs 00 Mins	PASS

Logged Data Summary

Type	Points	Recorded Period	Start Time	Stop Time	Download Time
Normal	135	11 Hrs 15 Mins 00 Secs	10/16/2016 18:29:28	10/17/2016 05:44:28	10/17/2016 05:46:17

Statistical Summary

Minimum	Maximum	Average	Degree Minutes	Mean ± Standard Deviation	Mean Kinetic Temperature
-18.2 °C -0.7 °F	-12.2 °C 10.1 °F	-16.5 °C 2.3 °F	0.0 °C x Mins 0.0 °F x Mins	-16.5 °C ± 1.0 °C 2.3 °F ± 1.8 °F	-16.5 °C 2.3 °F

11. Configure the backup data logger(s) following the same VFC Program requirements.

A. Store the backup device's buffered probe in the vaccine storage unit.
B. Store the digital display in a cabinet.

(For purpose-built, auto-dispensing units without doors, store the entire device in a cabinet.)

12. Update the practice's vaccine management plan with the primary and backup devices' relevant information.

TEMPERATURE MONITORING DEVICE (DATA LOGGER) MAINTENANCE

Calibration Company/Laboratory		Contact		Phone	
Calibration Company/Laboratory		Contact		Phone	
Location of Certificates of Calibration					
Location of Backup Data Logger					

13. Begin using the new device to record storage unit temperatures after 3-5 days of practice and use.

Routine Maintenance

Normal wear and tear. Periodically inspect primary and backup data loggers.

- Routinely check cables and probes to verify they are not damaged.
- Replace batteries on a regular schedule.
- If a data logger is dropped, hit against the side of a storage unit, or potentially damaged in any other way, verify its accuracy against another calibrated data logger.

Calibration testing. Because all temperature monitoring devices experience over time a "drift" that affects their accuracy, calibrate primary and backup devices (device and probe) annually, or every other year when manufacturers recommend a period longer than two years. Devices must be certified for accuracy at most every two years—even if the certificate of calibration extends to more than two years. Calibration testing might be performed on-site or shipped to a laboratory that meets VFC Program requirements, [1] ideally to a laboratory with accreditation from an ILAC MRA signatory body.

If there is any question about a device's accuracy, have the device calibrated or purchase a new one. Calibrate primary and backup devices on different schedules to ensure vaccines are always monitored by working devices.

When to replace devices. If calibration testing indicates that a data logger is no longer accurate within +/-0.5° C (+/-1.0° F), the device must be replaced. Keep in mind that purchasing a new device might be less expensive than calibration testing. If a device or probe is damaged, replace the entire device.

Procedure

Follow these step-by-step instructions for calibration testing of existing temperature monitoring devices.

TABLE 12. Instructions for device calibration testing

Step	Description
1.	For each vaccine refrigerator and freezer, confirm that existing data loggers meet current VFC Program specifications. Do not rely solely on device photo.

2. Have devices calibrated by an accredited laboratory (or alternately, a non-accredited laboratory that meets the credentialing requirements listed in **TABLE 10**).
   A. Search for accredited laboratories online by going to http://eziz.org/vaccine-storage/calibrated-thermometers/accredited-laboratory.
   B. Confirm that the selected laboratory provides a certificate of calibration that meets VFC Program requirements.
   C. Schedule calibration for backup devices on a different schedule than primary devices to ensure that a data logger remains in each vaccine storage unit at all times.

   Important. On-site calibration testing might be permitted if the certifying agency can prove they meet VFC Program calibration requirements.[1]

3. To prepare digital data loggers for shipment:
   A. Stop the device.
   B. Download and save any existing temperature data files.
   C. Place the probe in bubble wrap or other protective material to prevent leakage then place in a sealed plastic bag.
   D. Wrap device in protective material and place in a sealed plastic bag.
   E. Place both the data logger and probe in a padded envelope or box, label, and include any forms requested by the calibration laboratory.
   F. Ship the envelope or box to the calibration laboratory.

4. If shipping data loggers for calibration, follow up to ensure the laboratory has received the device and ask when to expect the updated certificate of calibration and device.

5. When the calibration results come back, review the certificates of calibration to confirm their results as *pass* or *in tolerance*.
   A. Replace immediately any devices that failed the calibration testing.

6. Keep the certificates of calibration on file and make them available to VFC Field Representatives upon request.

   Tip. Schedule a reminder for recalibration in advance of each device's certificate of calibration expiration date.

Notes

1. "Certificate of Calibration Quick Guide" can be found by searching for "IMM-1119" at http://EZIZ.org.

Additional resources:

"Data Logger Setup & Use" can be found by searching for "IMM-1206" at http://EZIZ.org.

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Receiving Vaccine Deliveries

Overview

Vaccine shipments must never be rejected. Providers must open and verify vaccine packages immediately and store vaccines in the appropriate storage units. Once delivered, practices and clinics assume responsibility for ensuring that vaccines are stored in temperature-controlled environments. Shipments that are mishandled after delivery are considered negligent losses, and a replacement vaccine order might not be expedited.

Target Audience

Typically Vaccine Coordinator and Backup, or staff designated in the provider's vaccine management plan with responsibilities for receiving vaccines

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).
- Account for every dose of VFC-supplied vaccine ordered and received by the provider's practice (California VFC "Provider Agreement Addendum" #7D).
- Never reject vaccine shipments (P.A.A. #8A).
- Receive, inspect, and store vaccines and diluents within manufacturer recommended ranges immediately upon delivery (P.A.A. #8B).
- Inspect vaccines for out-of-range temperatures and shipping times during transport (P.A.A. #8C).
- Check package contents to ensure funding source, brands, and quantities match packing slips and approved VFC orders (P.A.A. #8D).
- Report immediately all shipment issues using the VFC "Vaccine Receiving Log and Checklist" (IMM-1112) (P.A.A. #8E).
- Keep packing slips for all vaccine shipments received, including publicly funded and private vaccine shipments (P.A.A. #8F).
- Ensure the practice 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 (P.A.A. #8G).

Rationale

Each vaccine shipment might contain thousands of dollars of vaccines that ensure practices have sufficient inventory to vaccinate patients. Following proper procedures helps to ensure vaccines are viable and minimizes risk of negligent loss. Mishandling might lead to costly vaccines losses and missed opportunities to vaccinate.

Best Practices

- When placing vaccine orders, make sure the practice's open hours are up to date. If a delivery is made while the practice is closed and the result is a vaccine loss, the practice might be held financially accountable for the vaccines.
- When a notification of order approval is received, alert practice staff of the delivery window.
- Additionally, it is strongly encouraged that practices cancel any signature release on file. Otherwise, Fed-Ex or UPS might drop off vaccine shipments without a signature—regardless of office hours.

Refrigerated Vaccines

Refrigerated vaccines are shipped by McKesson Specialty and are shipped with two monitor indicators: a cold indicator (FREEZEmarker®) and a warm indicator (3M MonitorMark) that alert the recipient if vaccines were exposed to out-of-range temperatures. Monitor indicators come with instructions on use.[1]

Cold Indicator *Warm Indicator*

FIGURE 3.8. Illustration of temperature indicators.

Frozen Vaccines

Frozen vaccines (varicella-containing products) are shipped directly from Merck. Although there is no temperature indicator, the shipper insert indicates a "delivery by date," which must be checked to ensure shipment arrived during the specified window.

Vaccine diluents might be packaged separately from its vaccine. Check the lid of the shipping container if diluents appear to be missing.

Shipper inserts. The *shipping time* indicates how many days proper temperatures will be maintained from the shipment date shown on the packing slip.

If vaccine shipments exceed that shipping time, vaccines might no longer be viable. Call the vaccine manufacturer for assistance and report the issue to the VFC Call Center.

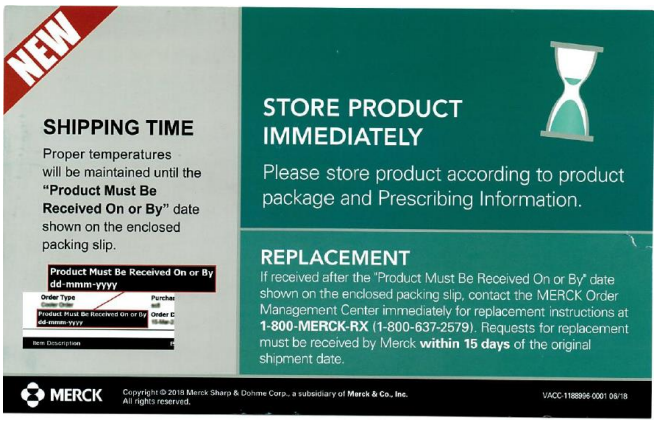


FIGURE 3.9. Illustration of shipper insert.

Partial Shipments

Occasionally, packages on a single order might arrive in separate deliveries due to temporary vaccine supply issues and backorders. Partial shipments are considered "temporarily incomplete." The doses will ship when the vaccines become available. The VFC Program will notify the practice on the order confirmation in the event of partial shipments.

Special-Order Vaccines

In limited situations in which ordering for a single-dose vaccine is allowed, McKesson will repackage the vaccine using amber bags, which count as original packaging. These bags offer protection for light-sensitive vaccines. Vaccines should remain in these bags in the vaccine refrigerator until ready to be administered.

Verification of Practice Hours

The Vaccine Coordinator should request delivery during office hours and update vaccine orders to reflect any period of time the office will be closed, such as holidays or scheduled vacation time. Ensure the clinic is open with the appropriate staff available to receive

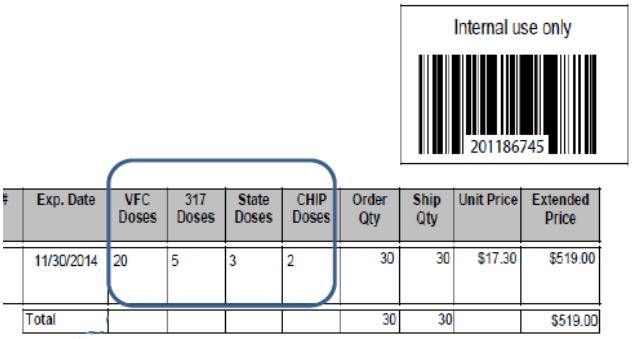
vaccines at least one day a week (other than Monday) and for at least four consecutive hours.

In the event the practice or clinic will be closed unexpectedly and a delivery is expected, the practice should contact the VFC Call Center to verify the shipping status. If the order is already in transit, the practice must make alternate arrangements to accept and properly store the vaccines. The VFC Call Center cannot stop the shipment.

Packing Slips

When receiving vaccine deliveries, check the packing slips carefully to determine the number of doses that shipped by funding source (e.g., VFC). Doses and vaccines on the packing slip should match the VFC order confirmation.

Packing slips also indicate the vaccine expiration dates, which can be used to identify any vaccines that should be used up or transferred within six months.



Exp. Date	VFC Doses	317 Doses	State Doses	CHIP Doses	Order Qty	Ship Qty	Unit Price	Extended Price
11/30/2014	20	5	3	2	30	30	$17.30	$519.00
Total					30	30		$519.00

FIGURE 3.10. Sample McKesson packing slip with funding sources.

What to Do with Questionable Deliveries

Delivered vaccines that are questionable (either were exposed to out-of-range temperatures or received outside the shipping time specified on the shipper insert) must be labeled "Do Not Use" and stored in vaccine refrigerators or freezers—separate from the rest of the vaccine stock—until the VFC Call Center provides additional instructions.

FIGURE 3.11. Illustration of questionable delivery separated from rest of the vaccine stock.

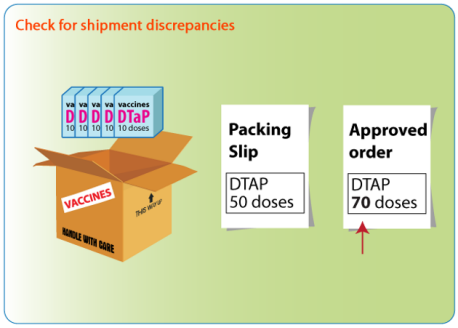
Procedure

Follow these step-by-step instructions to receive vaccine deliveries in compliance with VFC Program requirements and best practices.

TABLE 13. Instructions for receiving vaccine deliveries

Step	Description
1.	Front-office staff: Accept all vaccine shipments and immediately notify the Vaccine Coordinator or Backup that vaccines have arrived. ***Tips:*** • Do not reject vaccine shipments for any reason—even if the package is addressed to a different practice. • Make sure the Vaccine Coordinator or Backup picks up the shipment.
2.	Vaccine Coordinator (or designated role): Inspect all vaccine packages immediately upon receipt and note any issues on the VFC "Vaccine Receiving Log and Checklist."[2] A. Ensure package is addressed to the practice. B. Visually inspect each box to ensure it hasn't been previously opened and isn't broken, torn, or tampered with.
3.	Open the shipment immediately. ***Tip.*** Never leave a vaccine shipping container unpacked and unattended.
4.	Inspect vaccine shipments (vaccines and diluent) to ensure the temperature during transit was in range. ***Tips:*** Follow the instructions on the McKesson temperature indicators.[1] • If the MonitorMark index reads 3-5, record the number on the log. • If the FREEZEmarker indicator does not show a check mark or is not activated, note the issue on the receiving log.
5.	For frozen vaccines: A. Check the shipper insert and the packing slip's shipment date to determine if the vaccines are still good; note the receiving log if the shipment arrived beyond the allowed time.

6. Check the packing slip for discrepancies.
   A. Ensure shipment's vaccines and quantities match the packing slip for the correct funding source (e.g., VFC).
   B. Compare packing slip to the approved doses and diluents on the e-mailed VFC order confirmation—not the original order.
   C. Check the Brand Received on the checklist.
   D. If vaccine products and quantities are not accurate, document the "# Doses Missing" or "# Diluent Missing", or the "# Extra Doses" on the receiving log. (Check the container carefully as diluents might be shipped in the top compartment of the shipping container.)



7. For each vaccine, note on the receiving log any vaccines or diluents with expiration dates within six months.

8. Use VFC stickers[3] to label the vaccines to identify VFC vaccines from other funding sources.

Tip. Labels help to identify to which baskets vaccines should be returned to prevent mixing up funding sources.

9. Store vaccines and diluents immediately.
   A. Store vaccines with the earliest expiration dates in front of vaccines with later expiration dates. (Refer to "Storing Vaccines.")

10. For all vaccines that either were exposed to out-of-range temperatures or exceeded shipping times recommended on the shipper inserts:
    A. Store vaccines in the storage unit apart from other vaccines.
    B. Label the vaccines "Do NOT Use."
    C. Notify the VFC Call Center to receive further instructions.

11. Report any damage or shipment issues immediately.
    A. Fax the completed receiving checklist and packing slip to the VFC Call Center.
    B. Call the VFC Call Center for further instructions.

12. Attach packing slips to the VFC "Vaccine Receiving Log and Checklist"[2] and file in the provider's VFC Program binder.

13. Recycle frozen shipping containers using the UPS label enclosed in the Merck shipping container alongside the packing list.

Notes

1. "McKesson's Instructions for Reading Temperature Indicators" can be found by searching for "IMM-1253" at http://EZIZ.org.
2. VFC "Vaccine Receiving Log and Checklist" can be found by searching for "IMM-1112" at http://EZIZ.org.
3. VFC stickers can be ordered at http://www.eziz.org/store.

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Storing Vaccines

Overview

Vaccines are expensive and fragile. It's important that they are stored in proper equipment and at the correct temperatures to ensure children are protected against vaccine-preventable diseases. When receiving a delivery, vaccines must be unpacked immediately upon arrival and stored under recommended temperatures to protect vaccine viability. Vaccines and diluents should be stored in their designated areas to prevent administration errors and following proper stock rotation protocol to ensure older vaccines are used first.

Target Audience

Typically Vaccine Coordinator and Backup, or staff designated in the provider's vaccine management plan with responsibilities for storing vaccines

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).
- Store vaccines under proper storage conditions at all times (P.A. #9C).
- 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 (California VFC Program "Provider Agreement Addendum" #9A).
- 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 (P.A.A. #9B).
- Store all other refrigerated vaccines between 36.0°F and 46.0°F (2.0°C and 8.0°C) according to manufacturer recommendations (P.A.A. #9C).
- Store vaccines in original packaging and within closed boxes to protect from light and allow for air circulation (P.A.A. #9D).
- Store VFC-supplied and privately purchased vaccines separately and grouped by vaccine type (P.A.A. #9E).
- Do not store vaccines in storage unit doors, drawers, or bins (P.A.A. #9F).
- Place vaccines with the earliest expiration dates toward the front of vaccine storage units and use first (P.A.A. #9G).

Proper Storage Temperatures

Store MMR, MMRV, and Varicella in freezers between -58.0°F and +5.0°F (-50.0°C and -15.0°C). Store all refrigerated VFC vaccines in refrigerators between 36.0°F and 46.0°F (2.0°C and 8.0°C).

Vaccine Storage Equipment

Store VFC-supplied vaccines in storage units that meet VFC Program requirements. (Refer to "Vaccine Storage Unit Specifications.") All storage units must be monitored using VFC-compliant data loggers. (Refer to "Data Logger Specifications.")

Storage of Diluents

When diluents are packaged with vaccines, store them together. Otherwise, diluents may be stored in the refrigerator or at room temperature; never freeze diluents.

