2021-2022 CDC VFC Compliance Visit Requirements & Recommendations

ELIGIBILITY & DOCUMENTATION

Changes to Key Staff

All changes in key staff must be communicated to the immunization program in the manner and timeframe defined by the immunization program. Key staff include: the medical director or equivalent who signed the provider agreement, the vaccine coordinator, and the backup coordinator. VFC providers are required to ensure that all key staff are fully trained on VFC program requirements at all times. All training must be documented.

VFC Eligibility Categories

VFC providers must possess a working knowledge of ALL VFC eligibility criteria and use those criteria to screen children prior to administering VFC vaccines. To receive VFC vaccine, a patient must be under the age of 19 and must be at least one of the following: (1) **Medicaid eligible;** (2) **uninsured** (i.e., child has no health insurance); (3) **underinsured** (i.e., child has health insurance, but does not have cover for any or certain vaccines– underinsured children may only receive VFC vaccines in any FQHC/RHC or deputized VFC provider offices and may only receive vaccines not covered by insurance; and (4) **American Indian** OR **Alaska Native)**. (AI/AN).

Billing Practices

VFC providers must adhere to proper billing practices for vaccine administration fees and clearly understand that VFC vaccine is provided at no cost to either the VFC provider or eligible children. At no time should billing occur for the cost of VFC vaccine. When administering VFC vaccine, providers should never bill two different “payers” (i.e., patient, Medicaid, insurance) for the same vaccine administration fee amount. For Medicaid-eligible children, Medicaid should be billed for the vaccine administration fee. For all other VFC-eligible populations, the patient may be billed for an amount within the state/territory cap established by the Centers for Medicare and Medicaid Services (CMS); however, patients cannot be turned away or reported to collections for inability to pay the administration fee. Providers who choose to bill for the vaccine administration fee of a non-Medicaid, VFC-eligible child after the date of service may issue only a single bill to the patient within 90 days of vaccine administration.

Vaccine Administration Fee

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

Eligibility Screening & Documentation

VFC providers must screen for and document VFC eligibility at EACH immunization visit. Documentation must include the date of the visit and the child's specific eligibility category. VFC providers must use screening results to ensure that only VFC-eligible children receive VFC vaccine and that administration fees are billed for as appropriate. Eligibility status must be readily available to staff administering vaccine prior to selecting which vaccine stock to use. Comprehensive certificates are no longer allowed in the VFC program.

Vaccine Dose Documentation

In accordance with federal law, VFC providers must maintain immunization records that include ALL of the following elements: (1) name of vaccine administered; (2) date vaccine was administered; (3) date VIS was given; (4) publication date of VIS; (5) name of vaccine manufacturer; (6) vaccine lot number; (7) name and title of person who administers the vaccine; (8) address of clinic where vaccine was administered.

Record Retention

VFC providers are required to maintain all records related to the VFC program for a minimum of three years (or longer if required by state law) 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.

Vaccine Management Plan

VFC providers must maintain and implement a Vaccine Management Plan for routine and emergency vaccine management. The plan should consist of clearly written, detailed, and upto-date storage and handling standard operating procedures (SOPs). The plan must contain the name and contact information for the current vaccine coordinator and backup coordinator; proper storage and handling practices; shipping and receiving procedures; emergency procedures for equipment malfunctions, power failures, or natural disasters; vaccine ordering procedures; inventory control (e.g., stock rotation); procedures for handling vaccine loss and waste; and staff training/documentation on vaccine management, storage, and handling. The plan must be reviewed/updated annually or more frequently if changes occur. A review date and signature are required on all plans in order to validate they are current.

VIS & VAERS

VFC providers are required to distribute the current VIS each time a vaccine dose is administered and to 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). For a list of current VISs, visit: http://www.cdc.gov/vaccines/hcp/vis/.

Borrowing Documentation / Reasons

VFC Providers are expected to maintain an adequate inventory of vaccine for all patients served - it is the responsibility of the Provider to appropriately schedule and place vaccine orders and ensure vaccine stock is properly rotated to ensure timely use of short-dated vaccine. Borrowing of vaccine between private and public inventories must be a rare, unplanned occurrence and CANNOT serve as a replacement system for a Provider's privately purchased vaccine inventory. All instances of borrowing must be properly documented, reported and replaced.

