Overview

• VFC Updates
  ✓ Vaccine Management Plans
  ✓ Staff Training Requirements
  ✓ Digital Data Loggers
  ✓ Temperature monitoring
  ✓ Program Integrity
  ✓ Afternoon TEAch
Disclosures

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VFC Program
Requirements
# 2019 Program Participation Requirements at a Glance

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Summary</th>
<th>Resources/Job Aids</th>
</tr>
</thead>
</table>
| Vaccine Management Plan      | Maintain a current and completed vaccine management plan (for routine and emergency situations) that includes practice-specific, vaccine-management guidelines and protocols, names of staff with temperature monitoring responsibilities, and completion dates of required EZ2 lessons for key practice staff. Review and update the plan at least annually, when VFC program requirements change, and when staff with designated vaccine-management responsibilities change. Designate a staff member responsible for updating the practice's management plan, and execute planned actions in emergency situations. Conduct vaccine management drills to maintain competency and readiness for emergency procedures, such as vaccine transport. Ensure staff with assigned vaccine-management responsibilities review, sign, and date the vaccine management plan annually and each time it is updated. Keep the vaccine management plan in a location easily accessible by staff, ideally near the vaccine storage units. | EZ2 VFC Payment Requirements Lessons  
Vaccine Management Plan (IMM-1129)  
Provider Operations Manual (IMM-1246) Chapter 3                                                                                                    |
| Key Practice Staff           | Designate and maintain key practice staff in the practice's profile, and report key practice staff changes immediately on the online form on MyVFC/Vaccines. Changes to the Provider or Provider of Record designee cannot be made online, and a Key Practice Staff Change Request form needs to be completed and submitted to the VFC Program. Add new key practice staff to the practice's vaccine management plan; ensure required EZ2 lessons are taken. There are four required VFC roles:  
Provider of Record (POR): The physician-in-chief, medical director, or equivalent role that signs and agrees to the terms of the VFC "Provider Agreement" and the California VFC Program "Provider Agreement Addendum" and is ultimately accountable for the practice's compliance. Must be a licensed MD, DO, NP, PA, pharmacist, or a Certified Nurse Midwife with prescription-writing privileges in California.  
Provider of Record Designee: The on-site person designated by the Provider of Record to sign VFC documents on his/her behalf and to assume responsibility for VFC matters in his/her absence.  
Vaccine Coordinator: An on-site employee who is fully trained and responsible for implementing and overseeing the provider's vaccine management plan.  
Backup Vaccine Coordinator: An on-site employee fully trained in the practice's vaccine management activities and fulfills the responsibilities of the Vaccine Coordinator in his/her absence.  
Immunization Champion (optional): A staff member who goes above and beyond their normal duties to promote immunizations to patients and in the community. | Vaccination Coordinator Roles & Responsibilities (IMM-968)  
VFC Key Practice Staff Change Request Form (IMM-1162)  
Provider Operations Manual (IMM-1246) Chapter One, Program Requirements                                                                                   |
VFC Program Requirements

• Reviewed and update by the California VFC program on annual basis
• Providers are responsible for reviewing program materials that come out during the year
• Providers are required to update their internal policies/protocols to reflect those changes
• Review this document prior to annual recertification
  ✓ Program requirements can be found here
• Can be found on eziz.org
Vaccine Management Plans
Written Vaccine Management Plan

- All facilities storing and administering vaccines should have them

  ✓ These plans are a requirement for participation in the VFC Program

- Vaccine Management Plan (2 parts)

  ✓ Routine – include all aspects of vaccine management, from ordering, storage conditions to temperature monitoring.