Medications & Biologics

If storage of medications or biologics is necessary, store them below the vaccines and on a different shelf to prevent contamination of vaccines due to spills.

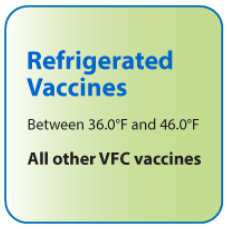
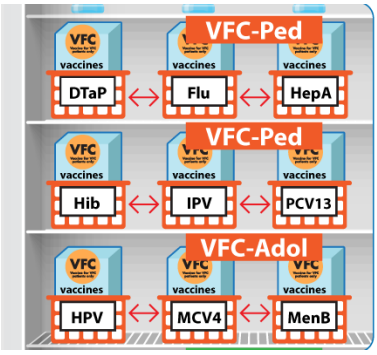
Never Store Food in Storage Units

Do not store food or beverages in vaccine storage units. Vaccines will be at risk of damage by temperature fluctuations and excessive light exposure (due to frequent door openings as staff access food) and contamination from spills.

Procedure

Follow these step-by-step instructions to store vaccine deliveries in compliance with VFC Program requirements and best practices. Make sure your storage units have already been configured properly before storing vaccines. (Refer to "Configuring Vaccine Storage Units.")

TABLE 14. Instructions for storing vaccine deliveries

Step	Description
1.	Ensure that all delivered vaccines and diluents are stored in the labeled mesh boxes or shelf space of the designated storage unit. ***Tips:*** • Store MMR, MMRV and VAR in vaccine freezers. • Store all other vaccines in vaccine refrigerators. • Store diluents that are not packaged with their vaccines in the refrigerator or at room temperature. • Do not store vaccines in doors, vegetable bins, floor, or near/under cooling vents. • Refer to your Vaccine Coordinator or supervisor with questions. 
2.	Check and arrange vaccines and diluents according to expiration dates. A. Move vaccines with the earliest expiration dates in front to ensure older vaccines are used first.
3.	Store all vaccines in original packaging; leave tops on to protect light-sensitive vaccines. A. Position vaccines 2-3 inches away from walls and floor, and allow space for air circulation. B. Separate VFC and privately purchased vaccines. C. Group and label spaces by pediatric, adolescent, and adult types. 
4.	Ensure the storage unit door is shut when all vaccines and diluents are stored.

If Storage Unit is Too Small

If a vaccine storage unit does not have enough storage capacity to accommodate stock during the busiest times of the year, providers must purchase a new storage unit with sufficient capacity. (Refer to "Vaccine Storage Unit Specifications" for more details.)

In the interim, a portion of the vaccines must be moved to a storage unit that

- meets VFC Program requirements,
- has sufficient storage capacity, and
- is monitored by a VFC-compliant data logger with a current, valid certificate of calibration testing.

Notes

Additional resources:

- The "Storing Vaccines" lesson can be found on the EZIZ.org website under the "EZIZ Training" menu at http://EZIZ.org.
- "Refrigerator Setup for Vaccine Storage" can be found by searching for "IMM-963" at http://EZIZ.org.
- "Freezer Setup for Vaccine Storage" can be found by searching for "IMM-966" at http://EZIZ.org.

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Monitoring Storage Unit Temperatures

Overview

Twice daily temperature monitoring helps to prevent loss of expensive vaccines and the potential need for revaccination of patients by identifying out-of-range temperatures quickly and allowing immediate corrective action. Temperature monitoring is dependent on four key factors: 1) well-trained staff, 2) reliable and accurate equipment, 3) complete documentation, and 4) appropriate follow-up for any out-of-range temperatures.

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

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).
- Ensure vaccine storage unit temperatures are recorded on VFC temperature logs (California VFC Program "Provider Agreement Addendum" #10A).
- 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 (P.A.A. #10B).
- Ensure staff respond to all data logger alarms by reporting temperature excursions to SHOTS (Storage and Handling Online Triage System) (P.A.A. #10C).
- 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 (P.A.A. #10D).
- 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 (P.A.A. #10E).
- Ensure VFC temperature logs are legible, and completed accurately and in ink (P.A.A. #10F).
- Neatly cross out, correct, initial, and date any inadvertent documentation error immediately (P.A.A. #10G).
- 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 (P.A.A. #10H).
- Retain paper logs and electronic files related to temperature monitoring for three years (P.A.A. #10I).
- Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted (P.A.A. #10J).

Rationale

Vaccines are expensive and fragile. Excessive cold and heat can damage vaccines and impact vaccine viability. Consistently and accurately monitoring storage unit temperatures helps to prevent negligent loss of vaccines and provider liability.

Getting Familiar with Data Loggers

All key practice staff monitoring storage unit temperatures must be trained on how to operate the practice's data loggers and interpret their temperature readings.

Preparing new data loggers for use. Refer to the device's product guide or video to get familiar with its functionality. Call the vendor's support number with all questions regarding setup, functionality, or configuration. Refer to "Data Logger Setup & Use"[1] for guidance on how to use the device to monitor temperatures according to VFC Program requirements.

Patient & Provider Benefits

Consistent and accurate monitoring of vaccine storage unit temperatures benefits both patients and providers:

- Helps ensure vaccines protect patients from preventable diseases
- Helps ensure vaccines are available when patients need them
- Helps ensure ordering privileges aren't put on hold until storage and handling incidents are resolved
- Minimizes time-consuming revaccination recalls for patients who received ineffective vaccines

Importance of Staff Training

All staff who monitor vaccine storage temperatures—including supervisors who certify staff documentation—must be properly trained on temperature monitoring, use of the practice's data loggers, and the required actions for out-of-range temperatures—even if temperature monitoring is not their routine activity. Because of the importance of temperature monitoring, practices must update their vaccine management plan each year (and whenever changes are made) to include the names and signatures of staff with temperature monitoring responsibilities, as well as the dates they completed the required EZIZ training lessons.

Definitions of Key Terms

Temperature excursions. Manufacturers might refer to out-of-range temperatures (either too warm or too cold) as temperature excursions. Staff communicating with manufacturers should be familiar with this term.

CURRENT. Internal storage unit temperature now.

MIN. Minimum (coldest) storage unit temperature since the data logger was reset.

MAX. Maximum (warmest) storage unit temperature since the data logger was reset.

FIGURE 3.12. Illustration of digital display showing current, MIN, and MAX temperatures.

How Temperature Excursions Affect Vaccine Viability

Repeated exposures to temperatures that are too warm can affect vaccine viability gradually.

A single exposure to temperatures that are too cold might destroy vaccines immediately.

FIGURE 3.13. Illustrations depicting how vaccines might be damaged by too warm and too cold temperatures.

Acceptable Storage Unit Temperatures

Maintain these recommended temperature ranges, which are designated as the OK range on the VFC refrigerator and freezer temperature logs:

Refrigerator: Between 36.0°F and 46.0°F (between 2.0°C to 8.0°C).
Freezer: Between -58.0°F and +5.0°F (between -50.0°C and -15.0°C).

These temperature ranges allow for normal temperature fluctuations caused by opening and closing of storage unit doors and automatic defrost cycles.

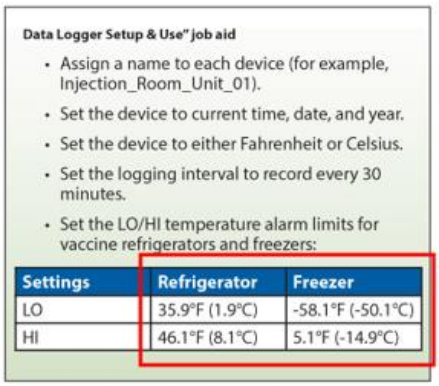
Taking Corrective Actions for Out-of-Range Temperatures

If storage unit temperatures drift out of range, take immediate action to assess the situation and prevent vaccine spoilage. All temperature excursions (out-of-range temperatures) must be reported to the Storage and Handling Online Triage System (SHOTS) at MyVFCvaccines.org. The system guides providers through the documentation process and determines whether it is necessary to contact vaccine manufacturers. (Refer to "Taking Action for Temperature Excursions.")

Alarm Alerts

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. Take these steps:

1. Ensure the alarm alert is set to the correct LO/HI temperature alarm limits. (Refer to Figure 3.14.)
2. Check the storage unit door and its power supply and thermostat setting.



Data Logger Setup & Use" job aid

- Assign a name to each device (for example, Injection_Room_Unit_01).
- Set the device to current time, date, and year.
- Set the device to either Fahrenheit or Celsius.
- Set the logging interval to record every 30 minutes.
- Set the LO/HI temperature alarm limits for vaccine refrigerators and freezers:

Settings	Refrigerator	Freezer
LO	35.9°F (1.9°C)	-58.1°F (-50.1°C)
HI	46.1°F (8.1°C)	5.1°F (-14.9°C)

FIGURE 3.14. Illustration of VFC job aid highlighting LO/HI alarm limit settings.

If alarms continue to go off frequently after taking these steps, contact the device manufacturer for guidance.

Important. Report all temperature excursions to ensure vaccines are viable. (Refer to "Taking Action for Temperature Excursions" for details.)

Attention Supervisors

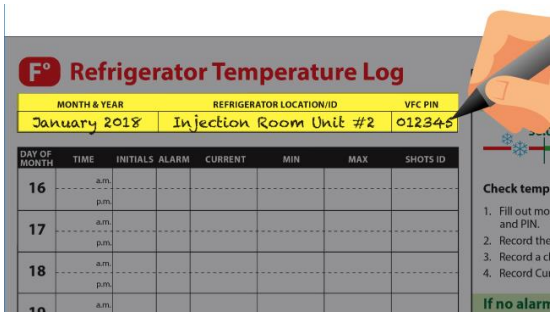
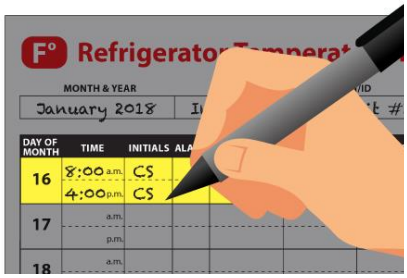
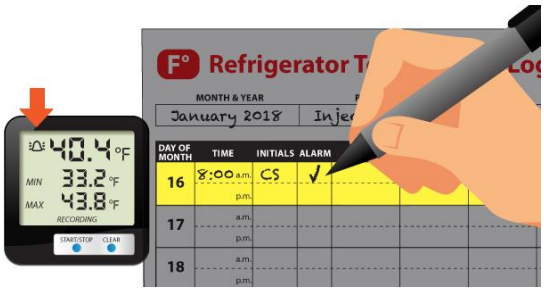
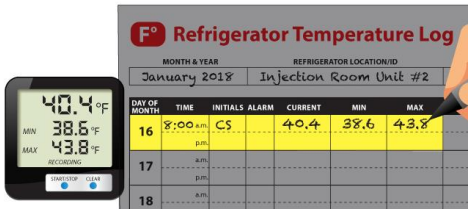
Supervisors are responsible for reviewing completed temperature logs and certifying that staff are monitoring and documenting temperatures according to VFC Program requirements. Because temperature log review allows supervisors to identify any training gaps, supervisors must be knowledgeable about proper temperature monitoring. (Refer to the EZIZ "Monitoring Storage Unit Temperatures"[2] lesson for training.)

Supervisors must review completed temperature logs at the end of each two-week reporting period. Look for a pattern that might indicate storage unit performance issues. Contact the VFC Field Representative or the VFC Call Center for guidance to resolve any issues before vaccines are damaged.

Procedure

Follow the step-by-step instructions to monitor storage unit temperatures in compliance with VFC Program requirements and best practices.

TABLE 15. Instructions for monitoring storage unit temperatures

Step	Description
1.	For each new sheet, fill out month, year, refrigerator location ID, and VFC PIN. A. Use the Fahrenheit or Celsius VFC temperature log that matches the data logger settings. B. Document all readings in ink—not pencil. C. If mistakes are made, cross out, correct, initial, and date the changes. 
2.	Record the time and your initials next to the current day of the month. • ***a.m.*** temperatures *before* opening the refrigerator or freezer • ***p.m.*** temperatures about an hour before the practice closes to allow time for corrective actions 
3.	Record a check if a visible or audible alarm went off. ***Tip.*** If an alarm did not go off, leave blank. 
4.	Record CURRENT, MIN, and MAX temperatures neatly, accurately, and in the correct columns. ***Tip.*** Refer to the data logger's product guide or video to learn how to use the device. Call the vendor's support number for all questions regarding setup, functionality, or configuration. 

If no alarm:

1. Clear MIN and MAX to ensure staff don't record the same temperatures during the next recording.

   Tip. Skip this step if the device resets automatically.

2. Ensure the data logger is in place and recording storage unit temperatures.

   Tip. Some devices might need to be reconnected and restarted. Refer to the device's product guide for details.

If an alarm went off:

Take immediate action and report any excursions to SHOTS at MyVFCvaccines.org. (Refer to "Taking Action for Temperature Excursions" for details.)

Supervisor's Review

Supervisors must certify and sign that temperatures were recorded twice daily and corrective actions taken for each two-week log:

Supervisor's Review

When log is complete, check all that apply:

- ☐ Month/year/fridge ID/PIN are recorded.
- ☐ Temperatures were recorded twice daily.
- ☐ I reviewed data files for all the days on this log to find any missed excursions.
  Date downloaded: _____/_____/_____
- ☐ Any excursions were reported to SHOTS at MyVFCvaccines.org.
- ☐ We understand that falsifying this log is grounds for vaccine replacement and termination from the VFC Program.

On-Site Supervisor's Name:

_____

Signature: _____

Date: ____/_____/_____

Staff Names and Initials:

_____

_____

_____

FIGURE 3.15. Illustration of fields to be completed by the supervisor.

When log is complete:

1. Ensure staff recorded month and year, storage unit location ID, and VFC PIN at the top of the log.

   Tip. Temperature logs faxed to the VFC Call Center without the practice's VFC PIN might delay vaccine order processing.

2. Ensure temperatures were recorded twice daily.

3. Download and review temperature data files for all days on the log and record the download date.

   Tip. Supervisors might find missed excursions that could impact vaccine viability by downloading data files for days not reported.

4. If missed excursions are found, report them immediately to SHOTS at MyVFCvaccines.org.

5. Ensure staff know that falsifying logs is grounds for vaccine replacement and provider termination from the VFC Program.

6. Certify the review by recording supervisor name, signature, and date.

7. Ensure names and initials of staff recording temperatures on this log have been recorded in case VFC representatives have questions about the temperature log.

Importance of Staff Training

Vaccines viability might be compromised by inconsistent or inaccurate temperature monitoring. The supervisor review is an opportunity to ensure staff understand and are following proper protocol that protects provider vaccines. If errors are found, review the step-by-step procedure with staff, or instruct them to retake the EZIZ "Monitoring Storage Unit Temperatures" lesson[2] on temperature monitoring.

Temperature Monitoring at Mass Vaccination & Outreach Clinics

Since vaccines are maintained in a temporary location during pre-approved mass vaccination and outreach clinics, temperature data must be monitored and recorded using a data logger—every hour during the clinic day. Print the relevant excursion data from the temperature data file (or summary report if available) and attach it to the "Hourly Vaccine Temperature Log for Mass Vaccination Clinics."[3]

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

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

- Ensure staff respond to all data logger alarms by reporting temperature excursions to SHOTS (Storage and Handling Online Triage System) (California VFC Program "Provider Agreement Addendum" #10C).
- Take immediate action to prevent vaccine spoilage and correct any improper storage condition for all out-of-range storage unit temperatures (P.A.A. #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

Staff must respond to all data logger alarms by reporting temperature excursions to VFC Program's Storage and Handling Online Triage System (SHOTS). 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.

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.

SHOTS can be accessed at MyVFCvaccines.org. (Refer to the "Storage and Handling Triage System (SHOTS)" job aid[1] for details.)

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.	Clear the MIN/MAX and any alarm symbol. ***Tip.*** This step ensures staff don't report the same excursion during the next recording; skip this step if your device resets automatically.
2.	Post the "Do Not Use Vaccines" sign to quarantine all vaccines. ***Tip.*** This step ensures vaccines are not administered until SHOTS or the vaccine manufacturer determines vaccines are okay to administer.
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.	Immediately report the temperature excursion to SHOTS at MyVFCvaccines.org and follow all instructions given. A. Download and save the temperature data file to the folder created for the device. (For example, Injection_Room_FRIDGE\2019\JAN.) (Refer to "Configuring Data Loggers" for guidance on setting up folders for data storage.) ***Tip.*** Specify a filename that includes VFC PIN, storage unit ID, and current date. For example: 012345_FRIDGE_01162019.

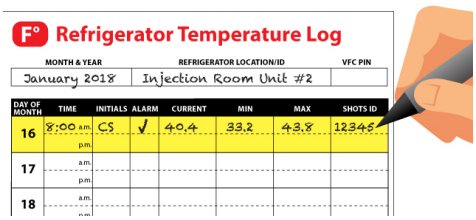
B. Look in the data file for any excursion details (alarm results that show temperatures outside the device's configured alarm limits).

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.