STORAGE & HANDLING

Storage Unit Grade [Recommendation]

CDC recommends the following vaccine storage unit types (in order of preference): pharmaceutical-grade stand-alone or combination units (preferred); household/commercial stand-alone units; household/commercial combination units using the refrigerator section only.

TEMPERATURE MONITORING DEVICE IN THE UNIT

VFC providers MUST have a working calibrated temperature monitoring device with a current and valid certificate of calibration testing. All certificates of calibration testing must contain the model number, serial number, date of calibration, and measurement results indicating that the unit passed testing. Documentation that uncertainty is within suitable limits (recommended uncertainty = +/-1 degree Fahrenheit or 0.5 degree Celsius) and the name of the device are recommended but not required.

TEMPERATURE MONITORING DEVICE TYPE

All VFC providers must use continuous temperature monitoring devices (i.e., digital data loggers) to monitor vaccines administered to VFC-eligible children. Routine review and accessibility of temperature data are critical for determining whether vaccine has been properly stored and for assessing usability of vaccine involved in a temperature excursion. To meet VFC program requirements, the device must also be equipped with:

- A temperature probe
- An active temperature display that can be easily read from outside of the unit The
- capacity for continuous monitoring and recording the data to be routinely downloaded

Additional recommended features for these devices that may be required by your Immunization Program:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperatures display
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)

- Memory storage of at least 4,000 readings
- User programmable logging interval (or reading rate) recommended at a maximum time interval of every 30 minutes
- Use of a probe that best reflects the temperature of the vaccine (such as a buffered probe)

Certificate of Calibration Testing

Certificates of calibration testing provide confidence that the temperature monitoring device is measuring temperatures accurately. All units storing VFC vaccines MUST have a calibrated temperature monitoring device with a current and valid certificate of calibration testing. All certificates of calibration testing must contain the model number, serial number, date of calibration, and measurement results indicating the unit passed testing. Documentation that uncertainty is within suitable limits (recommended uncertainty = +/-1 degree Fahrenheit or 0.5 degree Celsius) and the name of the device are recommended but not required.

TEMPERATURE MONITORING DEVICE PLACEMENT

The temperature monitoring device (or probe) must be placed in a central area of the storage unit directly with the vaccines to properly measure vaccine temperature. Devices should not be placed in the doors, near or against the walls, close to vents, or on the floor of the unit. For pharmaceutical-grade units with a built-in temperature monitoring device or a dedicated port for a probe that is not in the center of the storage unit, consult your immunization program for guidance on placement.

Temperature Documentation

Vaccines must be stored at appropriate temperatures as described in the manufacturer package inserts at all times. The acceptable temperature ranges vary by vaccine type, and the range is 36° F and 46° F (2° C and 8° C), for refrigerated vaccines and -58° F and +5° F (-50° C and -15° C) for frozen vaccines. Exposure to temperatures outside of the ranges detailed in the package inserts could affect vaccine viability and, ultimately, leave children unprotected against vaccine-preventable diseases. To maintain awareness of storage unit temperatures and ensure that vaccines are being stored at appropriate temperatures at all times, VFC Providers are required to monitor and document temperatures for all vaccine storage units AT LEAST once per day. Temperature documentation must contain: (1) at least one minimum/maximum temperature readings per day, (2) the date and time of each reading and (3) the name (or initials) of the person who assessed and recorded the readings.

Temperature Excursions

The provider must document all excursions and actions taken including the following: (1) Quarantine and label vaccines as DO NOT USE; (2) Place vaccines in a unit where they can be stored under proper conditions (3) Contact the Immunization Program to report an excursion; and (4) Contact the vaccine manufacturer to obtain documentation supporting the usability of the vaccine

Vaccine Placement [Recommendation]

Vaccines should be stored in their original manufacturer (or CDC centralized distributor) packaging. They should be placed in the middle of the pharmaceutical-grade unit with space between the vaccines and the side/back of the unit to allow cold air to circulate. Vaccines SHOULD NOT be stored in the doors, vegetable bins, or on the floor of the unit, or under or near cooling vents, and there should not be any food in the unit. Unless otherwise specified by the manufacturer of a pharmaceutical-grade unit, water bottles (for refrigerators) or frozen water bottles (for freezers) should be placed throughout each storage unit to: (1) stabilize or extend temperatures during a power outage and (2) serve as physical blocks preventing the placement of vaccines in areas of the unit at higher risk for temperature excursions (such as in doors, vegetable bins, floor, or near/under cooling vents).

