

SECTION 2 – PROVIDER ENROLLMENT

Required Enrollment Documentation

Pennsylvania Vaccines for Children (VFC) providers are required to adhere to all federal and state requirements. This includes annual submission of the PA Vaccines for Children Program Provider Agreement (PA VFC PPA). In order to receive publicly purchased vaccines, there are several required activities that each practice must complete. In order to remain enrolled in the Vaccine Program, it is mandatory to annually complete, sign and submit the PA VFC PPA. The form is updated and will be sent to you annually for completion. The form specifies the requirements the health care provider must agree to in order to participate in this program. A copy of the form can be found in Section 6-Forms. A separate form must be completed for each site receiving vaccine.

Provider Annual Enrollment

The PA VFC PPA (Section 6-Form) is part of the initial enrollment process. By signing the form, the healthcare provider agrees that he/she has read, understands and will comply with all program requirements. The PA VFC PPA contains facility demographic and facility contact information. The form enables facilities to provide the Department of Health (DOH) with a list of physicians that will be administering VFC-DOH supplied vaccines, as well as the necessary shipping information and special delivery instructions.

The PA VFC PPA contains the provider agreement section in which the facility agrees to screen patients, document eligibility, comply with immunization schedules and detail limitations on vaccine administration fees. It captures facility type, vaccines offered and provider population. The provider population section is a projection of the number of children within the clinic who are eligible to receive PA VFC vaccine. The estimated annual VFC patient population is used to determine how much vaccine each provider should order.

If a healthcare provider operates more than one site, a separate PA VFC PPA must be completed for each site annually. Failure to submit these forms as directed by PA VFC Program will result in suspension of vaccine ordering privileges.

The document must be updated annually or whenever there is a significant change in enrollment or when the physician who signed the PA VFC PPA leaves the practice. At time of initial enrollment the PA Statewide Immunization Information System (PA-SIIS) registry staff will assign all newly enrolled facilities with Internet access a PA-SIIS username and password. The logon credentials allow facility staff to order vaccines online, update changes in vaccine shipping hours, etc. **You must know your username and password to log into PA-SIIS.**

Log into PA-SIIS:

Using your Web browser, navigate to the PA-SIIS Web site:

PA-SIIS Website: <https://siis.health.state.pa.us/siis>

PA-SIIS Support Site: www.health.state.pa.us/pasiis

Phone Number: 717-783-2548 or 877 -774-4748

For those providers with no online capabilities this document may be emailed, faxed, or mailed to the DOH. A copy of the original document should be retained by the primary contact person. Updates should be documented and forwarded to the DOH as changes occur regarding staff with vaccine administration privileges. Vaccine orders may be suspended if the required forms are not returned by the annual renewal date.

New Provider Enrollment

Enrolling in the Pennsylvania Vaccines for Children (VFC) Program is easy. To enroll, a provider must agree to adhere to program requirements and responsibilities and complete the appropriate forms.

Provider Identification Number

Upon receipt of the completed PA VFC PPA document, the DOH will issue the provider a **Provider Identification Number (PIN)**. Please refer to this PIN number for all contacts and transactions with the VFC Program office. The PIN should be on all documentation sent to the VFC program.

PA-SIIS User Log on Credentials

All newly enrolled facilities with access to the Internet are provided a PA-SIIS user unique username and password. The logon credentials allow facility staff to order vaccines online, update facility address, vaccine shipping hours, etc.

New Provider Enrollment Site Visit and Training

Once the VFC Program receives all enrollment information, DOH staff will schedule an enrollment visit. The enrollment visit will include a review of VFC Program requirements, as well as give the provider the opportunity to ask questions regarding any segment of the VFC Program. The visit and training will take approximately two hours and will address the following areas:

- Ordering vaccines
- Receiving vaccine shipments
- Maintaining the cold chain
- Ensuring proper vaccine storage practices
- Monitoring temperatures
- Completing vaccine inventory management
- Maintaining an emergency vaccine recovery plan
- Securing an emergency retrieval storage place
- PA Statewide Immunization Information System (PA-SIIS)
- Recommended Immunization Schedules
- Vaccine Administration
- Patient eligibility screening
- Transfer of vaccines
- Return of expired/wasted vaccines
- Vaccine Information Statements (VIS)

- Reports:
 - Adverse reactions
 - Incident reports
 - PA VFC Pediatric & Accountability Ordering form

Vaccine Storage and Handling Equipment

Keeping vaccines at the recommended temperature is called maintaining the cold chain. The cold chain begins at the manufacturer, extends to the distributor and continues in the provider site until the vaccine is administered. Proper vaccine temperature must be maintained during transit and at every link in the chain to ensure its viability.