7. Do not administer vaccines until vaccine viability has been determined by vaccine manufacturers.

   A. ***If vaccines are okay to use:*** Alert your supervisor and remove the "Do Not Use Vaccines" sign.
   B. ***If vaccines are not okay to use:*** Remove the vaccines from the storage unit and submit a return form on MyVFCvaccines.org. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines" for details.)

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" lesson[2] 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.

Using an Immunization Registry or EHR/EMR?

Physical counting of vaccines might still be required if the number of VFC-supplied doses on hand doesn't match the quantities reported on current or previous vaccine orders. Discrepancies could occur if the data recorded in electronic systems is not accurate or consistent, or if quantities were incorrectly reported on vaccine orders.

Definitions of Key Terms

Providers must ensure that VFC-supplied vaccine inventory is routinely checked for expiration dates to help ensure patients receive viable vaccines.

Expiration date. All vaccines and diluents have expiration dates, which indicate the date by which a product must be used. Expiration dates vary by type of vaccine (or diluent) and lot number. They are printed on vials, manufacturer-filled syringes, and packages.

Interpreting Expiration Dates

When expiration dates are marked with only month/year, vaccines or diluents may be used up to and including the last day of the month indicated. If a day is included with month and year, vaccines may only be used through that day.

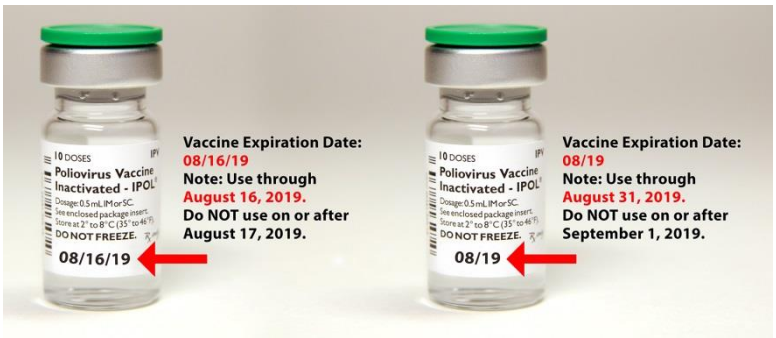


FIGURE 3.16. Illustration depicting how to interpret expiration dates with and without day of the month.

Exceptions to Expiration Dates

There are three instances when vaccines must be used prior to the expiration date printed on the label.

Reconstitution. Freeze-dried vaccines that are mixed with diluent and reconstituted into a liquid form must be administered within the timeframe indicated in the manufacturer's package insert.[1]

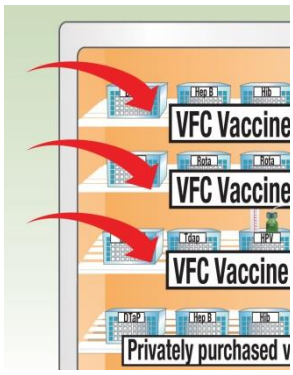
Multi-dose vials. Vaccines in multi-dose vials that do not require reconstitution may be used through the expiration date printed on the label as long as the vaccine is not contaminated—unless indicated otherwise by the manufacturer. For some vaccines, the manufacturer specifies that once the multi-dose vial has been entered or the rubber stopper punctured, the vaccine must be used within a certain number of days. This is commonly referred to as the "beyond-use date" (BUD).

Manufacturer-shortened expiration dates. If vaccines have been exposed to out-of-range temperatures, potency might be reduced before the expiration date printed on the label. A manufacturer could determine that the vaccine may be used—but with a shortened expiration date when temperatures excursions are reported. ***Tip:*** Write the new expiration date on the vial and/or box.

Procedure

Follow these step-by-step instructions to conduct physical vaccine inventories in compliance with VFC Program requirements and best practices.

TABLE 17. Instructions for conducting physical vaccine inventories

Step	Description
1.	Print the VFC "Vaccine Physical Inventory Form."[2]
2.	Determine which vaccines are VFC vaccines. ***Tips:*** • Storage units should have been set up to separate and clearly label private and VFC vaccines to ensure the correct vaccines are administered. (Refer to "Configuring Vaccine Storage Units" for details.) • Do not count private vaccines. 
3.	Remove all doses for the first VFC-supplied vaccine and close the storage unit door.
4.	Group vaccines by lot numbers. A. Look at lot numbers on every box. B. Place expired vaccines and diluents in a bag or container marked "DO NOT USE."
5.	Record vaccine information on the inventory form. VACCINE: DTaP BRAND: ☑ Daptacel–vials (DOSES PER BOX 10); ☐ Infanrix–vials (10); ☐ Infanrix–syringes (10) LOT NUMBERS: C3356AA EXPIRATION DATE: 09/26/19 # DOSES ON HAND: A. Record a check next to the brand and packaging. B. Record the first lot number and expiration date. C. Note any vaccines that will expire within six months.
6.	Count all doses of that lot number—including opened boxes. ***Tips.*** • If the vial caps are the same color, then count each vial as one dose. (In this example, there are eight doses.)

- If the vial caps are of different colors (diluents are packaged with vaccines), then count one pair of each color as one dose. (In this example, there are two doses.)

- If the box contains both vials and syringes, then count one pair of each as one dose. (In this example, there are four doses.)

- If the vial is labeled with multiple doses, then count the number of doses left—not used. (In this example, someone has made hash marks to indicate that three out of 10 doses have been administered, so the count remaining in inventory is seven.)

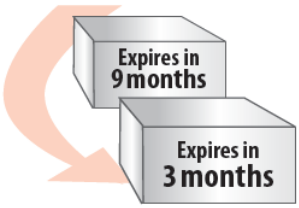
7. Record the count in the "# Doses On Hand."

VACCINE	BRAND	DOSES PER BOX	LOT NUMBERS	EXPIRATION DATE	# DOSES ON HAND
DTaP	☑ Daptacel–vials	10	C3356AA	09/26/19	30
	☐ Infanrix–vials	10			
	☐ Infanrix–syringes	10	C3359AA	12/31/19	31

8. Repeat steps 5-7 for each group of lot numbers for the same vaccine.

9. Total the "# Doses On Hand" for all the lot numbers of that vaccine and record the number in the "Total Doses on Hand" column.

10. Put vaccines back in the storage unit in order of expiration dates.
    A. Move vaccines with the earliest expiration dates in front of other vaccines that have later expiration dates (to ensure older vaccines are used first).
    B. Position vaccines 2-3 inches away from unit walls and floor to allow for air circulation.
    C. Remove expired vaccines and diluents from the storage unit and return to McKesson. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines.")



11. Repeat steps 3-10 for all VFC-supplied vaccines—one vaccine name/brand at a time.

Tip for registry users. If the number of doses on the current inventory report is different than the number recorded on the VFC "Vaccine Physical Inventory Form,"[2] research and correct any differences.

12. Make sure that all vaccines have been returned to the vaccine storage unit and that their doors are closed when the inventory is complete.

13. Confirm that the capacity of the vaccine storage units is adequate to accommodate current inventory plus any new orders—especially during back-to-school and flu seasons.

    Tip. Talk to your provider if the practice needs to purchase additional vaccine storage units to accommodate the inventory in a manner consistent with VFC Program requirements and patient population.

14. Contact the VFC Call Center to address any expired or soon to expire vaccines.
    - Expired vaccines must be reported at MyVFCvaccines.org. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines".)
    - Any vaccines that will expire within six months and are unlikely to be used should be transferred to another active VFC provider. (Refer to "Transferring Vaccines between Providers" for more details.)

Notes

1. "Package Inserts," Immunization Action Coalition, http://www.immunize.org/packageinserts/.
2. VFC "Vaccine Physical Inventory Form" can be found by searching for "IMM-1052" at http://EZIZ.org.

Additional resources:

- The "Conducting a Vaccine Inventory" lesson can be found on the EZIZ.org website under the "EZIZ Training" menu at http://EZIZ.org.

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Transferring Vaccines between Providers

Overview

Vaccine transfer can be minimized by consistent inventory management, but providers might need to transfer vaccines to other providers when vaccines will likely expire before administration.

Target Audience

Typically Vaccine Coordinator and Backup

Program Requirements

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

- Contact the VFC Call Center prior to transferring VFC-supplied vaccines (California VFC Program "Provider Agreement Addendum" #13A).
- Only transfer to alternate locations that have VFC-approved vaccine storage units and digital data loggers (P.A.A. #13B).
- Never routinely transfer VFC-supplied vaccines to other VFC providers (P.A.A. #13C).
- Never transfer VFC-supplied vaccines to non-VFC providers (P.A.A. #13D).
-

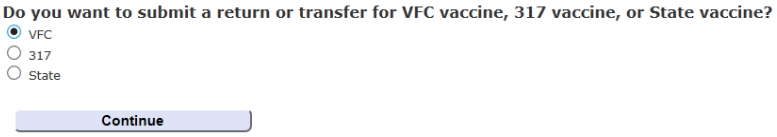
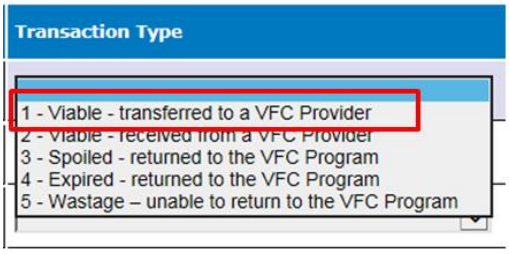
Key Points

- Follow proper vaccine packaging and temperature monitoring while transporting vaccines to another VFC provider. (Refer to "Transporting Vaccines.")
- Do not transfer vaccines exposed to multiple temperature excursions.
- Do not transfer multi-dose vials.
- Do not transfer VFC-supplied vaccines to non-VFC providers, including personal residences or any locations that don't have VFC-certified storage units and temperature monitoring devices.

Procedure: Preparing for Transport

Follow these step-by-step instructions to transfer vaccines to another VFC provider in compliance with VFC Program requirements and best practices.

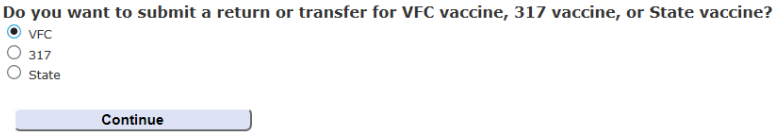
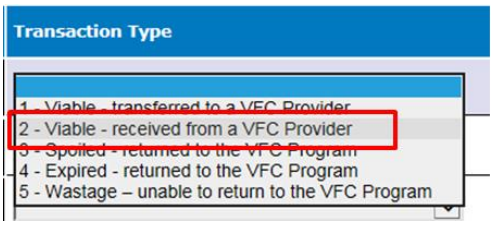
TABLE 18. Instructions for transferring vaccines between VFC providers

Step	Description
1.	Contact the VFC Call Center or Field Representative for approval prior to transferring vaccines.
2.	Contact the alternate storage location designated in the practice's vaccine management plan to verify that the facility can store (in the event of a vaccine-related emergency) or use (if vaccines will expire within six months) the quantity of vaccines to be transferred.
3.	Go to EZIZ.org and click the "Order, Transfer, or Return Vaccines" link in the top center of the web page.
4.	Enter the practice's VFC PIN and zip code, and click the "Sign On" button.
5.	Click the "Enter Returns & Transfers" button under the "Inventory" section.
6.	Click to indicate that VFC vaccines are being transferred then click "Continue." 
7.	Complete the "VFC Vaccine Return/Transfer Form" at MyVFCvaccines.org. A. Select the vaccine from the "Vaccine" dropdown list. B. Enter the lot number. C. Enter the expiration date. D. Enter the number of doses. E. Select the first option from the "Transaction Type" dropdown list. F. Repeat this step for each vaccine being transferred. 
8.	Print a copy of the confirmation of transfer submission for your records.
9.	Transport the vaccines to the designated provider and bring a copy of the transport job aid as reference. (Refer to "Transporting Vaccines".)

Procedure: Receiving Vaccines Transferred from another VFC Provider

Follow these step-by-step instructions to receive vaccines transferred from another VFC provider in compliance with VFC Program requirements and best practices.

TABLE 19. Instructions for receiving vaccines transferred from another VFC provider

Step	Description
1.	Go to EZIZ.org and click the "Order, Transfer, or Return Vaccines" link in the top center of the web page.
2.	Enter the practice's VFC PIN and zip code, and click the "Sign On" button.
3.	Click the "Enter Returns & Transfers" button under the "Inventory" section.
4.	Click to indicate that VFC vaccines are being transferred then click "Continue." 
5.	Complete the "VFC Vaccine Return/Transfer Form" at MyVFCvaccines.org to receive the transferred vaccines into inventory. A. Select the vaccine from the "Vaccine" dropdown list. B. Enter the lot number. C. Enter the expiration date. D. Enter the number of doses. E. Select "Viable – received from a VFC Provider" (see below) from the "Transaction Type" dropdown list. F. Repeat this step for each vaccine transferred. G. Print a copy of the confirmation of transfer submission for your records. 

Notes

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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Transporting Vaccines

Overview

Each vaccine transport exposes vaccines to potentially inappropriate temperature conditions. CDC discourages routine vaccine transport because manufacturers do not generally recommend it or provide any guidance. Contact your VFC Field Representative or the VFC Call Center for approval prior to vaccine transport. While being transported to alternative locations, temperatures must be monitored and recorded using VFC transport logs. Use these procedures for guidance in an emergency situation. Call the vaccine manufacturer if you have concerns.

Target Audience

Typically Vaccine Coordinator and Backup

Program Requirements

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

- Transport vaccines only when necessary and follow the guidelines for proper refrigerated vaccine transport (IMM-983) and frozen vaccine transport (IMM-1130) (California VFC Program "Provider Agreement Addendum" #13E).
- Complete the VFC "Refrigerated Vaccine Transport Log" (IMM-1132) or "Frozen Vaccine Transport Log" (IMM-1116) each time vaccines are transported (P.A.A. #13F).
- Transport VFC-supplied vaccines only to facilities designated in the provider profile and never to personal residences (P.A.A. #13G).
- 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 (P.A.A. #13H).
- Acknowledge that vaccines transported without proper documentation of temperature monitoring will be deemed non-viable (P.A.A. #13I).

Caution

Monitoring temperatures during transport is required. 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. If temperatures aren't monitored according to VFC Program requirements, vaccines will be deemed non-viable.

Refrigerated vaccines. In an emergency situation, this procedure might keep refrigerated vaccines within the required temperature range for up to eight hours—depending on transport conditions. Call the vaccine manufacturer with any concerns.

Frozen vaccines. Frozen vaccines (MMR, MMRV, and Varicella) should never be transported except in an emergency and, if necessary, must be transported under frozen conditions.

Temperature indicators. These products are not approved for monitoring vaccine temperatures during transport because they do not record time. Data loggers must be used during transport of all VFC-supplied vaccines.

Transporting Diluents

- Transport diluents with their corresponding vaccines to ensure there are always equal amounts of vaccines and diluents for reconstitution. Follow manufacturer guidance for specific temperature requirements.
- Do not freeze diluents for varicella-containing vaccines—even in transport.

Procedure: Refrigerated Vaccines

Follow these step-by-step instructions to transport refrigerated vaccines in compliance with VFC Program requirements and best practices.

TABLE 20. Instructions for transporting refrigerated vaccines

Step	Description
	Assemble packing supplies and documents
	• ***Cooler.*** Use a hard-sided cooler. • ***"Vaccines: Do Not Freeze" label.*** Attach the label to the cooler. • ***Conditioned cold packs or frozen water bottles.*** Condition cold packs by storing them at room temperature until they perspire (1-2 hours). Alternatively, condition frozen water bottles by placing them under cool or lukewarm water until the ice block inside spins freely (fewer than 5 minutes). • ***Data logger.*** Retrieve the backup device's buffered probe from the vaccine refrigerator and its digital display. • ***Insulating cushioning material.*** Use 2-inch layers of bubble wrap to prevent vaccines from freezing. Do NOT use packing peanuts or other loose material that might shift during transport. • ***Transport log.*** Print a copy of the VFC "Refrigerated Vaccine Transport Log". [1] • ***Vaccine management plan.*** Locate the alternate vaccine storage location in your practice's vaccine management plan.
	Prepare for transport
	If transferring vaccines to another VFC provider, complete the transfer form at MyVFCvaccines.org. (Refer to "Transferring Vaccines between Providers" for details.) 1. Verify that the alternate vaccine storage location can accommodate your vaccines. 2. Complete the top portion of the VFC "Refrigerated Vaccine Transport Log." 3. Record the "Time" and "Temperature of vaccines in refrigerator before transfer" on the bottom of the transport log. 4. Remove vaccines from the refrigerator. 5. Complete the "Vaccine Inventory Information" portion of the transport log before proceeding.

Pack vaccines

1. Place the conditioned cold packs or frozen water bottles to cover only half of the bottom of the cooler.

2. Completely cover the conditioned items and cooler bottom with a 2-inch layer of bubble wrap.
   A. Place the buffered probe on top of the bubble wrap—directly above a cold pack.

3. Layer vaccine boxes on the bubble wrap and probe. Do NOT let vaccine boxes touch the cold packs or water bottles.

4. Package diluents. ***Tips:***
   - Diluents stored in the refrigerator should be transported with refrigerated vaccines in the cooler.
   - Diluents stored at room temperature should be transported at room temperature.
   - Diluents packaged with their vaccines should be transported with the vaccine in the cooler.
   - Never freeze diluents—even in transport.