  ✓ Emergency - Outline steps and key contacts in case of an emergency, such as a planed or unplanned power loss.
Vaccine Management Plans

- Should have a one already in place
- Should include practice-specific vaccine management guidelines & protocols
- Review and update at least once per year or as needed
- Have names of staff with temperature monitoring responsibilities
- List of staff who have completed the EZIZ online lessons (for key staff)
- Ensure all staff with assigned vaccine management duties review, sign and date the plan annually
- *All internal staff are required to know what the plan contains*
Vaccine Management Plans

• Major changes from 2018:
  ✓ Designate a staff member responsible for updating the practice’s management plan and execute planned actions in emergency situations
  ✓ Keep the vaccine management plan in a location easily accessible by staff
    • Ideally near the vaccine storage units
Staff Training Requirements
Skilled and Properly Trained Staff:

- Designate a primary and a back-up vaccine coordinator (VC)
  - Oversee storage and handling activities within the clinic
  - A description of the vaccine coordinator’s role is included in this job aid
  - BOTH VCs must be equally trained

- The provider of record should be directly involved in overseeing vaccine management activities in the clinic
  - Financial implications of vaccine replacement cost AND clinical implications of mishandling of vaccines
Temperature Monitoring Lesson Required for key practice staff AND clinic staff responsible for temperature monitoring.
## Required EZIZ Lessons for Key Practice Staff

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

*Test-out option available

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California Department of Public Health, Immunization Branch
Digital Data Logger Requirement
Digital Data Loggers

Digital data loggers
VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines - Summary

All staff, including supervisors and new employees, must be properly trained on temperature monitoring including proper use of the practice’s DDL and the required corrective action for out-of-range temperatures:

- Equip all refrigerators and freezers (primary and back-up) storing VFC-supplied vaccines with VFC-compliant DDL.
- Ensure each device has a current certificate of calibration
- Configure key settings for primary and back-up DDL’s including device name, high and low temperature alarm limits and a 30 minute logging interval
- Keep on hand at least one back-up DDL (battery operated) for emergency vaccine transport.
- Store the back-up DDL’s buffered probe in the vaccine refrigerator and it’s display in a cabinet
  ✓ Document the device’s location on the practice’s vaccine management plan.
VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines- Summary

• Calibrate primary and back-up devices annually, or every other year when the manufacturer’s recommend a period longer than two years
• Keep certificates of calibration on file and make them available to the VFC program upon request
• If any data logger or probe is damaged, replace the entire device
VFC Requirement: Use of DDL for Temperature Monitoring of VFC Supplied Vaccines

Minimum required features for your DDL:

- Detachable temperature probe immersed in buffered material
- Programmable logging interval
- Digital display with current, MIN, and MAX temperatures
- Accuracy of +/-1.0°F (+/-0.5°C) for refrigerator and freezer
- Visual or audible alarm for out-of-range temp
- Low battery indicator
- Memory storage of at least 4,000 readings
- Current and valid certificate of calibration

http://eziz.org/assets/docs/IMM-1236.pdf
Data Loggers Job Aids

Preparing New Data Loggers for Use
Refer to your device's product guide or videos to learn how to use your data loggers. Please call your vendor's support contact number for all questions regarding setup, functionality, or configurations.

Set Up and Get Familiar with Functions
1. Determine what data you will need to set up and prepare your data loggers to receive.
   - Install software and configure the device as instructed by the manufacturer. The data download may require setup of a serial connection or purchase of a serial cable.
   - Locate the vendor's support contact number in case you need to reach them during the software installation or device setup.
2. Get familiar with your data logger.
   - Make sure you can find the CDFEVT, MDF, and MDF events. Some devices display all of these readings on the main digital display. For others, you may need to access menus by toggling buttons such as:BDFEVT, MDF, and MDF events.
   - Determine how your device will communicate temperature alarms; some data loggers may display simple light or a visual element on the digital display. Test these features to ensure that messages on external alert monitors.
3. Locate the necessary steps to download temperature data files.
   - Determine if your device must be plugged in before downloading data files to prevent losing recorded temperatures.
   - Determine if your device must be unplugged from the power to download data files. Power must remain on in storage at all times.
4. Locate the necessary steps to resume temperature recording after data downloads.
   - Determine how your device must be readied. You may have testing the data logger back limits the probe and press the START button.
   - Determine if your device must be readied manually after recording temperatures; data loggers may or may not be readied automatically.

