

## ***SECTION 5 – QUALITY ASSURANCE (QA)***

### **Overview of the Pennsylvania Vaccines for Children Program (PA VFC) Enrollment and Site Visit Process**

Once a provider expresses interest in enrolling in the PA VFC program by contacting the Division of Immunizations (DOI) or one of the Quality Assurance (QA) Immunization Nurse Consultants, the PA VFC program initiates the enrollment process. An enrollment packet consisting of Provider Site Profile/Enrollment Form (PEF), PA VFC temperature logs, a list of manufacturers who sell National Institute of Standards and Technology (NIST)-certified thermometers, PA-SIIS brochure, pictures of acceptable storage units and an introduction letter is sent to the prospective provider by the DOI Vaccine Management Unit.

Requirements for PA VFC immunization provider enrollment are simple, yet promote accountability. To enroll, a provider must:

- Complete the PEF that defines the compliance parameters of the PA VFC program and projects the provider's vaccine needs based on the number of PA VFC-eligible patients in the practice.

When the provider completes and returns the PEF to the DOI, a Provider Identification Number (PIN) is issued, the PA VFC Provider Handbook is mailed and the QA Immunization Nurse Consultant in that district is notified to contact the provider to schedule an enrollment site visit.

The QA Immunization Nurse Consultant will be the provider's main resource for questions, education and assistance regarding the PA VFC program.

The purpose of the **PA VFC Enrollment Site Visit** is to educate the provider office personnel on the PA VFC program requirements, which includes the following:

- Immunization schedule

- Vaccine storage and handling
- Vaccine ordering procedure
- PA VFC eligibility
- Immunization documentation and record retention requirements
- The PA Statewide Immunization Information System (PA-SIIS)

Upon completion of the PA VFC enrollment visit, the QA Immunization Nurse Consultant notifies the DOI that the site may order PA VFC vaccine. The DOI then sends a final enrollment letter and a PA VFC Program certificate to the newly enrolled provider.

If the provider does not have adequate vaccine storage and handling, proper temperature monitoring equipment or if there other problems are identified (such as lack of staff to administer vaccines, inability to designate a vaccine primary contact and/or fluctuating temperatures) the provider will not be approved to order vaccines. A verbal corrective action will be discussed with the provider, including a mutual date and time to return to evaluate the site to see if they have implemented the required changes for enrollment.

If a PA VFC provider voluntarily disenrolls or has been inactive for twelve months and wishes to re-enroll, a reactivation visit is conducted. This type of visit is identical to the initial enrollment visit. No vaccine orders are processed for the reactivating provider until the reactivation visit is conducted and all requirements are satisfactorily met.

## **Overview of PA Vaccines for Children (PA VFC) QA Site Visits**

At a minimum, a QA VFC site visit will occur every other year at all PA VFC-enrolled provider offices. Additional site visits will occur at the request of the provider for educational purposes or at the request of the DOI for programmatic issues including unannounced site visits. The model used to achieve Quality Assurance in the PA VFC Program is the Assessment, Feedback, Incentives and Exchange (AFIX) model. AFIX is a quality improvement strategy to raise immunization coverage levels and improve standards of practices at the provider level.

The acronym for this four-part dynamic strategy stands for:

**Assessment** of the health care provider's vaccination coverage levels and immunization practices,

**Feedback** of results to the provider along with recommended strategies to improve coverage levels,

**Incentives** to recognize and reward improved performance, and

**eXchange** of health care information and resources necessary to facilitate improvement.

A **PA VFC compliance site visit** determines if PA VFC vaccines are being distributed, handled and administered in accordance with the laws and policies that govern the PA VFC program, which includes the following:

- Appropriate vaccine handling, storage and ordering procedures which include:
  - Assessment of refrigeration units.
  - Assessment of the use of appropriate thermometers and twice daily temperature recording.
  - Monitoring vaccine accountability.
  - Reviewing procedures for vaccine retrieval and storage in times of emergencies.
  - Reviewing vaccine inventory and management practices.
- Proper documentation of children's PA VFC eligibility status which includes:
  - Sampling patient records to ensure appropriate PA VFC eligibility screening (e.g., those on Medicaid, uninsured, Alaskan Native/American Indian or underinsured).

- Ensuring the administration of PA VFC-purchased vaccines only to PA VFC eligible children.
- Compliance with documentation and record-retention requirements which include:
  - Proper use and documentation of the Vaccine Information Statements (VIS), which must be offered to the parent/guardian prior to each immunization.
  - Maintaining records of children who had an adverse reaction to a vaccine in accordance with the National Childhood Vaccine Injury Act.
  - Maintaining accurate inventory of vaccine lot numbers received and administered.
- Compliance with other PA VFC program requirements which includes:
  - Agreeing not to charge a vaccine administration fee that is higher than the maximum fee established by the state.
  - Agreeing not to charge for the cost of the vaccine.
  - Agreeing not to deny immunizations because of the parent's inability to pay a vaccine administration fee.

