VACCINES FOR CHILDREN PROGRAM (VFC)

VFC Site Visit Follow-Up Plan

Site Visit #:08222017WIA 4402

Provider PIN:WIA 4402

Kurt Eggebrecht 8/23/2017
APPLETON CITY HEALTH DEPARTMENT
100 N APPLETON ST
Appleton, WI 54911

Dear Kurt Eggebrecht,

Thank you for participating in a VFC Site Visit on 08/22/2017. We hope you found the visit to be informative and educational.

Congratulations: no compliance issues were identified during this visit! We appreciate your efforts to upholding the standards of the VFC Program. Below, you will find the following:

1. Notes from your site visit reviewer (if applicable)
2. A full listing of all VFC Program Requirements and Recommendations assessed during the visit

On behalf of the Wisconsin Immunization Program Immunization Program, I thank you for your participation in the VFC Program and your continued efforts to ensure that all children are fully immunized. Please do not hesitate to contact me if you have any questions.

Sincerely,

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REVIEWER'S SITE VISIT NOTES

Staff download data logger information monthly, will start to do it weekly. Also documents 2 X day temperatures manually on temperature graphs that are attached to each monitoring unit (LOG TAG)

2017 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 Back-up 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. In order 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 coverage does not cover any or certain vaccines - underinsured children may only receive VFC vaccines in FQHC/RHC or deputized VFC Provider offices and only for vaccines not covered by insurance; and (4) AMERICAN INDIAN OR ALASKA NATIVE (AI/AN). Generally, underinsured patients should be rare, however, when they do come in for vaccinations, those children must be referred to an FQHC/RHC or other VFC provider deputized to immunize the underinsured, in order to receive VFC vaccines for the specific vaccines not covered by their insurance policy).

For the purposes of the VFC Program, if, on the day of the visit, a child presents with health insurance and coverage for vaccine is not known (i.e. not verified) by the provider, the child must be treated as though they are insured for all vaccines. Children who have insurance that covers vaccines are not VFC eligible even if the patient has a high deductible or copays. Additionally, children with insurance seeking vaccination services either from an out-of-network provider or outside the geographic coverage area of their policy are considered fully insured and are therefore not eligible to receive VFC vaccines.

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 both the VFC Provider and

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 within the state/territory cap established by the Centers for Medicare and Medicaid (CMS). However, patients cannot be turned away or reported to collections for inability to pay the administration fee.

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 and Medicaid (CMS). For current fee caps, refer to 'http://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, all 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) lot number; (7) name and title of person who administer 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.

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.

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 up-to-date storage and handling standard operating procedures (SOPs). The plan must contain: the current Vaccine Coordinator and Back-up Coordinator; proper storage and handling practices; shipping and receiving procedures; emergency procedures such as equipment malfunctions, power failures, or natural disasters; procedures for vaccine ordering; inventory control (e.g. stock rotation); how to handle vaccine wastage; 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 that they are current.

VIS & VAERS

VFC Providers are required to 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). For a list of current VIS visit: http://www.cdc.gov/vaccines/hcp/vis/.

STORAGE & HANDLING

Storage Unit Type [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.

Thermometer in the Unit

VFC Providers MUST have a working calibrated thermometer with a current and valid certificate of calibration testing issued either by an ILAC MRA-accredited laboratory or, if not ILAC MRA-accredited, the certificate must contain the measurement results and a statement indicating that it meets ISO 17025 standards. All certificates of calibration testing must contain: model number; serial number; date of calibration; 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 (optional).

Thermometer Type [Recommendation]

Unless required sooner by your Immunization Program, **as of January 1, 2018** all VFC providers must use continuous temperature monitoring devices (data loggers) to monitor vaccines that will be administered to VFC eligible children. Routine review and accessibility of temperature data is critical for determining whether vaccine has been properly stored and for assessing usability of vaccine that was involved in a temperature excursion. To meet VFC Program requirements the device must also be equipped with:

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

The following are 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 thermometer with a current and valid certificate of calibration testing. All certificates must contain: model/device name or number; serial number; date of calibration testing (report or issue date); and Instrument Passed testing (Instrument in Tolerance) (Recommended uncertainty =+/-0.5°C (+/-1°F)).

Thermometer Placement

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

Temperature Documentation

Vaccines must be stored under appropriate temperatures **as described in the package inserts** at all times. The acceptable temperature ranges vary by vaccine type and the range is now 36° F and 46° F (2° C and 8° C, and for frozen vaccines the range is -58° F and +5° F (-50° C and -15° C). Exposure to temperatures outside of those included in the vaccine package inserts could affect vaccine viability and, ultimately, could leave children unprotected against vaccine-preventable diseases. In order 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 twice a day. Temperature documentation must contain: (1) at least two temperature readings per day, (2) the time and date of each reading and (3) the name (or initials) of the person who assessed and recorded the readings. CDC also recommends that VFC Providers using a data logger record the minimum and maximum temperatures of each unit once each workday (preferably in the morning).

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 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 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 unit, water bottles (for refrigerators) or frozen water bottles (for freezers) should be placed throughout each storage unit in order to: (1) stabilize or extend temperatures during a power outage and (2) to serve as physical blocks preventing the placement of vaccines in areas of the unit that are 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 means of 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 that they have comprehensive policies and standard operating procedures to prevent vaccine storage units from being physically 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 non-viable and must be returned to the centralized distributor. 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

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 when a new shipment comes in 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 Thermometer

VFC Providers must have a readily available back-up thermometer with a current and valid certificate of calibration testing. To prevent the certificates of calibration testing of the primary and back-up thermometers from expiring at the same time, the date of calibration testing (or issue date) of the back-up thermometer should be different from the date of calibration testing (or issue date) of the primary thermometer.

As of January 1, 2018, all devices in use including back-up devices must be a continuous monitoring and recording device that meets VFC Program requirements.

Preparation of Vaccine [Recommendation]

CDC recommends preparing vaccines immediately prior to administration in order 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.

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 Advisory Committee on Immunization Practices (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 child;
2. The particular requirements contradict state law, including laws pertaining to religious and 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 non-routine vaccines as needed.

Separation of Stock

In order to ensure that VFC vaccines are only administered to VFC-eligible children, VFC Providers that serve both VFC and non-VFC-eligible children must maintain their vaccine inventories in such a way that they can clearly differentiate public stock from private stock as well as VFC from other public stock.