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TO: Vaccines for Children (VFC) Providers

FROM: Maria Volk, M.P.A., Acting Chief *Maria E. Volk*
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Division of Communicable Disease Control, Immunization Branch

SUBJECT: **New (2013) VFC Provider Participation Requirements**

Background

The federal Centers for Disease Control and Prevention (CDC) recently added several VFC Program participation requirements in order to enhance VFC Program oversight and ensure VFC vaccines administered to eligible children are appropriately stored and managed. These requirements were included in the 2013 VFC Program Participation Agreement, agreed upon by enrolled providers as part of VFC's annual provider recertification process. It is the responsibility of VFC Providers to ensure that all staff involved in administering, ordering, and managing vaccines are familiar with all federal participation requirements.

This memo highlights key 2013 changes in order to ensure clinic compliance with new requirements. A number of tools, materials, and job aids are currently being developed to facilitate the implementation of these changes at your clinic. Additional details are forthcoming.

Designation of Key Clinic Staff

Each participating VFC provider must designate a Vaccine Coordinator and Backup Vaccine Coordinator who are fully trained in providing oversight for the clinic's vaccine supply. Both must be familiar with their role and responsibilities as described in the [Vaccine Coordinator](#) job aid.

The name and contact information for the primary Vaccine Coordinator was collected as part of the 2013 VFC Program recertification. This information must be current in the clinic's VFC Provider Profile. Any personnel changes in this role must be immediately reported to the VFC Program through [MYVFCVaccines](#).

Annual Training Requirements

Each clinic's VFC Provider of Record and Vaccine Coordinator must complete annual EZIZ lessons to meet new federal education requirements on key program areas. Providers cannot recertify until training has been completed. Lessons must be completed between January 2013 and December 2013.

The designated Provider of Record is required to complete the “VFC Program Requirement Overview” lesson (available fall 2013); however, completion of all lessons is highly encouraged. The designated Vaccine Coordinator must complete the following lessons:

1. Storing Vaccines (20 min)
2. Monitoring Refrigerator Temperatures (17 Min)
3. Monitoring Freezer Temperatures (15 min)
4. Conducting a Vaccine Inventory (19 min)
5. VFC Program Requirements (available this fall-estimated time: 15 min)

For instructions on how to access, register, and complete these lessons, visit [the EZIZ Training Required for Annual VFC Recertification page](#). To access, register, and complete these lessons, VFC providers may log into [MYVFCVaccines](#) using the clinic's VFC Provider PIN and zip code. Upon login, the VFC Provider of Record and Vaccine Coordinator will be instructed to confirm their roles, and re-set their lesson completion history (if lessons were taken prior to January 1, 2013). Since Vaccine Coordinators have five lessons to complete by December 31, 2013, we recommend they begin taking the available lessons now. (Providers of Record and/or Vaccine Coordinators who are responsible for more than one clinic will only be required to take the lessons once.)

VFC Eligibility Screening & Documentation

Screening for VFC eligibility must occur with all clinic patients 0-18 years of age, prior to vaccine administration, and be documented in the patient's permanent medical record (paper-based or electronic medical record) at each immunization encounter.

Documentation of eligibility screening must include the following elements:

- Date of screening
- Whether the patient is VFC eligible or not VFC eligible
- If patient is VFC eligible, eligibility criteria met.

Providers may use [VFC's Patient Eligibility Screening Record form \(IMM-1111\)](#) to document eligibility or a similar form containing the above listed elements, or they may document eligibility elements on a practice electronic medical record (EMR) or immunization information system.

Eligibility documentation must be kept in the patient's medical record for three years.

VFC Vaccine Administration Fees

Effective January 1, 2013, the federal maximum regional administration charge set by the Centers for Medicare & Medicaid Services (CMS) for California increased from \$17.55 to \$26.03 per dose (not antigen) of vaccine. Providers may charge VFC-eligible children not covered by Medi-Cal (i.e., uninsured, American Indian/Alaska Natives, and, when administered by a FQHC or RHC, underinsured children) up to the new federal maximum regional administration charge. Providers, however, must waive the fee if the parent cannot afford the administration fee.

Pharmacies, urgent care, and other specialty providers enrolling in the VFC Program agree to vaccinate all “walk-in” VFC-eligible children and not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.