Providers not scheduled to receive a VFC compliance visit during the calendar year must be scheduled to receive training on-line, by webinar, or through an in-person classroom style presentation.

An **AFIX site visit** is to evaluate quality improvement activities, including the following:

- Assessing the provider's immunization coverage levels via an assessment of patient immunization records for both PA VFC and Non-PA VFC eligible patients.
- Providing feedback of performance data to clinicians and office staff to make them aware of their immunization practices.

- Providing guidance to help staff diagnose service delivery problems and adopt interventions for improvement. This may include information on the following:
  - Current Advisory Committee on Immunization Practices (ACIP) recommendations
  - Valid contraindications to immunizations
  - Record-keeping practices
  - Patient flow sheets
  - Reminder/recall systems.

An **Educational visit** is a visit to a PA VFC- enrolled provider office to perform an educational in-service. A PA VFC provider may request a PA VFC educational visit whenever the need arises. Often this is conducted for new staff at the practice site. All aspects of the VFC program are reviewed during an education visit. In addition, the PA VFC Provider Handbook is reviewed thoroughly with office staff during this visit.

All site visit data is entered into the Comprehensive Clinic Assessment Software Application (CoCASA). After the site visit data has been entered into CoCASA, data analysis capabilities can be utilized to pinpoint strengths and areas of improvement for a provider and to enable the DOI to evaluate and analyze the status of the PA VFC Program. These reports are used to report PA VFC Program status to the Centers for Disease Control and Prevention (CDC).

A **Follow-up PA VFC visit** is a contact/visit to a PA VFC provider site to review progress on their Corrective Action Plan (CAP) which was developed during the PA VFC/AFIX site visit.

Given the amount of funding and considerable resources that are invested in implementing and managing the PA VFC program, Quality Assurance site visits are important to evaluate whether the program is managed appropriately and is achieving the desired outcomes. Evaluation provides objective insight into a program and identifies opportunities to assess its impact, make improvements or build program capacity. For the PA VFC program, it is important to evaluate

program processes and outcomes. The desired outcome of the PA VFC program is that viable vaccine is administered to eligible children.

**Unannounced Storage and Handling Visits:** Are now a requirement from CDC. Unannounced visits are separate from the VFC Compliance visits and Unannounced Visits will serve as a spot check for proper storage and handling practices.

## **Pennsylvania Vaccines for Children Immunization Program Participation Requirements**

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- may not charge a vaccine administration fee in excess of \$23.14 per shot to patients receiving publicly- purchased vaccine
- must waive any administration fee on publicly-purchased vaccine if patient is unable to pay
- must offer a current Vaccine Information Statement (VIS) every time a patient receives a vaccine. If the patient or guardian does not speak English, provide a VIS in the appropriate language
- must screen patients for program eligibility and document VFC status at every visit
- must have a written and signed plan for vaccine management that is updated annually
- must not store vaccine (refrigerated or frozen) in a dormitory-style refrigerator
- must have working National Institute of Standards and Technology (NIST)-certified thermometers placed in a central location of the refrigerator and freezer compartments
- must certify and calibrate thermometers at a minimum of every two years

- must check and document temperatures a minimum of twice a day
- must take immediate action on out-of-range temperatures and if found within 30 minutes document actions on the temperature logs
- must immediately notify the vaccine manufacturers if the vaccine has been stored outside the appropriate temperature range longer than 30 minutes and must be labeled to not be used
- must complete an Incident Report and Worksheet form and notify Pennsylvania Vaccines for Children Immunization Program within 5 days of a Cold Chain Failure
- must not store food or drink with vaccines
- must not store vaccine in doors, crisper bins, or bottom of the refrigerator
- must store the vaccine in original boxes in the middle of the refrigerator or freezer to allow air to circulate around it without overcrowding
- must keep water bottles in the crisper section of the refrigerator and frozen packs in the freezer to help maintain temperature in the event of a power outage
- must have a “DO NOT DISCONNECT” sticker on the circuit breaker, as well as refrigerator and freezer electrical outlets
- must rotate stock weekly, using short-dated vaccines first and notify your immunization nurse if vaccines will expire within 90 days and will not be used
- must be able to physically differentiate between publicly-purchased and privately-purchased vaccine