Vaccine cold chain failure occurs when there is a break in any link of this chain. Cold chain failure may occur due to a power failure, staff error, etc. To prevent vaccine cold chain failure, it is essential to have properly functioning equipment, appropriately trained staff, clearly written procedures and easily accessible emergency operating protocols for handling vaccines.

In the event of a cold chain failure a Vaccine Incident Report and Worksheet must be completed for each cold chain failure incident. Forms **MUST** be received in the Division of Immunizations at the times specified. Failure to comply with these requirements may result in vaccine orders being suspended until proper documentation requirements are met.

Freezers and Refrigerators

CDC strongly recommends use of stand-alone freezers and stand-alone refrigerators for vaccine storage. The Department of Health supports the above as a best practice however will accept: A combination storage unit (refrigerator/freezer) that has separate exterior doors with dual controls OR if a single control unit is used then you may use the refrigerator portion of that unit but must purchase a stand-alone freezer unless otherwise approved by the VFC program. Storage units must be approved by the VFC program for enrolled VFC

providers. For new providers it is strongly recommended use of stand-alone freezers and stand-alone refrigerators for vaccine storage.

- By January 2015, single control units are required to be accompanied by a stand-alone freezer to avoid suspension of ordering privileges.
- By January 2015, dual control units are recommended to be accompanied by a stand-alone freezer. A 90-day grace period will be given during a site visit to providers to obtain a stand-alone freezer.

Absolutely NO DORMITORY style units will be accepted, this is an immediate suspension of vaccine ordering privileges.

Certified Thermometer Calibration

CDC recommends the use of continuous digital data loggers with detachable probes for temperature monitoring.

Providers must use digital min/max thermometers with a biosafe glycol-encased probe and a certificate of traceability and calibration. The best calibration is annual however the Department of Health will accept manufacturer suggestion but not to exceed two years.

Staff Training

Facilities are responsible for providing internal training on proper vaccine storage and handling guidelines and vaccine administration protocols to each new employee. This training should occur at the time of employment orientation and review this information annually with all staff. Documentation of these trainings and those who attended is required.

Written Procedures

Develop, maintain and update annually a current written Vaccine Disaster Recovery Plan, providing guidelines to ensure the vaccine cold chain is maintained. The plan should include:

- Identification of an alternative storage facility, recommend a site with 24/7 access, such as a hospital, packing plant, or local pharmacy, with back-up

power (generator) where the vaccine can be stored and monitored during an emergency;

- Identification and training of staff responsible to pack and move vaccine during an emergency;
- Maintenance of a supply of appropriate packing materials (insulated containers, ice packs, etc.); and
- Identification of transportation to move vaccine to a secure storage facility during an emergency.

Temperature Log Form

Part of the enrollment process includes recording temperatures twice daily for the refrigerator and freezer where vaccines are stored. Twice-daily documentation should include the time when temperature was checked and initials of staff checking vaccine temperatures. Copies of the temperature logs are included in the “provider enrollment package” and in Section 6-Forms of this handbook. These logs list the correct temperature ranges for the safe storage of vaccines. Due to the high cost and critical importance of administering safe and effective vaccines, the provider must maintain a temperature log that reflects the refrigerator and freezer temperatures for a one-week period prior to enrollment. This will ensure adequate storage of vaccines. Providers must verify that a current temperature log is maintained and temperatures are documented twice daily during hours of operation prior to placing any vaccine order.

Withdrawing from the VFC Program

There may be a number of reasons a provider may choose to disenroll from the PA VFC program. In order to assure a smooth transition of services we ask that the following steps be taken should you choose to discontinue participating in the PA VFC Program.

First notify the PA VFC program if your office plans to disenroll. Next take a complete inventory of all PA VFC vaccines on-site to include brand, lot number, expiration date and number of doses. Use the Pennsylvania VFC Pediatric Vaccine Order and Accountability Form (Section 6) to document this information or print a current inventory list from PA-SIIS.

Make arrangements through your Department of Health Immunization nurse (list located in Section 5) to transfer your PA VFC vaccines to another approved PA VFC practice. Please do not refer these children to the State Health Center. If you need help finding another VFC provider in your area, please contact the program. If you are receiving a capitated payment from a Medicaid managed care organization, referral to the State Health Center is **not** appropriate.