Thermometers

Providers should have two thermometers in each unit, a primary and a back-up thermometer. According to the CDC, thermometers:

- Should be accurate within +/- 1°F (+/-0.5°C).
- Should be digital, with the digital display placed outside the unit to allow for temperature monitoring without opening the unit door.
- Should have a biosafe glycol-encased probe, placed in proximity with vaccines.
- Should display current temperature, as well as the minimum and maximum temperatures, and have an audible alarm.

Thermometer's Calibration & Certification

Primary and back-up thermometers must be calibrated annually (or every other year at the most if recommended by the manufacturer), and each device should be covered by a Certificate of Traceability and Calibration Testing, also known as a Certification of Calibration.

Calibration should be conducted by an ILAC/MRA accredited laboratory. If calibration is conducted by a non-accredited laboratory, calibration certificates must include:

- Name and address of laboratory conducting testing
- Date of calibration
- Thermometer Identification (serial #)
- Measurement results
- Statement of conformance with ISO/IE 17025 calibration procedure standards
- Certificate report number.

Thermometer no longer accurate within, +/-1°F (+/-0.5°C) as indicated in calibration measurement results must be replaced.

A valid Certification of Calibration must be kept on file and be readily available for review during VFC visits.

Temperature Monitoring

Temperatures for each unit must be read and documented twice each workday, at the beginning of the day and before closing. Additionally, minimum and maximum temperatures must also be read and documented at the beginning of each workday.

- Thermometer temperatures must be cleared after each daily MIN/MAX readings.
- Temperatures must be recorded on VFC-provided temperature logs, even if using a continuous temperature-recording device or digital data logger.
- Temperature logs must be posted in a visible location.
- Temperature logs must be maintained for three years.

Current VFC Temperature Logs are being modified and tested to allow space for documentation of Minimum and Maximum readings. The VFC Program will notify providers via e-mail once new logs are readily available on www.eziz.org.

Vaccine Ordering and Accountability

Adequate vaccine supply must be maintained in accordance with practice's patient population. Stock records for both VFC and privately purchased vaccines (vaccine orders and privately purchased vaccine invoices) must be readily available for review during VFC visits.

VFC vaccine supply and private vaccines should be kept separate and clearly labeled to allow easy identification and to prevent inadvertent use on ineligible patients.

Providers must carefully track vaccine usage and account for all doses of VFC supplied vaccine within each ordering cycle. Vaccine usage may be tracked using the [VFC Program's Daily Vaccine Usage Log \(IMM-1053\)](#), similar form, or using an electronic Immunization Information System. Doses administered logs do not have to be submitted with vaccine orders; however, they may be requested for review during VFC site visits.

Administration logs must be kept for a period of 3 years.

Vaccine Transfers and Returns

Transfers

Ordered vaccines must be stored only at the facility indicated in the vaccine order. Transfer of VFC supplied vaccines should occur in limited situations. Routine re-distribution of vaccines is not allowed. Providers must contact the VFC central office for approval prior to transferring vaccines to another VFC provider. VFC-supplied vaccine doses cannot be transferred to non-VFC provider sites.

Returns

Reconciliation of all expired/wasted vaccine doses returned to the VFC Program's vaccine distributor by participating providers must occur within 3 months of report. Therefore, providers must ensure all reported doses of expired or spoiled VFC supplied vaccines are returned to the program's vaccine distributor soon after the submission of a VFC Return. Return Reports must be submitted prior to submitting a new vaccine request.

Site Visits

Providers agree to participate in VFC Program site visits, including:

- Scheduled compliance visits, also known as Quality Assurance Reviews (QARs)
- Unannounced Storage & Handling visits
- Other visits for educational and programmatic support.

The goal of unannounced storage and handling visits is to ensure VFC supplied vaccines administered to VFC eligible children are managed and stored according to program requirements; any active VFC provider may be chosen to receive an unannounced storage and handling visit.

Additional VFC Participation Requirements

For additional details on all other program participating requirements, please refer to your 2013 VFC program participation agreement.

Questions?

We appreciate your continued efforts to immunize California's children against dangerous vaccine-preventable diseases. If you have any questions, please contact your VFC Representative or VFC Customer Service at 1-877-243-8832 or (877-2Get-VFC). You can also visit our website at www.eziz.org.

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