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California Department of Public Health, Immunization Branch, Vaccines for Children (VFC) Program
EZIZ1901

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California Department of Public Health, Immunization Branch, Vaccines for Children (VFC) Program
Temperature Monitoring
Temperature Monitoring:

- Ensure vaccine storage unit temperatures are recorded on current VFC temperature logs.
- Monitor and record current, minimum and maximum temperatures in vaccine refrigerators and freezers twice each day,
- Any VFC-approved mass vaccination clinic must monitor and record temperatures every hour and attach data logger download summary report to the transport log.
- Download and analyze temperature data files (feature of digital data loggers) at the end of every two-week
Temperature Monitoring:

- Acknowledge that if temperatures are not monitored and documented, if temperature logs are missing, or if temperature logs are falsified, all affected vaccines will be automatically deemed non-viable and considered a negligent vaccine loss.
- Ensure VFC temperature logs are legible and completed accurately, and in ink.
- Immediately cross out, correct, and initial neatly any inadvertent documentation error.
- Ensure the supervisor certifies and signs that temperatures were recorded twice daily,
- Acknowledge that temperature logs missing during a VFC site visit but found at a later date will not be accepted.
2018 Temperature Monitoring Logs

Refrigerator Temperature Log

Freezer Temperature Log
2018 Temperature Monitoring Logs

### Refrigerator Temperature Log

**Instructions**
- Check temperature once a day.
- Record high and low temperatures.
- Record check-out dates and times.
- Record alarms.
- Report any issues to the supervisor.

**If ALARM WENT OFF:**
- Clear alarm.
- Record the alarm.
- Report to supervisor.

**Supervisor's Review**
- Ensure all records are completed.
- Sign-off.

<table>
<thead>
<tr>
<th>DAY OF MONTH</th>
<th>TIME</th>
<th>INITIALS</th>
<th>ALARM</th>
<th>CURRENT</th>
<th>MIN</th>
<th>MAX</th>
<th>SHOTS ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example</td>
<td>2:00 a.m.</td>
<td>NN</td>
<td></td>
<td>40.6</td>
<td>38.1</td>
<td>43.7</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4:00 p.m.</td>
<td>NN</td>
<td>✓</td>
<td>37.4</td>
<td>33.6</td>
<td>39.2</td>
<td>12345</td>
</tr>
</tbody>
</table>

**Notes:**
- Keep all records for at least one year.
- Ensure all records are completed.
- Sign-off.

**Refrigerator Temperature Log**

<table>
<thead>
<tr>
<th>MONTH &amp; YEAR</th>
<th>REFRIGERATOR LOCATION/ID</th>
<th>VFC PIN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Refrigerator Location/ID:**

- 12345

**VFC PIN:**

- 12345

**Example:**

- 2:00 a.m., NN, 40.6, 38.1, 43.7
- 4:00 p.m., NN, ✓, 37.4, 33.6, 39.2

**SHOTS ID:**

- 12345
2018 Temperature Monitoring Logs

**Refrigerator Temperature Log**

**Instructions**

**Keep refrigerator in OK range.**

- **36.0°F**
- **46.0°F**

**Check temperatures twice a day.**

1. Fill out month, year, refrigerator ID, and PIN.
2. Record the time and your initials.
3. Record a check if an alarm went off.
4. Record Current, MIN, and MAX.

**If no alarm:**

1. Clear MIN/MAX.
2. Ensure data logger is in place and recording.

**IF ALARM WENT OFF:**

3. Alert your supervisor.
4. Report excursion to SHOTS at MyVFCvaccines.org.
5. Record assigned SHOTS ID.
6. Ensure data logger is in place and recording.

Notes:

- Keep all 4°C temperature logs and получи four times for temperature checks.

- Maintain accurate log and always report any variances.

- Verify that the temperature is within the OK range (36.0°F to 46.0°F).

- Record all necessary information to ensure accurate monitoring.

- Compliance with these guidelines is essential for maintaining vaccine integrity.

*California Department of Public Health, Immunization Branch*
## 2018 Temperature Monitoring Logs

### Refrigerator Temperature Log

<table>
<thead>
<tr>
<th>Time (UTC)</th>
<th>Temp (°C)</th>
<th>Min</th>
<th>Max</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>00:00</td>
<td>15.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>06:00</td>
<td>16.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12:00</td>
<td>17.2</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Instructions**
- Check temperature twice a day.
- If alarm set, check alarm settings and try again.