5. Completely cover vaccines with another 2-inch layer of bubble wrap.

6. Place conditioned items to cover only half of the bubble wrap. Do NOT let any vaccine boxes touch the condition items.

7. Complete the final steps.
   A. Layer bubble wrap to fill the remaining empty space and close the cooler.
   B. Record the temperatures before departure on the transport log.
   C. Attach the digital display and transport log carefully to the outside of the cooler.

8. Record the "Time" and "Temperature of vaccines in cooler before departure" on the bottom of the transport log.

9. Drive the vaccines to your alternate storage location.

Unpack vaccines at the alternate storage location

1. Confirm the alternate vaccine storage unit temperatures are within recommended ranges.

2. Record the "Time" and "Temperature of alternate vaccine storage unit" on the bottom of the transport log.

3. Record the "Time" and "Temperature of cooler upon arrival" on the transport log before removing vaccines.

4. If the cooler temperature is

   Between 36.0°F and 46.0°F (2.0°C and 8.0°C): Unpack and store vaccines in the alternate vaccine refrigerator.

   Below 36.0°F (2.0°C) or above 46.0°F (8.0°C): Label the vaccines "Do Not Use" and store them in the vaccine refrigerator; alert your supervisor; immediately report the excursion to SHOTS at MyVFCvaccines.org.

Procedure: Frozen Vaccines

Follow these step-by-step instructions to transport frozen vaccines in compliance with VFC Program requirements and best practices.

TABLE 21. Instructions for transporting frozen vaccines

Step	Description
	Assemble packing supplies and documents • ***Cooler.*** Use a hard-sided cooler. • ***Frozen cold packs.*** NEVER USE DRY ICE. Keep enough frozen cold packs in your vaccine freezer to make two layers in the transport cooler. • ***Data logger.*** Retrieve the backup device's buffered probe from the vaccine refrigerator and its digital display. • ***Insulating cushioning material.*** Use 2-inch layers of bubble wrap to prevent vaccines from shifting. Do NOT use packing peanuts or other loose material that might shift during transport. • ***Transport log.*** Print a copy of the VFC "Frozen Vaccine Transport Log".[2] • ***Vaccine management plan.*** Locate the alternate vaccine storage location in your practice's vaccine management plan.

Prepare for transport

If transferring vaccines to another VFC provider, complete the transfer form at MyVFCvaccines.org. (Refer to "Transferring Vaccines between Providers" for details.)

1. Verify that the alternate vaccine storage location can accommodate your vaccines.
2. Complete the top portion of the VFC "Frozen Vaccine Transport Log."
3. Record the "Time" and "Temperature of vaccines in freezer before transfer" on the bottom of the transport log.
4. Remove vaccines from the freezer.
5. Complete the "Vaccine Inventory Information" portion of the transport log before proceeding.

Pack vaccines

1. Place a layer of cold packs to completely cover the bottom of the cooler. NEVER USE DRY ICE.

2. Layer vaccine boxes directly on top of the frozen cold packs.

3. Place the buffered probe with the top layer of vaccines.

4. Spread another layer of frozen cold packs to completely cover the vaccines.

5. Complete these final steps:
   A. Layer bubble wrap to fill the remaining empty space and close the cooler.
   B. Record the temperatures before departure on the transport log.
   C. Attach the digital display and transport log carefully to the outside of the cooler.

6. Record the “Time” and “Temperature of vaccines in cooler before departure” on the bottom of the transport log.
7. Drive the vaccines to your alternate storage location.

Unpack vaccines at the alternate storage location

1. Confirm their vaccine storage unit temperatures are within recommended ranges.

2. Record the "Time" and "Temperature of alternate vaccine storage unit" on the bottom of the transport log.

3. Record the "Time" and "Temperature of cooler upon arrival" on the transport log before removing vaccines.

4. If the cooler temperature is

   Below 5.0°F (-15.0°C): Unpack and store vaccines in the alternate vaccine freezer.

   Above 5.0°F (-15.0°C): Label the vaccines "Do Not Use" and store them in the vaccine freezer; alert your supervisor; immediately report the excursion to SHOTS at MyVFCvaccines.org.

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).
- Conduct regular vaccine transport drills to maintain competency and readiness for emergencies (P.A.A. #2G).
- 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. Conduct regular vaccine transport drills. Practice packing a 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. ***In the event of appliance failure.*** 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.) ***For power outages after hours.*** Report any excursion to SHOTS the next morning and take appropriate action. (Refer to "Taking action for Temperature Excursions.") ***For planned outages expected to be short-term (approximately fewer than 4 hours).**** Monitor storage unit temperature and report any excursions once power has been restored. (Refer to "Taking action for Temperature Excursions.") ***For planned/unplanned outages expected to be longer than approximately 4 hours,* or for any outage that extends beyond the current business day.*** 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: 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: 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: 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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Reporting Spoiled, Expired, or Wasted Vaccines

Overview

Providers are accountable for all VFC-supplied vaccines. While doses administered and doses on hand are reported with each routine vaccine order, providers must report separately all spoiled, expired, and wasted vaccines. All spoiled and expired vaccines must be returned to McKesson within six months. Doses reported as returned must match actual doses received by McKesson.

Target Audience

Typically Vaccine Coordinator and Backup, or the staff designated in the provider's vaccine management plan with responsibilities for shipping vaccines

Program Requirements

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

- Return all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration (VFC "Provider Agreement" #9D).
- I 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 (P.A. #13).
- Report all VFC-supplied spoiled, expired, or wasted vaccines prior to submitting a new vaccine order (California VFC Program "Provider Agreement Addendum" #12E).

Definitions of Vaccine Loss Terms

Spoiled or expired vaccines may be returned to the VFC Program for excise tax credit, but providers are responsible for disposing of wasted vaccines. Providers accurately report vaccines that are spoiled, expired, or wasted to ensure they are processed correctly.

Spoiled vaccines. Careful storage and handling should minimize spoiled vaccines. Vaccines still in their original container (vial or syringe) are considered spoiled and nonviable if the vaccine manufacturer has determined that vaccines were exposed to out-of-range temperatures. Vaccines could spoil as a result of the following conditions:

- natural disaster or power outage
- refrigerator or freezer temperatures that are too warm
- refrigerator temperatures that are too cold
- failure to store vaccines properly upon receipt
- vaccines spoiled during transfer
- mechanical failure
- unmonitored temperatures

Expired. Careful vaccine management (including stock rotation) should minimize expired vaccines. Vaccines are considered expired and nonviable if their expiration dates are past the manufacturer expiration date on the vial or the expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

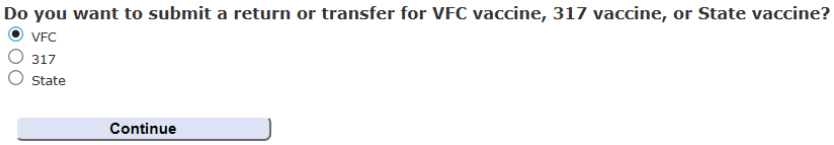
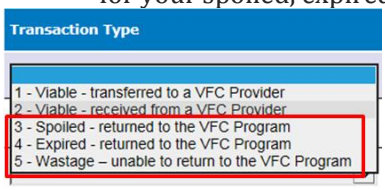
Wasted. Careful vaccine management and administration should minimize wasted vaccines. Vaccines may be designated wasted as a result of the following conditions:

- vaccines drawn into the syringe but not administered
- vaccines in open vials but doses not administered
- damaged vials (e.g., due to a drop causing damage to vial integrity or sterility)
- lost or unaccounted for vaccines

Procedure

Follow these step-by-step instructions to report spoiled, expired, or wasted vaccines in compliance with VFC Program requirements and best practices.

TABLE 25. Instructions for reporting spoiled, expired, or wasted vaccines

Step	Description
1.	Go to EZIZ.org and click the "Order, Transfer, or Return Vaccines" link in the top center of the web page.
2.	Enter the practice's VFC PIN and zip code, and click the "Sign On" button.
3.	Click the "Enter Returns & Transfers" button under the "Inventory" section.
4.	Click to indicate that VFC vaccines are being transferred then click "Continue." 
5.	Complete the "VFC Vaccine Return/Transfer Form" at MyVFCvaccines.org. A. Select each vaccine from the "Vaccine" dropdown list. B. Enter the lot number. C. Enter the expiration date. D. Enter the number of doses. E. Select the appropriate option from the "Transaction Type" dropdown list for your spoiled, expired, or wasted vaccines. 
6.	**Spoiled or Expired?** Package and ship refrigerated and frozen vaccines to McKesson. Cold packs are not necessary to include with the package since the vaccines are no longer viable. A. Click to request that a prepaid label be e-mailed to the practice. B. Label the package using the return shipment label. C. Ensure the doses packed match the doses reported above.
7.	**Wasted?** Properly dispose of all open vials drawn and not administered.
8.	Print a copy of the confirmation of transfer submission for your records.

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Conducting Off-Site Clinics

Overview

Providers must obtain special approval from the VFC Program prior to conducting mass vaccination clinics (e.g., seasonal flu outreach clinics) to ensure that efforts meet all VFC Program requirements.

Target Audience

Typically Coordinator Vaccine and Backup

Program Requirements

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

- 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 (California VFC Program "Provider Agreement Addendum" #9B).
- 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 (P.A.A. #9H).
- For mobile units, follow all VFC Program requirements including vaccine storage, transport, and temperature monitoring (P.A.A. #9I).
- 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 (P.A.A. #13H).
- 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).

Definitions

Mass vaccination clinics. These are large-scale vaccination clinics conducted outside the medical home. ***Note:*** For local health departments only. Prior authorization from the VFC Program is required.

Outreach clinics These are small-scale vaccination clinics conducted outside the medical home. ***Note:*** Prior authorization from the VFC Program is required.

Mobile units. Mobile units act as an extension of the medical home and are often used to provide outreach to under-served, high-risk populations. For mobile units, follow all VFC Program requirements including vaccine storage, transport, and temperature monitoring. ***Note:*** Mobile units are identified during VFC Program enrollment and recertification.

Submitting a Request for Approval

Document the following information and keep on file for review upon request by representatives of the VFC Program:

- off-site location
- proposed clinic dates
- clinic locations
- anticipated population to be vaccinated
- breakdown of VFC and private vaccine need
- transport plans (e.g., which vaccines and quantities) to and from the clinic locations

- point of contact for overseeing and coordinating the clinics and vaccine supply

Vaccine Management

Because most temporary mass clinics require vaccine transport on the day of the clinic, CDC has determined that enhanced storage and handling practices are required. In addition to adhering to all general VFC Program requirements, the following additional requirements must also be met:

- Transport vaccines—do not ship them—from the approved VFC PIN to the location of the temporary clinic.
- Transport only amounts of vaccines that are appropriate based on the anticipated need.
- Transport refrigerated[1] and frozen[2] vaccines following VFC Program requirements.
- Monitor vaccine temperatures using a VFC-compliant data logger and record temperatures—every hour the clinic is open—using the VFC "Hourly Vaccine Temperature Log for Mass Vaccination Clinics." [3]
- Vaccines exposed to out-of-range temperatures must be labeled "Do Not Use" until further information can be gathered from the manufacturer(s) on the usability of the vaccines.
- If vaccines were exposed to out-of-range temperatures, report the excursion to SHOTS as soon as possible.
- After each clinic day, complete the appropriate refrigerated[4] or frozen[5] transport log and return vaccines to their original storage units in the location of the approved VFC PIN.

Resources

1. "Transporting Refrigerated Vaccines" job aid can be found by searching for "IMM-983" at http://EZIZ.org.
2. "Transporting Frozen Vaccines" job aid can be found by searching for "IMM-1130" at http://EZIZ.org.
3. "Hourly Vaccine Temperature Log for Mass Vaccination Clinics" job aid can be found by searching for "IMM-1255" at http://EZIZ.org.
4. "Refrigerated Vaccine Transport Log" job aid can be found by searching for "IMM-1132" at http://EZIZ.org.
5. "Frozen Vaccine Transport Log" job aid can be found by searching for "IMM-1116" at http://EZIZ.org.

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Vaccine Orders

Chapter Four
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Introduction

Ordering vaccines should be part of a well-organized and well-managed clinic so vaccines are always readily available when needed. CDC recommends that providers order vaccine brands and presentations to meet patient needs. Under-ordering puts providers at risk of not having enough vaccines to immunize their patients. Conversely, over-ordering leads to crammed storage units, compromising inventory management and increasing the risk of vaccines being unused before expiration.

Figure 4.1 highlights the topics covered in chapter four.

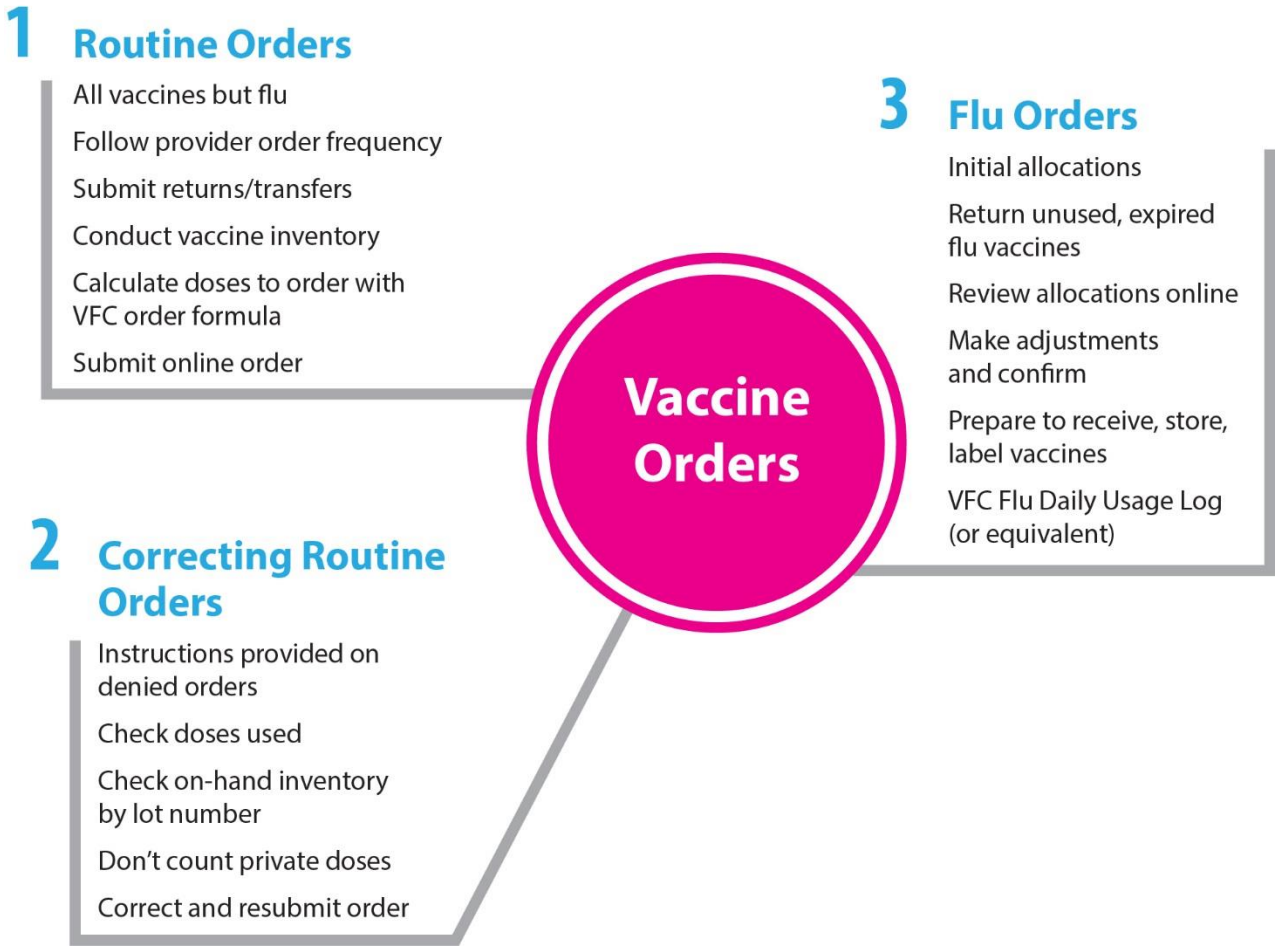


FIGURE 4.1. Overview of the key topics of vaccine ordering.

Submitting Routine Vaccine Orders

Overview

VFC providers are expected to maintain an adequate vaccine inventory for all patients served. Providers submit electronic vaccine orders for all age-appropriate, ACIP-recommended vaccines for their patient population as identified and agreed upon in the VFC provider profile—excluding influenza, which is allocated separately. Orders should be carefully timed to ensure sufficient inventory is on hand to allow time for order processing. The California VFC Program offers a choice of vaccine brands and presentations (e.g., single-dose vials or manufacturer-filled, single-dose syringes). Selection is at the discretion of providers.

Target Audience

Typically Vaccine Coordinator and Backup

Program Requirements

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

- Order vaccine and maintain appropriate vaccine inventories (VFC "Provider Agreement" #9A).
- Replace vaccine purchased with federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a dose-for-dose basis (P.A. #13).
- 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).
- 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 (P.A.A. #7B).
- Stock one brand and formulation for each vaccine to avoid administration errors (P.A.A. #7C).
- Account for every dose of VFC-supplied vaccine ordered and received by the provider's practice (P.A.A. #7D).
- Report on each vaccine order the VFC vaccine doses administered since the previous order and the current doses on hand (P.A.A. #7E).
- 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 (P.A.A. #7F).

