



**DIVISION OF IMMUNIZATIONS PROVIDER BULLETIN**

**SUBJECT: Vaccine Cold Chain Protocol for Immunization Providers**

**Revised 2/1/2016**

**By Direction Of:** Cindy Findley, Director   
Division of Immunizations, Bureau of Communicable Diseases

**Policy Statement:** 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 the chain. Cold chain failure may occur due to a power failure, staff error, equipment failure, etc. Preventing vaccine cold chain failure requires: properly functioning equipment, appropriately trained staff, clearly written procedures and easily accessible emergency operating protocols.

**Procedures:** Vaccine Cold Chain Protocols provide vaccine-handling procedures to maintain the cold chain and action steps to be taken in the event of a cold chain failure by provider sites receiving vaccine from the Department of Health (DOH).

**I. Utilizing DOH Supplied Vaccine - Providers Shall:**

- A. Follow the vaccine management guidelines as outlined in the DOH provided Vaccines for Children (VFC) Provider Handbook.
- B. Freezers and Refrigerators:  
DOH approved equipment for vaccine storage and temperature monitoring.

DOH supplied vaccine must be stored in one of the following:

- Stand-alone storage unit
- Household combination unit (refrigerator portion only, must have separate stand-alone freezer)
- Medical grade combination units

All 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.

- C. Absolutely NO DORMITORY style units will be accepted, this is an immediate suspension of vaccine ordering privileges.
  - **Effective 2016**, all vaccines stored in a dormitory style unit are considered non-viable and must be returned to McKesson Specialty Distribution. Complete and Submit a Vaccine Return Form found in the *VFC Provider Handbook*, section 6.
  
- D. DOH approved household combination units will be given 90 days to acquire a stand-alone freezer.
  - During the 90 days, the provider will not be allowed to order additional frozen VFC vaccine.
  - Providers making no accommodation to acquire a stand-alone freezer within 90 days will be suspended from ordering all VFC vaccines.
  - Providers will remain suspended until a stand-alone freezer is acquired
  - After one year of suspension, the provider will be disenrolled from the VFC program.
  - **Effective 2017**, if a DOH approved household combination unit is not accompanied by a stand-alone freezer, providers will be immediately suspended from ordering all VFC vaccines,
    - Providers will remain suspended until a stand-alone freezer is acquired. After one year of suspension, the provider will be disenrolled from the VFC program.
  
- E. Certified Thermometer Calibration
  - CDC recommends the use of digital thermometers with a biosafe glycol-encased probe rather than measurement of ambient air temperatures.
  - CDC recommends the use of continuous digital data loggers with detachable probes for temperature monitoring.
  - Providers must use calibrated thermometers with 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.
    - Refer to the VFC Provider Handbook for a listing of thermometer manufacturers with certificates of traceability and calibration of products from National Institute of Standards and Technology (NIST).

- **Effective 2018**, CDC will require all VFC Providers to purchase a digital data logger with an active temperature display, continuous monitoring and recording capabilities, and a detachable biosafe glycol-encased probe in all VFC storage units. Please refer to PA digital data logger policy in the VFC provider handbook, section 6J.
- F. Provide training on proper vaccine storage and handling guidelines and vaccine administration protocols to each new employee at the time of employment orientation and review this information annually with all staff. Maintain documentation of this training for three years.
- G. Participate in annual training /education provided by the Department of Health on proper storage and handling requirements and VFC program requirements. Maintain documentation of attendees.
- H. Develop and maintain 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, 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, frozen water bottles etc.); and
  - Identification of transportation to move vaccine to a secure storage facility during an emergency.

## **II. Suspected Vaccine Cold Chain Failure - Providers Shall:**

- A. Refer to the Vaccine Disaster Recovery Plan and the *VFC Provider Handbook* for vaccine management guidance.
- B. Contact the appropriate vaccine manufacturers within one (1) workday of a suspected vaccine cold chain failure, to determine viability of the vaccine. Be prepared to provide:
- Vaccine name;
  - Lot number;
  - Expiration date;
  - Number of doses at risk;
  - Documented refrigerator and freezer temperatures; and
  - Duration of exposure to out of range temperatures.

- C. Complete and submit the *Vaccine Incident Report & Worksheet* form and fax to the VFC Program at (717) 214-7223 within five (5) days of a suspected cold chain failure.

### **III. Confirmed Vaccine Cold Chain Failure - Providers Shall:**

- A. Notify Division of Immunizations (DOI) by completing the Vaccine Incident Report & Worksheet Form within five (5) days of confirmation of the vaccine cold chain failure. The Quality Assurance staff will assist you if needed at 1-888-646-6864.
- B. Review refrigerator/freezer temperature logs to verify whether other “out of range” temperatures occurred that could indicate other periods of cold chain failure and submit copies with the Incident Report to DOI.
- C. Complete a Vaccine Return Form found in the *VFC Provider Handbook*, section 6. A form is attached and may be copied for use by provider sites.
- D. Unopened vials of all expired/wasted vaccines, including influenza vaccine, must be returned within six months to McKesson Specialty Distribution in a prepaid McKesson shipping container. Complete the Vaccine Return Form found in section 6 of the VFC Provider Handbook and fax to (717) 214-7223 at the Division of Immunizations and a vaccine return label from McKesson Specialty Distribution will be emailed/mailed to the provider site. When label arrives enclose a copy of the Vaccine Return Form with the expired/wasted vaccines in a box and set out for UPS to pick up.
- E. Any new refrigerator/freezer equipment purchased must be approved by the VFC program through a site visit by the immunization nurse, prior to storing vaccine.
- F. Within fourteen (14) workdays of confirmation of vaccine cold chain failure, review office databases, registries, patient charts to identify those persons receiving vaccines during the identified cold chain failure period(s) and determine who needs to be revaccinated.
- G. Within twenty-one (21) workdays of confirmed cold chain failure, prepare and submit a Corrective Action Plan to the Division of Immunization Quality Assurance staff outlining the steps to identify, recall and revaccinate patients who had received potentially compromised vaccine.

- H. Within six (6) weeks of confirmation of cold chain failure, contact identified patients and/or guardian of children by telephone or written correspondence with the following information:
- Purpose of recall;
  - Need for revaccination
  - Information about available clinics and times for revaccination.
  - Set appointments to revaccinate persons who were vaccinated during the cold chain failure timeframe.
- I. Document appropriate vaccination information on the patient's medical record and/or immunization record.
- J. Instruct parent/guardian of a revaccinated child to provide revaccination information to the child's school and/or childcare facility.
- K. Keep an ongoing log of the number of persons revaccinated and the number of doses of each vaccine administered.
- L. Submit interim status report and/or final report as directed by Division of Immunizations to: Pennsylvania Department of Health  
Division of Immunizations  
Room 1026 Health and Welfare Bldg.  
625 Forster Street, Harrisburg, PA 17120.  
Fax: 717-214-7223

A template report form is attached to this Bulletin and may be copied.

Attachments:

Transporting Refrigerated Vaccine  
Transporting Frozen Vaccines by Necessity  
Vaccine Hourly Monitoring Form (Provider Use)  
Vaccine Return Form (Provider Use)  
Interim/Final Status Report