**IF ALARM WENT OFF**
- Check alarm settings and try again.
- Post data on refrigerator logs.
- Notify supervisor.
- Report alarm to ISO.
- Record alarm time and alarm ID.

**Supervisor’s Review**
- Check log to ensure temperatures are recorded and monitored.
- Verify that all entries are accurate.
- Sign off on log.

**Date:**
- Date of last entry.

**Staff Name:**
- Name of staff member.

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### 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 MyVFCaccees.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 Name and Initials: ________________
Temperature Monitoring Changes:

- As of January 1st, 2018, the new acceptable temperature for refrigerated vaccines is 36º - 46º Fahrenheit
Vaccine Storage Units
# Acceptable Vaccine Refrigerators

<table>
<thead>
<tr>
<th>Grade (Type) Rating</th>
<th>Description</th>
<th>Practice Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy- or biologic-grade (any) Best</td>
<td>Purpose-built to maintain consistent temperatures for storage of vaccines or biologics. Come in stand-alone and combination units.</td>
<td>Very high (required) Others: preferred</td>
</tr>
<tr>
<td>Compact pharmacy- or biologic-grade (stand-alone) Best</td>
<td>These under-the-counter storage units are suitable for smaller practices with limited space.</td>
<td>Low, Medium, High</td>
</tr>
<tr>
<td>Commercial units (stand-alone) Good</td>
<td>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.</td>
<td>Low, Medium, High</td>
</tr>
<tr>
<td>Household (stand-alone) Discouraged</td>
<td>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.</td>
<td>Low, Medium, High</td>
</tr>
</tbody>
</table>
TABLE 3. Vaccine freezers by practice volume

<table>
<thead>
<tr>
<th>Grade (Type) Rating</th>
<th>Description</th>
<th>Practice Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy- or biologic-grade (stand-alone) Good</td>
<td>Specifically designed to maintain consistent temperatures for storage of vaccines or biologics.</td>
<td>Any practice</td>
</tr>
<tr>
<td>Pharmacy- or biologic-grade (combination) Good</td>
<td>These storage units have more than one compressor allowing for better and separate temperature control of the refrigerator and freezer compartments.</td>
<td>Any practice</td>
</tr>
<tr>
<td>Commercial units (stand-alone) Good</td>
<td>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.</td>
<td>Any practice</td>
</tr>
<tr>
<td>Household (stand-alone) Good</td>
<td>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.</td>
<td>Any practice</td>
</tr>
</tbody>
</table>
Acceptable Storage Units

Key Terms:

- **Purpose-built.** These grades are specifically designed to maintain consistent temperatures for storage of vaccines or biologics. They might be designed for pharmacy, biologic, or laboratory environments.

- **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 Storage
Vaccine Storage Requirements

REQUIRED SPECIFICATIONS

All refrigerator units must:

- Maintain required vaccine storage temperatures (35°F – 46°F) year-round.
- Be automatic defrost (frost-free) and free of any frost, ice, water or coolant leaks. Manual defrost (cyclic defrost) refrigerators with visible cooling plates/coiling in the internal back wall are not acceptable.
- Provide enough space to store the largest number of doses expected at one time (including influenza season), allowing for vaccine storage at least 2-3 inches away from walls, floor, and other boxes, and away from cold air vents.
- Be reliable (with a quiet compressor) and has not needed frequent repairs. Replacement should be considered for household refrigerator/freezer combination units over 10 years old.
- Have doors that seal tightly and close properly.
- Have separate temperature controls for refrigerator and freezer for combination units.
- Not have convertible features that switch to an all-freezer unit.
- Have a working thermometer placed centrally in the unit. Thermometers must be certified in accordance with National Institute of Standards and Technology (NIST).
- Be used only for vaccine storage. In limited circumstance, and as space allows, other medications may be stored in the same units.

All Freezer units must:

- Maintain required vaccine storage temperatures (5°F or below) year-round.
- Provide enough space to store vaccines along with sufficient frozen cold packs.
- Have an automatic defroster. (Manual defrosters are acceptable only if the office has an alternate place to store vaccines when defrosting the unit.)