Rationale

VFC providers must have sufficient storage space to accommodate vaccine stock at the busiest time of year without overcrowding. To ensure adequate stock for VFC-eligible patients, practices must follow an assigned order frequency that is based on provider inventory volume. Following a regular cycle helps to minimize under-ordering, which results in insufficient inventory to meet patient need; over-stocking of expensive, fragile vaccines might result in loss due to expiration before use.

Best Practices

- Set aside enough time to prepare and submit the order in one sitting, if possible.
- Run daily usage and vaccine inventory reports before submitting the order.
- Ensure that all returns and transfers of VFC-supplied vaccines have been submitted before ordering vaccines.
- Set up an automatic reminder to submit vaccine orders according to the provider's assigned order frequency.
- Take into account vacation or other temporary closures when submitting vaccine orders; please do not call to hold orders after order submission.

Important. If vaccines are delivered when the office is closed, vaccines wasted would be considered a negligent loss to be replaced by the provider on a dose-for-dose basis.

- Maintain adequate inventories to administer all age-appropriate, ACIP-recommended vaccines for both private and VFC-eligible children.

When Ordering Combination Vaccines

When ordering combination vaccines—namely Pediarix (DTaP, IPV, HepB) and Pentacel (DTaP, IPV, Hib)—providers must remember to order all complementary single-antigen vaccines to complete the recommended immunizations for the patient's age. For example, when ordering Pediarix, providers must order Hib vaccine because Pediarix doesn't include that antigen, which complements the series due at that visit. This practice ensures all indicated vaccines are readily available and administered, and avoids missed opportunities.

Guidance on Vaccine Brand Selection

Staff should be familiar and trained on all vaccine products used within the practice. This recommendation includes dosages, schedules, and familiarization with the packaging for each formulation. In order to prevent administration errors, VFC limits providers to only selecting and ordering one brand of vaccine, in most situations.

Guidelines When Switching Vaccine Brands

VFC Program's standard guidelines apply when switching to another vaccine brand:

- Careful consideration should be given when selecting alternative brands or products in order to minimize the impact on provider practices.
- Implementation of a different vaccine brand or product should be routinely approved by the practice's medical director or Provider of Record.
- Staff should be thoroughly informed and educated on changes to vaccines and the impact on vaccine ordering, storage, administration, and documentation.
- Review the ACIP-recommended immunization schedules[1] as well as minimum intervals and licensed age ranges (refer to VFC vaccine fact sheets[2]) prior to implementation to avoid errors in administration.
- As the practice transitions to a new product, managing on-hand inventory appropriately is a key factor in preventing unnecessary vaccine wastage. A plan to deplete excess inventory must be in place prior to transitioning to a new product. It is the provider's responsibility to ensure all VFC-supplied vaccines are used prior to their expiration dates or transferred to another VFC provider who can use them. Viable unused doses of these individual vaccines cannot be returned to the VFC Program.
- Determine appropriate number of corresponding single-antigen vaccine doses to compliment the new combination vaccine chosen.
- Subsequent vaccine requests for a different vaccine product will not be automatically approved and justification might be required.

Provider Category & Order Frequency

Order frequency depends on the provider category and number of VFC-supplied doses ordered each year. Provider category is assessed annually as part of provider recertification, and order frequency is adjusted accordingly and displayed on the provider's account page at MyVFCvaccines.org.

TABLE 1. Assigned provider category and order frequency

Provider category	# Doses received per year	Order frequency
Very high volume	>10,000	Monthly (or more frequently if approved by the VFC Program)
High volume	2,000 – 10,000	Monthly
Medium volume	500 - 2,000	Every 2 months
Low volume	< 500	Every 3 months

Essential Inventory Terminology

When ordering VFC vaccines, providers electronically report doses administered and on hand, as well as the vaccine brands and quantities they wish to order. In order to accurately estimate the order quantities, the following key components must be factored in.

Total doses administered. This value represents the total number of doses used since the previous vaccine order. For example, the practice or clinic might have administered the following VFC-supplied doses since the previous order was placed:

Vaccine	Brand	Total doses administered
DTaP	Daptacel®, Infanrix®	22

FIGURE 4.2. Illustration depicting total doses administered by vaccine.

Total doses on hand. This value represents the total number of VFC-supplied doses currently stocked in vaccine storage units at the time the order is to be submitted. For example, after conducting a physical vaccine inventory, the practice might have the following doses on hand:

Vaccine	Brand	Total doses on hand
DTaP	Daptacel®, Infanrix®	8

FIGURE 4.3. Illustration depicting total doses on hand by vaccine.

Safety stock. This value represents enough extra doses to last about four weeks to ensure practices don't run out of vaccines while orders are being processed and vaccines shipped.

Estimated need. This value represents the number of doses needed to cover immunizations over the next order period. This estimate includes a safety stock to ensure practices don't run out of vaccines while orders are being processed and vaccines shipped.

Total doses to order. This value represents the total number of doses to be requested at MyVFCvaccines.org. This number takes into account the estimated need and total doses on hand to arrive at an accurate order quantity that minimizes under- and over-ordering.

VFC Order Formula

The VFC order formula estimates the number of routine vaccines needed over the next order period and factors in a safety stock of surplus vaccines in case there are unexpected delays in processing or delivery. The formula makes use of the essential inventory terminology explained above.

Doses to Order = (Total Doses Administered x Safety Stock) – Total Doses on Hand

The VFC "Vaccine Ordering Worksheet"[3] walks providers through the VFC order formula using provider daily usage logs and physical vaccine inventory forms.

Figure 4.4 uses the VFC order formula to estimate the doses of DTaP to order for a provider with an order frequency of "Monthly."

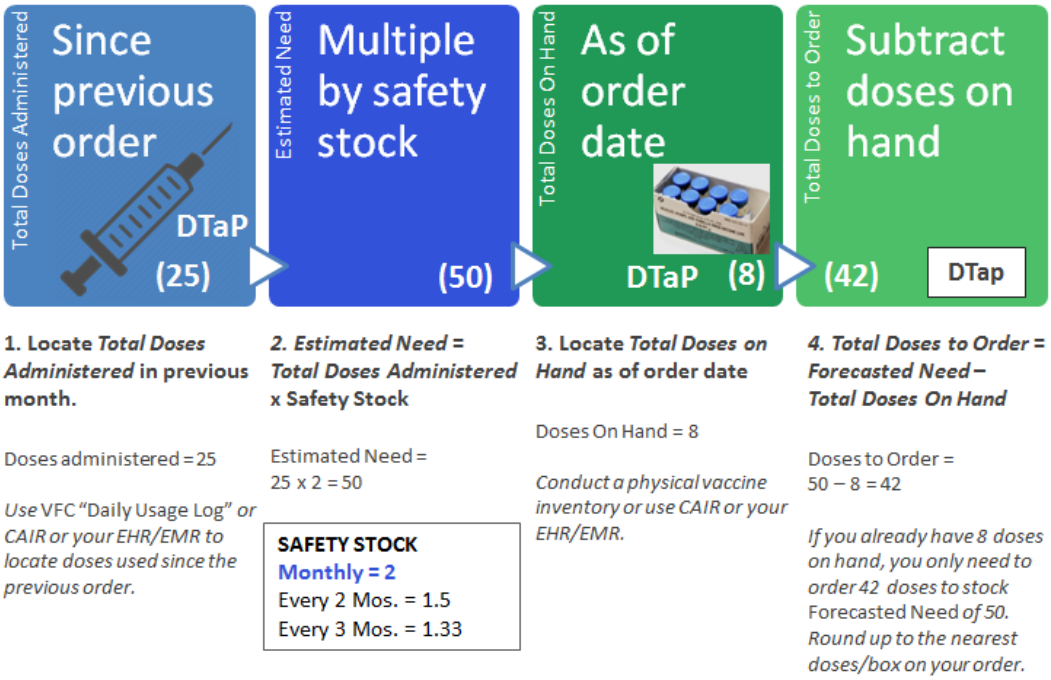


FIGURE 4.4. Sample estimate of DTaP doses to order for a provider with a monthly order frequency.

Procedure: *Before* Submitting Routine Vaccine Orders

Before submitting routine orders, complete the preparatory steps as outlined in table 2 to ensure routine vaccine orders are complete and accurate.

TABLE 2. Instructions to complete *before* submitting routine vaccine orders

Step	Description
1.	Determine whether it's time to place the next order at MyVFCvaccines.org. A. Go to EZIZ.org and click the "Order, Transfer, or Return Vaccines" link in the top center of the web page. B. Enter the practice's VFC PIN and zip code, and click the "Sign On" button. C. Review the assigned "Provider Category" and "Order Frequency" to ensure they haven't been reassigned. In the example below, the Order Frequency is "Monthly" for a Provider Category of "High Volume". **Provider Category: Very High Volume** **Order Frequency: Monthly** **Date of last order:** December 08, 2017 **Last order processed on:** December 11, 2017 **Order should be submitted on or after:** Jan 10, 2018 D. Note the date when new orders can be submitted. E. If it's time to place the next order: Proceed with the remaining steps. ***Best practice.*** Create an automatic reminder to place the next order.
2.	Ensure all returns and transfers of VFC-supplied vaccine have been submitted. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines" or "Transferring Vaccines between Providers" for details.) ***Important.*** Delays in order processing might result if returns and transfers are not completed before submitting routine vaccine orders.
3.	Run daily usage and vaccine inventory reports before submitting the order. ***Tip.*** The VFC "Daily Usage Logs" (VFC[4] | Flu[5] | Private[6]) and "Physical Vaccine Inventory Form" [7] help providers account for their inventory.
4.	Estimate the total number of doses to order using the VFC "Vaccine Ordering Worksheet"[3] following the instructions provided with the worksheet.
5.	If usage and on-hand inventory indicate that doses must be ordered, submit the routine vaccine order following the instructions in **TABLE 3**. A. If ordering vaccines for the back-to-school season, pull last year's order now to estimate how much larger the quantities should be to meet the larger than usual demand.

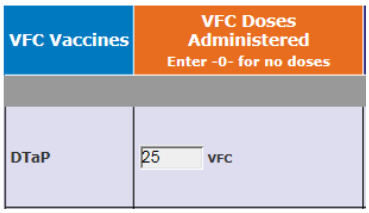
Vaccine Accountability

Providers must report both total doses administered (since the previous order) and doses on hand (at the time the order is submitted) for every routine vaccine order—even if no doses will be requested. If doses are not reported, vaccine orders will be denied, and providers will need to account for the missing doses before the order will be processed.

Procedure: Submitting Routine Vaccine Orders

The table below outlines the procedure that practices should follow to minimize errors or delays in order fulfillment.

TABLE 3. Instructions for submitting routine vaccine orders

Step	Description
1.	From EZIZ.org, click the "Order VFC Vaccine" button under the "Orders" section.
2.	Verify that the provider's profile (including delivery days and times) will be accurate when the order arrives in approximately two weeks. ***Tips:*** • Click "My information is incorrect" to update the provider's profile if necessary. • Otherwise, click "My information is correct".
	Report accountability data for all VFC-supplied vaccines
3.	Enter *Total Doses Administered* since the previous order for each vaccine in the "VFC Doses Administered" column of the online "VFC Vaccine Order Form". **Tip:** Make sure this quantity is accurate to avoid ordering delays. A. Enter the number of doses as recorded on the VFC "Vaccine Ordering Worksheet," [3] or alternatively on the VFC "Daily Usage Logs" (VFC[4] | Flu[5] | Private[6]), in the practice's immunization registry, or the practice's EHR/EMR. In the example below, the Vaccine Coordinator will enter 25 to reflect 25 doses of VFC-supplied vaccines were administered since the previous order. 

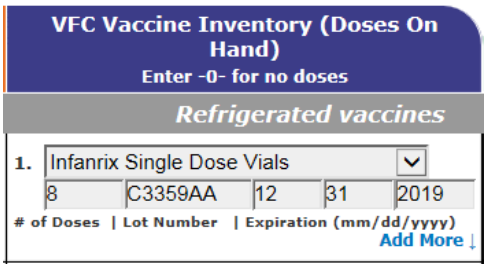
4. Enter the *Total Doses on Hand* in the "VFC Vaccine Inventory (Doses On Hand)" column.

   Tip: Make sure this quantity is accurate to avoid ordering delays.

   A. Select the brand from the dropdown.
      Enter the number of doses as recorded on the VFC "Vaccine Ordering Worksheet," [3] or alternatively on the VFC "Physical Vaccine Inventory Form,"[7] in the practice's immunization registry, or the practice's EHR/EMR.

   B. Click "Add More" to add additional lots for the same vaccine.

   In the example below, the Vaccine Coordinator will enter 8 (as well as the lot number and expiration date) to indicate that 8 doses of Infanrix are accounted for in the provider's inventory.



For each VFC-supplied vaccine requested

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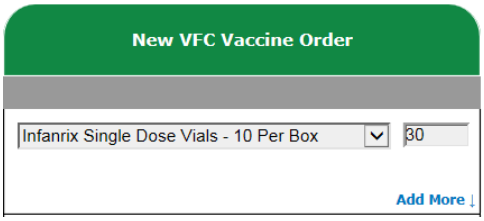
5. Enter *Total Doses to Order* in the "New VFC Vaccine Order" column from the ordering worksheet.

   Tip: If there are no doses to order, leave this section blank.

   A. Select the brand from the dropdown.
   B. Enter the *Total Doses to Order* from the VFC "Vaccine Ordering Worksheet."[3]

   In the example below, the Vaccine Coordinator will enter select "Infanrix Single Dose Syringes" and enter 30 as the number of doses to order.



6. For back-to-school season, increase vaccine order quantities as necessary to accommodate increased demand.

   Tip. Look to usage from the previous year and adjust the quantities to meet the expected demand.

   A. Add notes or justification in the "Comments" field, if necessary (e.g., if quantities are increased for back-to-school season).

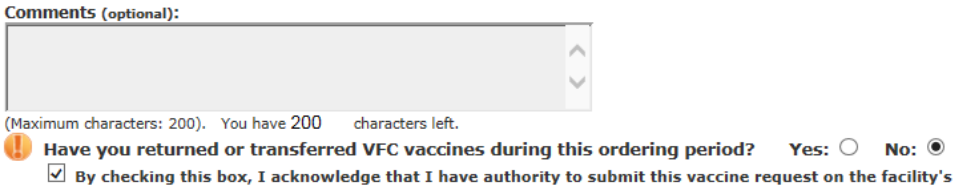
7. Repeat steps 5-6 for each vaccine on the order.

8. Add notes or justification in the "Comments" field, if necessary.

   Tip. If an order is being submitted early, add comments that the practice is aware the order is early and why vaccines are needed now.

9. Click Yes or No to indicate whether the practice has returned or transferred VFC-supplied vaccines during this ordering period.

   Tip: These numbers must be reported accurately to avoid unnecessary order delays.



10. Click the check box (see above) to acknowledge that you have authority to submit this vaccine request on the facility's behalf.

11. Click the "Preview" or "Save for Later" button.

    Tips:

    - Verify the practice's storage units can store the requested quantities before submitting the order.
    - Verify the practice will be open when delivery is expected to arrive (within two weeks).
    - If an order was started and can't be submitted immediately, click the "Save for Later" button to save the order for up to 24 hours.

12. ***Important.*** Orders cannot be canceled once approved and processed, so click the "Submit Your Order" button only when the order has been proofed and is ready for submission.

13. Save the order confirmation (e-mailed to the Vaccine Coordinator and Backup) for future reference.

When to Expect Vaccine Shipments

Providers can expect to receive their vaccines within 14 days after receiving the order-processed notification. During peak ordering periods (back-to-school, flu season, and during the launch of a new vaccine), VFC receives a larger volume of vaccine requests than is typical. Although orders are processed as efficiently as possible during these periods, it might take longer for vaccine orders to be processed and delivered. Contact the VFC Call Center if vaccines have not arrived within two weeks.

Shipment information. Check MyVFCvaccines.org "Shipping History" for tracking information. This information will be updated online once vaccines have shipped. The tracking number indicates the day the shipment will arrive.

Submitting Supplemental Vaccine Orders

There are limited exceptions to a provider's assigned order frequency that might require providers to submit a supplemental vaccine order.

When a new vaccine is launched or when there are vaccine shipment delays. Instructions will be provided by the California VFC Program through e-mails and postings on EZIZ.org.

Notes

1. "Recommended Immunization Schedules for Persons Aged 0 through 17 Years," CDC's website, http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.
2. "VFC Vaccine Fact Sheets" can be found by searching "vaccine fact sheets" at http://EZIZ.org.
3. VFC "Vaccine Ordering Worksheet" can be found by searching "IMM-1246" at http://EZIZ.org.
4. VFC "Daily Usage Log" can be found by searching "IMM-1053" at http://EZIZ.org.
5. VFC "Flu Usage Log" can be found by searching "IMM-1053F" at http://EZIZ.org.
6. VFC "Private Vaccine Daily Usage Log" can be found by searching "IMM-1053P" at http://EZIZ.org.
7. VFC "Vaccine Physical Inventory Form" can be found by searching "IMM-1052" at http://EZIZ.org.