Disconnection from Power Source

VFC providers must take steps to protect the power source for all vaccine storage equipment by having clear warning labels on both the plug and the circuit breaker associated with all vaccine storage units. Large hospitals and healthcare systems can meet this requirement by demonstrating they have comprehensive policies and standard operating procedures to prevent vaccine storage units from being disconnected from the power supply

Dorm-style units

Dorm- and bar-style units are prohibited for vaccine storage. Vaccines stored in dorm-style units are considered nonviable and must be returned to the centralized distributor. CDC recommends the following vaccine storage unit types (in order of preference): pharmaceuticalgrade stand-alone or combination units (preferred), household/commercial stand-alone units, or household/commercial combination units using the refrigerator section only.

Storage Unit Space Availability

VFC Providers must have sufficient storage space to accommodate vaccine stock at the busiest time of year without overcrowding.

Expired Vaccines

Vaccines should be rotated weekly and whenever a new shipment arrives so that longer-dated vaccines are stored behind shorter-dated vaccines. If vaccines expire, they can no longer be stored in the same storage unit with viable vaccines. They must be placed in a container or bag clearly labeled "Do not use" and separated from viable vaccines to prevent inadvertent use. Expired vaccine must be returned to the centralized distributor within six months of expiration.

BACK-UP TEMPERATURE MONITORING DEVICE

VFC Providers must have a readily available continuous temperature monitoring backup device (e.g. digital data logger) with a current and valid certificate of calibration testing. To prevent the certificates of calibration testing of the primary and backup devices from expiring at the same time, the date of calibration testing (or issue date) of the backup device should be different from the date of calibration testing (or issue date) of the primary device.

Preparation of Vaccine [Recommendation]

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

Emergency Transport of Vaccine [Recommendation]

CDC recommends providers keep on hand or have ready access to the supplies needed for emergency transport. Appropriate materials include:

- Portable vaccine refrigerator/freezer units (preferred option)
- Qualified containers and packouts
- Hard-sided insulated containers or Styrofoam™ (Use in conjunction with the Packing Vaccines for Transport during Emergencies† tool. This system is only to be used in an emergency.)
- Coolant materials such as phase change materials (PCMs) or frozen water bottles that can be conditioned to 4° C to 5° C
- Insulating materials such as bubble wrap and corrugated cardboard—enough to form two layers per container TMDs for each container
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INVENTORY

Inventory Comparison

VFC Providers must order and stock routine vaccines in accordance with their most recent provider profile in order to prevent missed vaccination opportunities. Having sufficient amounts of all stocks prevents the inadvertent use of VFC vaccines for non-VFC-eligible patients and vice versa

ACIP-Recommended Vaccines

VFC providers agree to comply with immunization schedules, dosages, and contraindications that are established by the ACIP for the vaccines identified and agreed upon in the provider agreement and provider profile UNLESS:

1. In the VFC provider's medical judgment, and in accordance with accepted medical practice, the VFC provider deems such compliance to be medically inappropriate for the individual child
2. The particular requirements contradict state law, including laws pertaining to religious and/or other exemptions.

The VFC program entitles children to the following vaccines: DTaP, hepatitis A, hepatitis B, Hib, HPV, influenza, meningococcal, MMR, pneumococcal, polio, rotavirus, Tdap/TD and varicella.

VFC providers are also required to ensure that VFC-eligible children have access to nonroutine vaccines as needed.

Separation of Stock

To ensure that VFC vaccines are administered only to VFC-eligible children, VFC providers serving both VFC and non-VFC-eligible children must maintain vaccine inventories in such a way that they can clearly differentiate public stock from private stock.