Most practices will need a separate refrigerator and freezer, but low and medium volume providers already enrolled in the VFC Program may continue to use household refrigerator/freezer combination units *IF* they meet all the required specifications.
**Vaccine Refrigerator Setup**

Carefully organizing vaccines in a refrigerator helps protect vaccine and facilitates vaccine inventory management. Refrigerate all vaccines except MMR, MMRV, Varicella, and Zoster vaccines.

**Refrigerator-only Unit**

- Always keep vaccine in its original line. Do not open the box until you are ready to use the vaccine.
- Place vaccines in breathable plastic mesh baskets or directly on shelves. Label baskets or shelves by type of vaccine.
- Group vaccines by pediatric, adolescent, and adult types.
- Separate VFC vaccines from privately purchased vaccine and label them clearly.
- Keep baskets 3-5 inches from walls and other baskets.
- Store only vaccine and other medications in vaccine storage units.
- Keep vaccines with shorter expiration dates to front of shelf. If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.
- Keep temperatures 36°F or colder.

If you have any problems with your refrigerator, keep the refrigerator door shut and notify the California VFC Program.

- **VFC Program Office**: (877) 243-8832
- **VFC Field Representative**

**Vaccine Freezer Setup**

Carefully organizing vaccines in a freezer helps protect vaccine and facilitates vaccine inventory management. Freeze MMR, MMRV, Varicella, and Zoster vaccines.

**Stand-alone freezer**

- Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.
- Separate the VFC vaccine supply from privately purchased vaccine.
- Keep vaccines with shorter expiration dates to front of shelf. If you have vaccine that will expire in 3 months or less that you will not be able to use, notify the VFC Program.
- Keep temperatures 0°F or colder.

**Chest freezer**

Do not block air vents with vaccine.

If you have any problems with your freezer, keep the freezer door shut and notify the California VFC Program.

- **VFC Program Office**: (877) 243-8832
- **VFC Field Representative**
Best practices for vaccine storage

- Store only vaccine in CDC/VFC Approved vaccine storage units.
- Separate the VFC vaccine supply from privately purchased vaccine.
- Place vaccine in breathable plastic mesh baskets and clearly label baskets by type of vaccine.
- Keep vaccines 2-3 inches from walls of the storage unit.
- Rotate vaccines (those expiring first should be placed in front)
- Transfer short-dated vaccine
- Place thermometer probe towards the center of the vaccine storage unit
ACIP Recommendations and Standards
ACIP Recommendations & Standards

• The VFC Program entitles eligible children to all vaccines recommended by ACIP.

• As a VFC Program participant, your practice is also required that VFC-eligible children have access to ACIP-recommended vaccines not routinely administered, and make them available when indicated or requested.
  ✓ i.e. Meningococcal Group B (Men B)
  ✓ i.e. Pneumococcal polysaccharide (PPSV23)
Vaccine Administration
Vaccine Administration

- Administer all ACIP-recommended vaccines, in-house
- Ensure that VFC-eligible children have access to non-routine, ACIP-recommended vaccines when indicated or requested
- Administer all VFC-supplied vaccines at the approved location for the VFC PIN
  - Administration of doses away from the approved location is NOT routinely allowed
- Report clinically significant adverse events to the Vaccine Adverse Events Reporting System (VAERS)
- Report vaccine administration errors (i.e. incorrect doses, wrong or expired vaccines) to the national Vaccine Errors Reporting Program (VERP)
Vaccine Administration

- Acknowledge and follow VFC Program and manufacturer guidance, including revaccinations, if non-viable vaccines have been administered to patients.
- Document all VFC vaccine doses administered using the VFC Daily Usage Log, Flu Usage Log, an immunization registry, or electronic or paper form.
- Acknowledge that revaccination is recommended if non-viable vaccines have been administered to patients.
Program Integrity
Program Integrity

• Clinic staff will conduct themselves in an ethical, professional, and respectful manner in all interactions with VFC Program staff.

• Never alter, or falsify immunization or VFC Program-related records

• It is a VFC Program requirement to maintain records for a period of three years
Educational Opportunity
Afternoon TEACH WITH VFC
Afternoon TEAch

-Began in 2018
-Webinar-based educational opportunity
-Topics range from VFC Program requirements to current ACIP recommendations
-Will be broadcast approximately every 2 – 3 months
Special Thanks to:

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