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Correcting Denied Orders for Routine Vaccines

Overview

The most common reason that routine vaccine orders are denied is due to accountability errors; namely, accounting for vaccines administered (since the previous order) and vaccines on hand (at the time the order is placed).

Target Audience

Typically Vaccine Coordinator and Backup

Provider Errors Resulting in Denied Orders

The most common mistakes during routine order submission are ordered below.

TABLE 4. Reasons vaccine orders might be denied

Order denial reason	Description
Accountability error	The number of doses reported with the order (administered and/or doses on hand) is inaccurate based on the quantities reported on the previous order. Not using a daily usage log, EMR report, or registry report to track and document actual doses used will lead to accountability errors. Not reporting transfers or returns will impact vaccine inventory and might lead to an accountability error.
Ordering too early	The order was submitted too early—and without valid justification—based on provider's order frequency and process date of previous order.
Storage and handling incident	An incomplete storage and handling incident is delaying processing of the vaccine order.
Missing or incomplete usage/inventory	The order did not include both doses administered and doses on hand—for all vaccines identified in the provider's profile.
Recertification not current	The order cannot be processed because the provider and key practice staff did not complete annual recertification by the deadline.
Sufficient inventory on hand	Based on the number of doses requested and doses on hand as reported on the previous order, the provider should already have sufficient inventory on hand.
Partial order	The provider did not submit a full routine order.
Under-ordering	Quantities ordered are insufficient to meet expected need, or not ordering at all.

Expired vaccines in inventory	Lot numbers reported have expired. Order is denied with instructions to remove inventory and submit a return for expired vaccines on hand.
Ordered a new brand	Denied for confirmation
Mandatory corrective actions	Follow-up actions stemming from a VFC site visit that need to be completed prior to receiving vaccines.
Other	Check custom message as instructions

In the Event of Order Errors

Routine vaccine orders will be denied if inaccurate or incomplete information is provided. The Vaccine Coordinator and Backup will receive a detailed e-mail instructing them of steps to be taken in order for the vaccine order to be approved. The order will be deleted within 14 business days if the required information is not corrected or supplied.

IMPORTANT. To avoid fraud and abuse and potential termination from the VFC Program, providers must not fudge the numbers to make the math add up.

Tips:

- Double check the daily usage logs (or electronic equivalent), the physical vaccine inventory forms, and the calculations recorded on the VFC "Vaccine Ordering Worksheet."[1]
- If the number of doses on hand is accurate but the numbers don't add up, practices might not be tracking doses administered consistently and accurately. Steps must be taken to improve internal tracking of doses administered.
- If doses administered are off and doses can't be accounted for, additional documentation could be requested before the vaccine order is approved.
- Conduct a physical vaccine inventory to double check doses on hand. If doses administered are not accurately tracked, this gap could impact doses on hand as reflected in immunization registries and EHR/EMR systems.

Understanding Calculated Inventory Quantities

The order system validates that providers are correctly accounting for their vaccine inventory by calculating provider *Doses On Hand* with each vaccine order:

Data from Previous Order		Submitted on Vaccine Order	
Previous Inventory *(Doses On Hand)*	***Previous Order*** *(Doses Requested)*	***Doses Used*** *(since last order)*	***Doses On Hand***
15 doses on hand	*+ 10 doses ordered*	*- 5 doses used*	***20 doses on hand***

FIGURE 4.5. Illustration depicting VFC's calculation of *Doses On Hand*.

If the provider's *Doses On Hand* does not match the calculated inventory, the system will report any error as reflected in red below under the "Calculated Inventory."

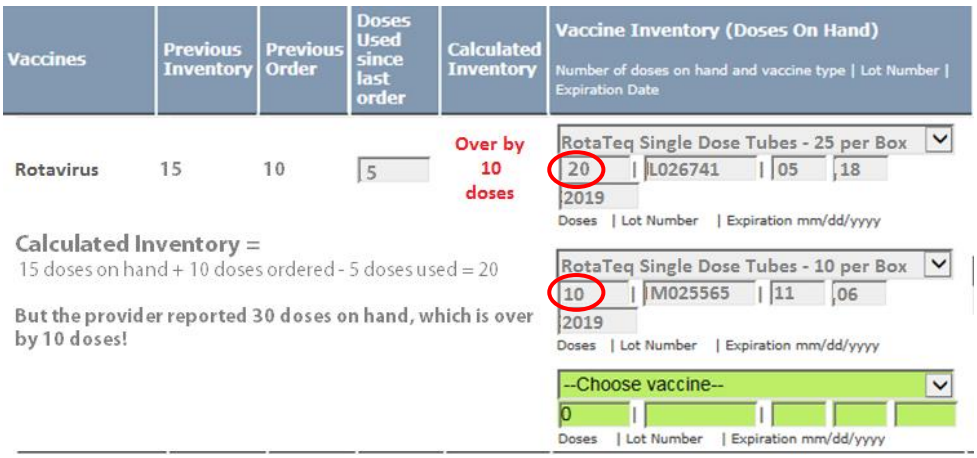


FIGURE 4.6. Illustration of error message generated when the provider's *Doses On Hand* does not match the system's calculated inventory.

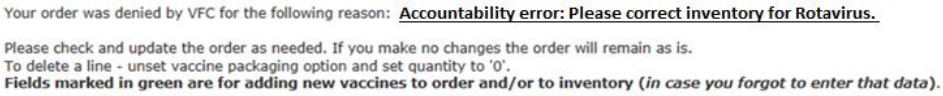
Calculated inventory could be over or under for the following reasons:

- Transfers and returns weren't submitted before placing the vaccine order.
- A complete physical vaccine inventory was not conducted before placing the order, or totals reported were inaccurate.
- Private vaccines were accidently reported as VFC doses on hand.
- Providers are not accurately accounting for doses administered.

Procedure

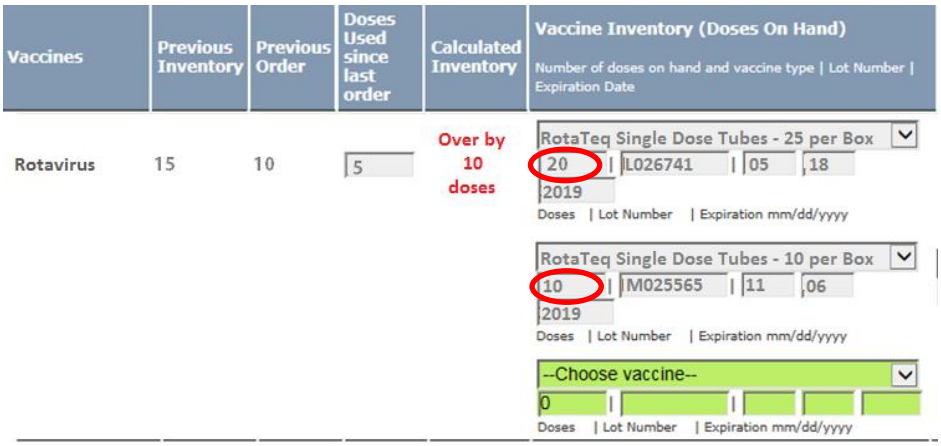
The table below outlines the procedure that practices should follow to correct denied routine orders.

TABLE 5. Steps to correct denied routine orders

Step	Description
1.	Go to EZIZ.org and click the "Order, Transfer, or Return Vaccines" link in the top center of the web page.
2.	Enter your VFC PIN and zip code, and click the "Sign On" button.
3.	Click the "Edit VFC Order" button under the "Orders" section. ***Tip.*** This button only appears if there are denied orders that must be corrected.
4.	Review the VFC notes at the top of the "Edit Your VFC Order" page to identify the steps that must be taken to correct the order. In this example, the Vaccine Coordinator must verify and correct inventory for Rotavirus: 

5. Scroll down to the section of the order with red comments (e.g., "Over by 10 doses" below) to determine why the order was denied.

   In the example below, the order reflects that 15 doses of RotaTeq were reported in inventory on the previous order, 10 doses were requested on the previous order, and 5 doses were reported as used on this order. VFC's "Calculated Inventory" shows that providers should have 15+10-5 (or 20) doses on hand in inventory. However, the reported number of 30 doses is "over by 10 doses".



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)
					RotaTeq Single Dose Tubes - 10 per Box | 10 | M025565 | 11 06 2019 (Doses | Lot Number | Expiration mm/dd/yyyy)
					--Choose vaccine-- | 0 | (Doses | Lot Number | Expiration mm/dd/yyyy)

6. Follow the instructions provided in the e-mail to resolve the problem; call the VFC Call Center with any questions.

   Tips:
   - Double check to ensure all doses administered and on hand were accurately recorded.
   - Double check the numbers recorded on the VFC "Vaccine Ordering Worksheet"[1] to ensure the calculations were done correctly.
   - If transfers were not submitted, complete the transfers now to reconcile the inventory then resubmit the order with comments.
   - If private vaccines were reported as VFC doses on hand, set the vaccine back to "Choose vaccine," empty the fields, and resubmit the order with comments.
   - If doses on hand were mistakenly reported as doses used, resubmit the order with comments.
   - If doses on hand are correct but doses administered are off, then resubmit the order with an explanation for why the doses administered are off.

7. Make any corrections.

   In the example below, if the extra doses were private vaccines mistakenly reported as VFC, the Vaccine Coordinator would empty the fields and resubmit the order with comments.

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

8. 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.

Update Order

Notes

1. 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 annually[1]
Hospitalizations: 140,000 and 710,000 annually[1]
Illnesses: between 9.2 million and 35.6 million annually[1]

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.

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

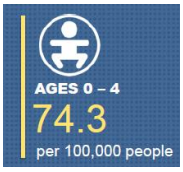

FIGURE 4.7. Hospitalization Rates in 2017-18 Flu Season.

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 risk[1]
High-risk group: 51% reduction of death risk[1]

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,

- the number of non-flu pediatric and adolescent doses administered, and
- the total number of doses of each flu product received in the preceding season (initially allocated plus any additional doses received as part of supplemental ordering of flu vaccines).

Newly enrolled providers with limited or no vaccine distribution history will have limited allocations based on selected pediatric vaccine distribution. Providers may contact the VFC Call Center or their VFC Field Representative if their VFC-eligible patient population has significantly increased since their enrollment date.

Confirming Your Clinic's Vaccine Allocation

Detailed instructions will be provided to all enrolled providers in the annual VFC Program influenza letter, but in general the following steps must be completed.

TABLE 6. Key steps for confirming provider vaccine doses

Step	Description
1.	Go to EZIZ.org and click the "Order, Transfer, or Return Vaccines" link in the top center of the web page.
2.	Enter your VFC PIN and zip code, and click the "Sign On" button.
3.	If your practice has unused, expired doses from the previous flu season, go to EZIZ.org and click the "Order, Transfer, or Return Vaccines" link. (Refer to "Reporting Spoiled, Expired, or Wasted Vaccines" for details.)
4.	Click the "Flu Order" button to access VFC's Online Flu Order Confirmation System.
5.	Review and make adjustments based on your VFC-eligible populations served following the instructions provided in the flu ordering letter.
6.	Submit confirmed vaccine allocations for the practice by the announced deadline.
7.	Save the VFC confirmation of submission e-mail for your records.
8.	Upon review of the flu allocation request, the VFC Program will e-mail a final approved email confirmation.
9.	Prepare room in your vaccine storage unit and label space for VFC influenza doses according to VFC Program storage and handling requirements. ***Tip.*** Flu doses expire each year. Remove all expired doses from the previous year have been removed and sent to McKesson Specialty. (Refer to vaccine return procedures).
10.	Look for an e-mail and fax from the VFC Program when flu products are received at the distribution center and delivery of approved orders begins.

Vaccine Shipments

Influenza vaccine supplies for all different manufacturers arrive at VFC's national vaccine distributor at different times and in multiple shipments throughout the season. Providers will receive their allocated vaccine doses in multiple shipments throughout the season. In the event of significant vaccine delays or shortages, the VFC Program might automatically substitute allocated vaccine brands for another product that is readily available for shipment.

Vaccine Usage and Reporting

As with all other VFC-supplied vaccines, tracking the administration of VFC flu doses is required for each practice. Doses administered must be documented on VFC's "Flu Usage Log"[1] (or electronic or paper equivalent) and reported to the VFC Program as part of the submission process for supplemental vaccine ordering. Providers may also use the practice's immunization registry or an electronic health record system that tracks doses administered and generates vaccine usage reports.

Tips for a Successful Flu Season

Discuss and outline key strategies to achieve high influenza vaccination coverage rates and decrease missed vaccinations opportunities for practice patients:

- remind patients to come in for their annual influenza vaccination
- expand hours for influenza vaccination
- allow influenza vaccine-only visits
- discuss mechanisms to track patients that will be due to return to the practice for a second dose

Submitting Supplemental Flu Orders

After the initial allocation, providers may request additional doses of the flu vaccine once the VFC Program has opened up supplemental flu ordering. Supplemental ordering is contingent upon two conditions: 1) available vaccine supply and 2) 100% distribution of provider-confirmed doses at the beginning of the season. Supplemental ordering will remain open throughout influenza season as vaccine supply permits.

Who may place supplemental orders? Supplemental ordering is available to providers who were not able to submit confirmation for their initial allocation. Ordering will also be enabled for providers who have already received 100% of initially confirmed doses of available flu vaccines. The number of unused doses must be reported as part of supplemental ordering.

Vaccine shipments. Supplemental orders are processed by the VFC Call Center several times per week and sent to the VFC Program's national vaccine distributor for fulfillment. Supplemental influenza orders ship in full.

Best practices. The following best practices are recommended:

- Submit supplemental orders frequently (rather than placing one large order) to keep inventory manageable and minimize vaccine waste at the end of the season.
- Keep in mind any planned reminder/recall influenza vaccination outreach efforts for the particular ordering period before placing your order.
- Ensure that all the doses requested can be properly stored as orders cannot be canceled once sent for fulfillment.
- Contact the VFC Call Center if you find that the supplemental order limitation is inconsistent with your current VFC-eligible population.

Questions?

Please call your VFC Field Representative or the VFC Call Center at 877-243-8832 (877-2GET-VFC), or alternatively, visit our website at www.eziz.org.

Notes

1. VFC's "Flu Usage Log" can be found by searching for "IMM-1053F" at http://EZIZ.org.

Additional resources:

- The current "Pediatric/Adult Influenza Vaccine Guide" can be found by searching "IMM-859" at http://EZIZ.org.

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Provider Accountability

Chapter Five
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Introduction

The VFC Program establishes accountability systems that strike a balance between the needs of providers and federal and state requirements. This chapter outlines the ways accountability is verified so that providers and key practice staff know what to expect.

Figure 5.1 highlights key topics covered in chapter five to help practices understand how their compliance with VFC Program requirements is measured.

FIGURE 5.1. Overview of the topics orienting new providers to provider accountability checks.

Vaccine Accountability

Overview

Vaccine accountability is a critical component of the VFC Program. VFC providers must manage their vaccine inventory effectively to prevent negligent vaccine loss. VFC-enrolled providers are accountable for all VFC-supplied vaccines upon receipt and must be able to provide documentation to support their numbers. Providers must report vaccine accountability numbers with each vaccine order in order to receive new vaccines.

Target Audience

Provider of Record and Designee, Vaccine Coordinator and Backup

Program Requirements

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

- Providers must maintain all records related to the VFC Program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records (VFC "Provider Agreement" #4).
- I 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 (P.A. #13).
- Account for every dose of VFC-supplied vaccine ordered and received by the provider's practice (California VFC Program "Provider Agreement Addendum" #7D).
- Maintain accurate and separate stock records (e.g., purchase invoices, receiving packing slips) for privately purchased vaccines and make them available upon request (P.A.A. #7F).
- Never borrow VFC-supplied vaccines to supplement private stock, or vice versa (P.A.A. #12B).
- 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).

Rationale

Although VFC-supplied vaccines are distributed to providers at no cost, vaccines are purchased with public funds, and providers might maintain an average vaccine inventory ranging from tens of thousands to more than $500,000 over the course of a year. By signing the VFC "Provider Agreement", providers agree to account for all doses received (including vaccines that later were spoiled, expired, or wasted) and could be held liable for negligent vaccine losses.

No-Borrowing Policy

CDC's expectation is that VFC providers maintain adequate inventories to administer all age-appropriate, ACIP-recommended vaccines to both private and VFC-eligible children. Providers may not borrow VFC-supplied vaccines to supplement their privately purchased vaccines, or vice versa.

Providers should not use privately purchased vaccines to vaccinate VFC-eligible patients as the VFC Program will not compensate providers for those doses used.

Accountability in Practice

VFC Program requirements, procedures, and forms help providers account for their vaccine inventory and minimize spoiled or expired doses. Ensure all staff who handle VFC-supplied vaccines are properly trained and understand how to account for all doses.

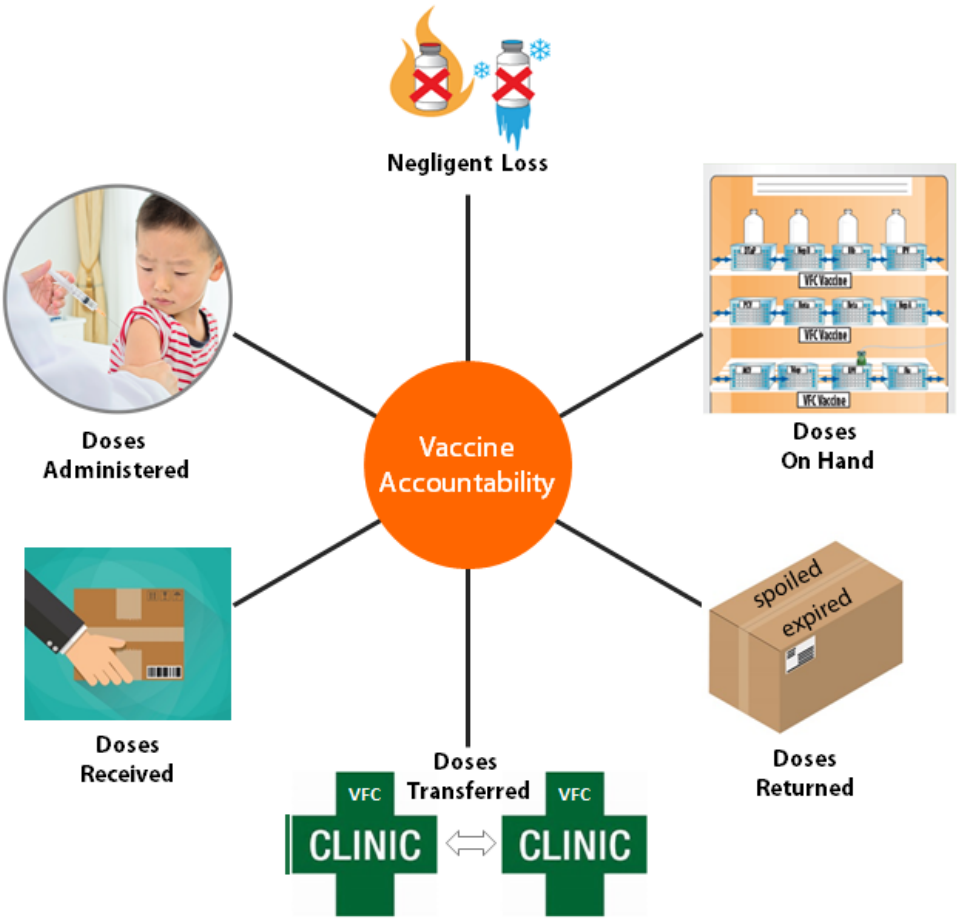

FIGURE 5.2. Doses that must be accounted for in provider practices and clinics.

Accountability Forms

While electronic systems such as immunization registries and EHR/EMR systems are designed to simplify vaccine administration and management tasks, the following forms—if used routinely—serve as paper substitutes that simplify the routine vaccine ordering process when electronic systems are not an option.

Whichever method is used, providers will use documentation of doses administered to determine patient estimates during annual recertification.

TABLE 1. Alternative paper forms that simplify provider vaccine accountability

Procedure	Form	IMM
Receiving	VFC "Vaccine Receiving Log and Checklist"	IMM-1112
Administration	VFC "Daily Usage Log"	IMM-1053
	VFC "Flu Usage Log"	IMM-1053F
	VFC "Daily Usage Log-Private Vaccine"	IMM-1053P
Inventory	VFC "Vaccine Physical Inventory Form"	IMM-1052
Transfers	MyVFCvaccines.org confirmation	Online
Returns	MyVFCvaccines.org confirmation	Online

Reporting of Accountability Data

Accountability data is reported to and verified by the VFC Program with each vaccine order, and orders will not be approved until all doses are accounted for. Under-ordering might lead to missed immunization opportunities in the event of vaccine shortage; over-ordering might lead to vaccine waste.

Providers must report the following data with each vaccine order:

- doses administered since the previous order
- doses on hand at the time the order is placed

In the Event of Unaccounted Doses

The California VFC Program is required by CDC to ensure every enrolled provider is properly accounting for all vaccine doses received. In the event of unaccounted doses, vaccine orders will not be processed until the provider accounts for the missing doses. For example, if a provider forgets to submit the online VFC transfer form for doses transferred to another VFC provider, the provider will need to submit the transfer form so the vaccine order can be processed. Providers are required to replace doses that cannot be accounted for—on a dose-by-dose basis.

Notes

Refer to the following sections in the *Provider Operations Manual* for more details on policies and procedures that help ensure accurate vaccine accountability:

- "Receiving Vaccine Deliveries"
- "Administering Vaccines"
- "Conducting a Physical Vaccine Inventory"
- "Transferring Vaccines between Providers"
- "Reporting Spoiled, Expired, or Wasted Vaccines"

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Fraud & Abuse

Overview

To protect VFC Program integrity, providers agree to participate in a manner intended to avoid fraud and abuse. Federal fraud and abuse laws apply to the entire VFC Program; state laws apply to portions of the program involving state funds. A provider found guilty of fraud and/or abuse will be subject to vaccine restitution and possible removal from the VFC Program.

Target Audience

Provider of Record and Designee, Vaccine Coordinator and Backup

Program Requirements

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

- Operate within the VFC Program in a manner intended to avoid fraud and abuse as defined in the Medicaid regulations at 42 CFR §455.2 (VFC "Provider Agreement" #10).
- Fraud is defined as an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law (P.A. #10).
- Abuse is defined as provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient patient practices that result in unnecessary cost to the Medicaid program (P.A. #10).

Rationale

As vaccines become more expensive and immunization programs more complex, the VFC Program becomes more vulnerable to fraud and abuse. The California VFC Program investigates all suspected and reported cases of fraud and abuse in order to protect the integrity of the program and ensure federally purchased vaccines remain available to VFC-eligible pediatric populations.

Examples of Fraud

Fraud results in a financial gain for the provider but with an inadvertent cost to the VFC Program. Many actions might constitute fraud:

- failing to screen patients for VFC eligibility
- providing VFC-supplied vaccines to non-VFC-eligible children or adults
- selling or otherwise misdirecting VFC-supplied vaccines
- billing a third party for VFC-supplied vaccines
- charging more than the maximum regional charge for administration of VFC-supplied vaccines to VFC-eligible children
- denying vaccines to VFC-eligible children because of a parent's or guardian's inability to pay the vaccine administration fee
- failing to fully account for VFC-supplied vaccines

Examples of Abuse

Abuse results in an inadvertent cost to the VFC Program. Abuse consists of any actions that lead to a negligent loss that could have been prevented by proper vaccine management. Providers agree to replace all vaccines deemed non-viable due to provider negligence. Many actions might constitute abuse leading to negligent loss:

- allowing VFC-supplied vaccines to expire or spoil due to inappropriate vaccine management, including temperature monitoring

- failing to store vaccines upon arrival
- failing to monitor and document temperatures
- failing to transport vaccines according to program requirements
- failing to properly store and handle VFC-supplied vaccines
- failing to fully account for VFC-supplied vaccines

How to Report Suspected Fraud and Abuse

Any suspected fraud or abuse should be immediately reported to the VFC Call Center. The VFC Program maintains the anonymity of the person submitting the report.

Investigations of Fraud and Abuse

The California VFC Program carefully investigates every case of alleged fraud and abuse. If the non-compliance appears intentional and the provider benefited financially, the case might be referred to Medicaid's Integrity Program[1] for further investigation.

Any vaccine loss is investigated to determine the cause and whether the provider actions are deemed negligent. If the VFC Program determines that loss is due to negligence, the provider will be required to compensate the VFC Program.

Restitution Policy

Providers must replace the same number and type of vaccines that were lost—on a dose-for-dose basis. Providers must submit a receipt of vaccine purchase (reflecting a dose-for-dose replacement) to the VFC Program within 90 days of vaccine loss, or within an acceptable timeline as negotiated with the VFC Program. In general, restitution requires the following actions:

- Providers must sign a VFC Program vaccine restitution agreement.
- Providers must provide copies of vaccine invoices for privately purchased vaccines to replace doses lost.
- Providers must submit a detailed listing of vaccines for all VFC patients who received privately purchased vaccines.
- The VFC Program might suspend provider vaccine ordering privileges.

Vaccines for Health-Care Workers

Vaccinations are as important for practice staff as they are for patients. While it is important for staff to be up to date on their immunizations, VFC-supplied vaccines may never be used on staff and doing so constitutes fraud.

The VFC Program encourages practices to establish their own policies to ensure all employees are protected against vaccine-preventable diseases. Refer to the CDC's "Recommended Vaccines for Healthcare Workers."[2]

Notes

1. "Medicaid Integrity Program – General Information", Centers for Medicare and Medicaid Services, https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/MedicaidIntegrityProgram/index.html.
2. "Recommended Vaccines for Healthcare Workers", Centers for Disease Control and Prevention, http://www.cdc.gov/vaccines/adults/rec-vac/hcw.html.

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Site Visits

Overview

As a condition for participation in the VFC Program, providers must allow site visits from authorized VFC representatives. Site visits are educational opportunities designed to improve compliance with the VFC Program and thereby improve patient immunization levels. Failure to allow a site visit might result in the temporary suspension from the VFC Program and removal of VFC-supplied vaccines.

Target Audience

Provider of Record and Designee, Vaccine Coordinator and Backup

Program Requirements

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

- Participate in VFC Program compliance visits including unannounced visits, and other educational opportunities associated with VFC Program requirements (VFC "Provider Agreement" #11).
- Ensure that clinic staff conduct themselves in an ethical, professional, and respectful manner in all interactions with VFC Program staff (California VFC Program "Provider Agreement Addendum" #15A).
- 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 (P.A.A. #15C).

Initial Site Visit

All new providers must receive a new provider enrollment site visit prior to receiving approval for enrollment in the California VFC Program. The purpose of the initial site visit is to ensure that the provider and the key practice staff are educated on and have the appropriate resources to implement program requirements, including vaccine storage units and data loggers that meet VFC Program requirements. A follow-up compliance visit will be scheduled approximately three to six months after initial enrollment.

Compliance Visits

Provider non-compliance might occur due to an unintentional lack of understanding of VFC Program requirements, so site visits present educational opportunities to train providers and key practice staff.

All enrolled and active providers must receive a VFC compliance visit at least every other year, or more frequently if indicated. Site visits help determine provider compliance with VFC Program requirements, including adherence to vaccine eligibility screening and documentation, accountability, and management.

The Provider of Record or Designee and all key practice staff responsible for vaccine management and administration must be present for site visits, which are scheduled to best accommodate the convenience of the practice.

Goals of VFC site visits. Site visits are critical opportunities to engage provider staff and develop and strengthen ongoing relationships. Additionally, they

- identify areas where providers are doing well and areas needing additional follow up,
- identify the educational needs of VFC providers in order to help them meet program requirements, and
- ensure that VFC-eligible children receive properly managed and viable vaccines.

Visit format. Site visits are conducted by VFC Field Representatives who review provider compliance with CDC requirements through verbal discussions with practice staff, random assessments of patient charts, visual inspections of key documents and storage units, and completion of the online federal site visit questionnaire.

Evaluation criteria. Providers will be evaluated for compliance in accordance with CDC requirements, including but not limited to the following items:

Verbal discussions with practice staff
Changes to key practice staff
Key practice staff knowledge of VFC eligibility categories
Random assessments of patient charts
Billing practices (for cost of vaccines and administration fees)
Eligibility & screening documentation
Vaccine dose documentation including VISs
Visual inspections of documents
VISs and VAERS
Certificate of calibration testing
VFC temperature logs
Private vaccine invoices
Vaccine management plan
Visual inspections of storage units
Storage & handling conditions
Data loggers, including backups
Placement of data loggers
Vaccine placement
Capacity to store current vaccine plus additional stock during peak season
Inventory inspection, including expired vaccines
ACIP-recommended vaccines, stocked per provider profile
Separation of VFC and privately purchased vaccines

FIGURE 5.3. Overview of evaluation criteria used to measure compliance.

Patient chart review. Because VFC is authorized by law as a public health entity, VFC providers may disclose any patient health information (including private and VFC-eligible patient charts) to us without authorization. We are authorized to collect or receive information for the purpose of preventing or controlling disease, injury, or disability.

Site visit findings. At the conclusion of each site visit, the VFC Field Representative discusses key findings with the Provider of Record and Vaccine Coordinators, and Designee and Backup Vaccine Coordinator if available. Discussion could include requirements met, instructions to address problems or issues found during the site visit, and recommendations to improve immunization service delivery. Immediate actions might be identified to remedy the issue depending on its severity.

The VFC Field Representative will also issue a formal written report that summarizes areas for improvement and the timeline for correcting noncompliant areas. The Provider of Record or Designee must sign the "Acknowledgement of Receipt" form, which attests to the fact that the site visit was completed and the results were discussed on-site.

Future follow-up actions with designated due dates might be required, and if so, they must be completed in accordance with CDC-established deadlines. If deficiencies are not corrected by the deadline identified in the report, the practice's ordering privileges could be suspended. Practices with a history of non-compliance with the same issue identified in past site visits, or identification of a serious issue, might be added to the VFC Program's allegation and referral database. A provider who demonstrates non-compliance with the same issue might also be terminated from the VFC Program.

Site visit duration. Site visits last approximately two hours, or more if compliance issues are identified. Most of the time is spent with the Vaccine Coordinator with the Provider of Record attending the site visit findings.

Unannounced Storage and Handling Visits

VFC Field Representatives also conduct periodic unannounced visits, which are separate from VFC compliance visits. The goal of these storage and handling visits is to provide education, support, and resources related to proper vaccine storage and handling to ensure all VFC-eligible children are receiving properly managed vaccines.

Providers may request additional site visits. VFC Field Representatives will work with the practice as necessary to provide staff training, technical assistance, and in-services related to compliance with VFC Program requirements.

In-Service Visits

An in-service visit is conducted on site by VFC Field Representatives to provide training to key practice staff on one or more compliance issues. No formal evaluation or reporting is involved. Training issues might include reviewing

- immunization schedules and timing for doses,
- VFC eligibility and/or other policies and procedures,
- best practices regarding how to administer vaccines,
- proper vaccine storage and handling,
- how to order and account for vaccines,
- how to configure data loggers,
- how to document temperatures properly, and
- how to complete a storage and handling excursion report.

Notes

Additional resources:

- The current "Program Participation Requirements at a Glance" document can be found by searching for "IMM-1240" at http://EZIZ.org.
- The VFC "Provider Agreement" can be found by searching for "IMM-1241" at http://EZIZ.org.

- The current California VFC Program "Provider Agreement Addendum" can be found by searching for "IMM-1242" at http://EZIZ.org.
- The VFC "Key Practice Staff Change Request Form" can be found by searching for "IMM-1166" at http://EZIZ.org.

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Record Retention

Overview

Providers are required to maintain all records related to the VFC Program—paper and electronic—for a minimum of three years and make them available for review upon request.

Target Audience

Provider of Record and Designee, Vaccine Coordinator and Backup

Program Requirements

- Providers have agreed to comply with the following VFC Program requirements:
- Maintain all records related to the VFC Program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records (VFC "Provider Agreement" #4).
- 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's "Provider Agreement Addendum" #1A).
- Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted (P.A.A. #9H).
- 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 (P.A.A #10E).
- Never destroy, alter, or falsify immunization or VFC Program-related records (P.A.A #15B).
- 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 (P.A.A #15C).

Records Related to the Practice

Providers are required to maintain the following documents and records for a minimum of three years:

- VFC temperature logs
- vaccine accountability records (vaccine daily usage logs and inventory forms)
- vaccine invoices and packing slips (for VFC and privately purchased vaccines)
- certificate of calibration for each data logger (or other continuous temperature monitoring devices) including backup devices
- certificates of completion from required EZIZ lessons
- vaccine management plan
- medical records that verify vaccine administration
- VFC eligibility screening documentation
- billing records

Best Practices

Do not take VFC records off site. If VFC temperature logs are lost, providers might not have any documentation that proves vaccines were stored under recommended temperatures. Without proper documentation, vaccines might be considered spoiled and a negligent provider loss.

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Annual Recertification

Overview

Annual recertification is a federal requirement to remain enrolled in the VFC Program and continue receiving federally subsidized vaccines. Recertification is an online process, typically launched at the end of the calendar year. Recertification allows enrolled providers to renew their participation in the VFC Program by updating their information, completing online training, updating patient profiles, agreeing to the Program's federal requirements for participation, and certifying adherence with all items listed in the "Provider Agreement Addendum." The VFC Program will suspend ordering privileges for providers who do not complete the recertification process.

Target Audience

Provider of Record and Designee

Program Requirements

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

- VFC "Provider Agreement"[1] (federal agreement) and
- California VFC Program "Provider Agreement Addendum."[2]

Requirements at a Glance

The VFC Program summarizes any new or changes to existing requirements and procedures in its annual "Program Participation Requirements at a Glance"[3] document. Changes might impact the California VFC Program's "Provider Agreement Addendum", [4] "Vaccine Management Plan,"[5] online EZIZ training lessons, VFC temperature logs, job aids, and other key or supporting documents.

Training Requirements

All key practice staff (as identified in the MyVFCvaccines.org provider profile) are required to complete the federal educational requirements. New trainings, or a review of previous trainings, might be required to stay informed of VFC practices as requirements change slightly each year. Visit the EZIZ Training page[6] for the most up-to-date information.

Instructions for Recertification

The California VFC Program sends information a few weeks before recertification begins, and providers have approximately one month to complete the process. Instructions will be provided (both online and through e-mails) that direct providers to the online VFC e-Recertification Form. The instructions will include the deadline for meeting recertification requirements.

How to Prepare for Recertification

Recertification is an annual and online process accessible at MyVFCvaccines.org. Use the "VFC Recertification Worksheet"[7] to gather information ahead of time, including

- names and contact information for key practice staff;
- medical license numbers and National Provider Identification (NPI) numbers;
- number of VFC- and non-VFC-eligible children immunized;
- shipping address, delivery days, and times;
- brands and models of refrigerators and freezers storing VFC-supplied vaccines;
- type, serial number, and calibration expiration date of each data logger; and

Provider of Record's signatures attesting agreement to comply.

Verifying Medical License Numbers

The California Department of Consumer Affairs BreEZe online service[8] allows consumers to verify professional licenses.

Locating NPI Numbers

Providers can look up their National Provider Identification (NPI) number on the National Plan & Provider Enumeration System[9] (NPPES) website.

Submitting Practice's VFC Recertification Data

Most of the information that providers will need to complete and submit on the VFC e-Recertification Form will be preloaded in the online system. Providers will be instructed how to review, verify, and update their profiles. Updates could include the practice's key practice staff, the number of private and VFC-eligible children to be immunized in the coming year based on the previous year's data, and health-care providers in the practice with prescription-writing privileges who will be administering vaccines. In addition, key practice staff must take and pass (or test out of) required EZIZ training lessons as part of the recertification process.

Recertification FAQs

For more information on the recertification process—including training, testing out, and assistance completing the online form—refer to the VFC "Recertification FAQs".[10]

Reporting Changes in the Practice

To keep your provider profile current, submit the "Key Practice Staff Change Request Form"[11] anytime the practice has changes in the VFC Provider of Record or Designee, or the Vaccine Coordinator or Backup. Other changes that must be reported include

- practice name, ownership, or affiliation (submit a letter); and
- practice address and office hours (at MyVFCvaccines.org).

Notes

1. The VFC "Provider Agreement" can be found by searching for "IMM-1241" at http://EZIZ.org.
2. The current California VFC Program "Provider Agreement Addendum" can be found by searching for "IMM-1242" at http://EZIZ.org.
3. The current "Program Participation Requirements At A Glance" document can be found by searching for "IMM-1240" at http://EZIZ.org.
4. The current California VFC Program "Provider Agreement Addendum" can be found by searching for "IMM-1242" at http://EZIZ.org.
5. The "Vaccine Management Plan" Word template can be found by clicking on "VFC Program" at http://EZIZ.org.
6. The "EZIZ Training" page can be found under the "EZIZ Training" menu at http://EZIZ.org.
7. The "VFC Recertification Worksheet" can be found by searching for "IMM-1207" at http://EZIZ.org.
8. BreEZe online service, the California Department of Consumer Affairs.
9. NPPES NPI Registry, National Plan & Provider Enumeration System[4] (NPPES) website, https://npiregistry.cms.hhs.gov/.
10. The "VFC Recertification FAQs" can be found by searching for "IMM-1245" at http://EZIZ.org.
11. The "Key Practice Staff Change Request Form" can be found by searching for "IMM-1166" at http://EZIZ.org.

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Suspension & Termination

Overview

Providers may voluntarily withdraw from the VFC Program and terminate their VFC "Provider Agreement" at any time. 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 to the VFC Program or transfer to an approved VFC provider all unused VFC-supplied vaccines. Enrolled providers are responsible for all VFC-supplied vaccines in their practice until their agreement has been officially terminated.

Target Audience

Provider of Record and Designee

Program Requirements

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

- Understand that the provider's facility or the California Department of Public Health Vaccines for Children Program may terminate this agreement at any time. If the provider chooses to terminate this agreement, s/he agrees to properly return any unused federal vaccine as directed by the California Department of Public Health Vaccines for Children Program (VFC "Provider Agreement" #14).

Suspensions

A provider's ordering privileges might be suspended due to non-compliance with VFC Program requirements. Once the issue has been resolved, ordering privileges will be reinstated.

Provider-Initiated (Voluntary) Termination

Providers may voluntarily terminate their VFC "Provider Agreement" at any time. Since CHDP enrolled providers must be enrolled in the VFC Program, withdrawing from the VFC Program might affect participation in other programs, such as CHDP. The practice will need to

- notify the VFC Call Center at least 30 days prior to terminating the agreement and/or before closing the practice,
- complete the "VFC Participation Withdrawal Request Form,"[1]
- schedule a final site visit (a VFC Representative will contact the practice and determine if vaccines need to be retrieved/returned/transferred), and
- receive an official VFC Program termination letter.

VFC Program-Initiated Suspensions & Terminations

The VFC Program also might terminate a VFC "Provider Agreement" and remove the provider from the VFC Program for failure to comply with program requirements, including but not limited to the following:

- non-compliance with any VFC Program requirement
- failure to remedy any compliance issue
- failure to recertify
- fraud or abuse involving VFC-supplied vaccines
- administration of non-viable vaccines
- inadequate vaccine storage equipment or storage practices
- inability to account for VFC-supplied vaccines
- vaccine loss due to negligence
- transfer of VFC-supplied vaccines to non-VFC providers
- refusal/non-response to requests for VFC site visits from authorized personnel
- no VFC orders over the 12-month period prior to annual recertification

Repercussions of Termination

A provider who withdraws from the VFC Program and terminates their VFC Provider Agreement remains responsible for vaccine doses that expired or spoiled due to negligence or could not be accounted for during VFC Program participation. In such situations, requests for termination might result in delays or the provider could be subject to additional program actions.

Minimally, a provider who withdraws from the VFC Program and terminates their VFC "Provider Agreement"

- is responsible for every dose of VFC-supplied vaccine in their inventory,
- is required to store vaccines properly until they can be picked up by a VFC Field Representative or transferred to another VFC provider, and
- might need to wait up to one year before requesting to re-enroll.

Notes

1. The "VFC Participation Withdrawal Request Form" can be found by searching for "IMM-1244" at http://EZIZ.org.

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Appendices

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Glossary

AAFP. The American Academy of Family Physicians and its chapters represent over 120,000 family physician, resident, and medical student members. Family physicians play a critical role in improving the health of patients, families, and communities across the US.

AAP. The American Academy of Pediatrics is an organization of pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults.

abuse. Provider practices that are inconsistent with sound fiscal, business, or medical practices, and that result in unnecessary costs to the immunization program, a health insurance program, or a patient.

ACIP. The Advisory Committee on Immunization Practices is a team of medical and public-health experts that develops recommendations on the use of vaccines to reduce the incidence of vaccine-preventable diseases and increase the safe use of vaccines and related biological products in the US.

ACOG. The American College of Obstetricians and Gynecologists is a nonprofit professional association of physicians specializing in obstetrics and gynecology in the US.

AFIX. Assessment, Feedback, Incentives, and eXchange is a quality improvement program to raise immunization coverage levels, reduce missed vaccination opportunities, and improve standards of practice at the provider level.

CAIR. California Immunization Registry is an immunization registry and an important tool for providers. CAIR offers inventory and usage reports, tracks vaccine expiration dates, centralizes required information, automates which patients are due or past due for shots, and identifies patients with medical exemptions.

CBC. Community-Based Clinic is an entity owned by a nonprofit public benefit organization, exempt from taxation under Section 501(c)(3) of the IRS Code and from state franchise or income tax by the Franchise Tax Board, and are licensed by the California Department of Social Services.

CDC. Centers for Disease Control and Prevention is the nation's health protection agency that conducts critical science, provides health information that protects the nation against expensive and dangerous health threats, and responds when these arise.

CDPH. The California Department of Public Health is a department under the California Health and Human Services Agency.

CHDP. California Child Health and Disability Prevention Program is a program that provides well-child check-ups to children enrolled in Medi-Cal as well as those children not qualified for Medi-Cal but determined income-eligible.

CMS. The Centers for Medicare & Medicaid Services is part of the Department of Health and Human Services (HHS).

CHIP. Children's Health Insurance Program provides no-cost or low-cost health coverage for eligible children in California.

CoCASA. Comprehensive Clinic Assessment Software Application is a tool for assessing immunization coverage and practices within a provider clinic, or any other environment where immunizations are provided. This software is designed to be used in conjunction with the AFIX program.

data loggers. Battery-operated, continuous-recording devices that can be programmed to record temperatures at specific intervals throughout the day and night; the data can be downloaded onto a computer or retrieved from a website.

EHR. Electronic health records are digital versions of a patient's paper chart that provide real-time, patient-centered records including medical history, diagnoses, medications, treatment plans, immunization dates, and laboratory and test results. One key feature is the ability to share data among providers.

EMR. Also referred to as EHR. See "EHR".

excursion (temperature). Deviation outside the recommended temperature range.

expired doses. Vaccines are considered expired and nonviable if their expiration dates are past the manufacturer expiration date on the vial or expiration date after reconstitution, depending on the vaccine and according to manufacturer instructions.

FDA. US Food and Drug Administration is responsible for protecting and advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable.

family planning clinic. A clinic or provider whose main purpose is to prescribe contraceptives.

FQHC. Federally Qualified Health Center is a health center that is designated by the Bureau of Primary Health Care (BPHC) of the Health Services and Resources Administration (HRSA) to provide care to a medically underserved population. FQHCs include community and migrant health centers, special health facilities receiving grants under Section 330 of the Public Health Services (PHS) Act, and "look-alikes" which meet qualifications but do not actually receive grant funds.

fraud. An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or another person. It includes any act that constitutes fraud under applicable federal or state law.

fully insured. Anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay.

insurance. For the purposes of the VFC Program, insurance is defined as a plan that is regulated by a State's Insurance Commissioner and/or subject to the Employee Retirement Income Security Act of 1974 (ERISA).

job aid. Any on-the-job tool to help accomplish a task, such as a flyer, tip sheet, or instruction guide.

Medi-Cal (Medicaid). Medical assistance plan for poor and disabled Americans.

NCVIA. The National Childhood Vaccine Injury Act was passed by Congress in 1986 to reduce liability and respond to public health concerns about vaccine safety.

NCIRD. The National Center for Immunization and Respiratory Diseases operates under CDC, and its mission is the prevention of disease, disability, and death through immunization and by control of respiratory and related diseases.

NVAC. Established in 1987, the National Vaccine Advisory Committee (NVAC) recommends ways to achieve optimal prevention of human infectious diseases through vaccine development, and provides direction to prevent adverse reactions to vaccines.

OIG. Office of Inspector General.

ordering frequency. How often a provider may order vaccines (e.g., monthly, every other month, etc.) according to VFC Program requirements.

PBE. Personal Beliefs Exemption (when a patient chooses to exempt from immunizations, typically doses required for child care or school, for personal beliefs).

recertification. The annual process for providers to renew in the VFC Program.

returns. Vaccine doses a provider sends back to the manufacturer.

RHC. Rural Health Clinics are certified by a federal government agency (like FQHC), receiving special Medicare and Medicaid reimbursement to improve access to primary care in underserved rural areas. RHCs are required to be staffed by a physician assistant, nurse practitioner, or midwife at least half of the time the clinic is open. Facilities not meeting each of these requirements are not considered to be RHCs—even if they are located in rural areas. For more information, please refer to: http://www.cms.gov/center/rural.asp.

Safety stock. Enough extra doses to ensure practices don't run out of vaccines while orders are being processed and vaccines shipped.

Section 317 funds. Federal funds that support the purchase of vaccines for certain eligible populations, e.g. uninsured and insured children and adults in outbreak situations. Funds can be used only with the approval of the CA Department of Public Health.

short-dated vaccines. Vaccines that are soon to expire.

SHOTS. Storage and Handling Online Triage System, the California VFC Program's online documentation and reporting system for vaccine temperature excursions.

specialty provider. These providers do not provide general health-care services but instead offer limited care in a specialized environment or provide health care in a focused area, e.g. OB/GYN, STD clinic, or adolescent-only services

spoiled doses. Vaccines still in their original container (vial or syringe) are considered spoiled and nonviable if the vaccine manufacturer has determined that vaccines were exposed to out-of-range temperatures.

storage & handling incident. Event or occurrence related to (mis)management of vaccines.

temperature excursion. Event or occurrence of vaccines exposed to temperatures outside the recommended range based on manufacturer recommendations.

transfers. Vaccine doses a provider sends to another VFC provider.

uninsured child. A child who has no health insurance coverage.

underinsured child. A child who has health insurance but the coverage does not include vaccines; a child whose insurance covers only selected vaccines, or limits the number of annual visits. A child whose insurance caps vaccine coverage at a certain amount is considered under-insured only after that coverage cap amount is reached. Underinsured children are eligible to receive VFC vaccines only through FQHCs or RHCs, or under an approved deputization agreement.

VAERS. Vaccine Adverse Events Reporting System is a national vaccine safety program co-sponsored by CDC and the Food and Drug Administration (FDA).

VERP. Vaccine Errors Reporting Program is a national vaccine safety surveillance program developed in cooperation with the California Department of Public Health Immunization Branch and operated by ISMP.

VIS. Vaccine Information Statements are produced by CDC, in consultation with panels of experts and parents, to educate the public about the benefits and risks of vaccines.

VTrckS. The CDC online provider ordering and approval system.

wasted doses. Vaccines are considered wasted and nonviable if they have been opened and unused (such as multi-dose vaccine vials with leftover doses) but cannot be administered to patients.

Professional Resources

American Academy of Pediatrics (AAP)
www.aap.org

American College Health Association (ACHA)
www.acha.org

California Code of Regulations
govt.westlaw.com/calregs

California Department of Education (CDE)
www.cde.ca.gov

California Department of Public Health Immunization Branch (CDPH IZB)
www.cdph.ca.gov/Programs/CID/DCDC/Pages/immunize.aspx

California Department of Social Services (DSS), Community Care Licensing Division
www.ccld.ca.gov

California Immunization Registry (CAIR)
cairweb.org

California Vaccines for Children (VFC) Program
www.eziz.org

Center for Disease Control and Prevention (CDC) Vaccines & Immuniztaions
www.cdc.gov/vaccines/index.html

Child Health and Disability Prevention Program (CHDP)
www.dhcs.ca.gov/services/chdp/Pages/default.aspx

Every Child By Two (ECBT)
www.ecbt.org

Health Resources and Services Administration (HRSA)
www.hrsa.gov

Immunization Action Coalition (IAC)
www.immunize.org

Medi-Cal
www.medi-cal.ca.gov

Pink Book (Epidemiology and Prevention of Vaccine-Preventable Diseases)
www.cdc.gov/vaccines/pubs/pinkbook/index.html

Red Book® Report on the Committee on Infectious Diseases
redbook.solutions.aap.org/redbook.aspx

School immunization information
www.shotsforschool.org

Shot at Life
www.shotatlife.org

Shot by Shot
www.shotbyshot.org

Vaccine Adverse Event Reporting System (VAERS)
vaers.hhs.gov

Vaccine Errors Reporting Program (VERP)
verp.ismp.org

Provider Agreements

VACCINES FOR CHILDREN (VFC) PROGRAM

PROVIDER AGREEMENT

To receive publicly funded vaccines at no cost, I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent:

1.	I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if 1) the number of children served changes or 2) the status of the facility changes during the calendar year.
2.	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: A. Federally Vaccine-eligible Children (VFC eligible) 1. Are an American Indian or Alaska Native; 2. Are enrolled in Medicaid; 3. Have no health insurance; 4. Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement. B. State Vaccine-eligible Children 1. In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children. Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are **not** eligible to receive VFC-purchased vaccine.
3.	For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless: a) 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; b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4.	I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.
5.	I will immunize eligible children with publicly supplied vaccine at no charge to the patient for the vaccine.
6.	I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of $26.03 per vaccine dose. For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.

VACCINES FOR CHILDREN (VFC) PROGRAM

7.	I will not 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.
8.	I will 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).
9.	I will comply with the requirements for vaccine management including: a) Ordering vaccine and maintaining appropriate vaccine inventories; b) Not storing vaccine in dormitory-style units at any time; c) Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet California Department of Public Health Vaccines for Children Program storage and handling requirements; d) Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration
10.	I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR § 455.2, and for the purposes of the VFC Program: **Fraud:** is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law. **Abuse:** provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.
11.	I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.
12.	For pharmacies, urgent care, or school located vaccine clinics, I agree to: a) Vaccinate all "walk-in" VFC-eligible children and b) Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee. Note: *"Walk-in" refers to any VFC eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations then the policy would apply to VFC patients as well.*
13.	I 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.
14.	I understand this facility or the California Department of Public Health Vaccines for Children Program may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the California Department of Public Health Vaccines for Children Program.

VACCINES FOR CHILDREN (VFC) PROGRAM

To agree to these federal requirements, type your name, your medical license number, today's date, and sign in the boxes below.

By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the Vaccines for Children enrollment requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.	
Medical Director or Equivalent Name (print)	
Medical License Number	
Signature	Date
Name (print) *Second individual as needed*	
Medical License Number	
Signature	Date

Provider Agreement Addendum

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 ±1.0°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.