

MODULE

5

VACCINE STORAGE AND HANDLING

Immunization Section—Vaccines for Children Program

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MODULE 5-A: Vaccine Storage and Handling Vaccine Management Requirements

An important responsibility of the providers is to work with the VFC Program to develop and implement accurate but simple plans for routine and emergency vaccine management. Refer to Appendix 5 for a sample of a vaccine management plan and an emergency storage and handling plan.

All providers must meet the following requirements in order to participate in the VFC Program:

Vaccine Coordinators

Designate one staff member to be the primary vaccine coordinator, and at least one back-up vaccine coordinator who is able to perform the vaccine storage and handling responsibilities in the event that the primary coordinator is unavailable. These positions will be responsible for some key requirements and will provide oversight for all vaccine management within the office. The primary vaccine coordinator and/or back-up coordinator are the VFC contacts for the office, as documented on the VFC Program Agreement.

The primary and back-up vaccine coordinators are responsible for the following vaccine management activities:

- Conduct a monthly vaccine inventory and document vaccine usage daily.
- Ensure that refrigerator temperatures are between 35° to 46°F (2° and 8°C).
- Keep the freezer temperature at 5°F or lower (-15°C or colder).
- Adjust the temperature of the vaccine storage unit as needed.
- Ensure temperature monitoring is occurring in each VFC vaccine storage unit; see temperature monitoring section on page 4 of this module.

Vaccine Management Plans

Providers should use the vaccine management template at:

www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vaccine-management-plan.pdf. All Florida VFC Program providers must have current written vaccine management plan available for review.

The vaccine management plan includes the following aspects:

- Contact information of the person(s) responsible for managing the VFC vaccine.
- VFC Program roles and VFC Program activities tied those roles.
- Vaccine Storage and Handling Guidelines.

- Staff Training on Vaccine Management and VFC Program Requirements.
- Signature Log.

At a minimum, providers must review and update the vaccine management plan annually, or when there is a change in staff that has specific responsibilities in the plan. The Immunization Section Field Operational team and/or VFC Program staff may request a copy of the plan for review and evaluation at any time.

Vaccine Emergency Storage and Handling Plans

Providers should have a vaccine emergency response plan that includes the following:

- Role of vaccine coordinator and alternate (back-up).
- Emergency contact list.
- Storage unit specifications.
- Alternate storage facilities.
- Written instructions for after hours.
- Adequate supplies for packing and transport.
- Protocol for packing.
- Protocol for transport.

Review the May 2014 VFC Storage and Handling Toolkit, located at <http://www.cdc.gov/vaccines/recs/storage/toolkit/>, for information you might include in each of the above sections of a complete emergency plan. For a sample plan see **Appendix 5A** or http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/emergency-response-plan.pdf

Vaccine Storage Equipment

Please refer to Module 5B for detailed vaccine storage equipment information.

Temperature Monitoring

Temperature monitoring is the responsibility of the primary and back-up vaccine coordinators. If other staff must monitor temperatures, the primary or back-up coordinator should train these individuals on how to respond to and document actions taken when temperatures are outside the appropriate range.

Manage a Temperature Log using one of the following options:

- Upload a data file into Florida SHOTS from a continuous temperature monitoring data logger once during a seven calendar day period.* You do not need to maintain a paper temperature log if the data file includes

inspection marks which shows that someone reviews the storage unit's temperature twice each day. Maintain a paper log if the data file does not have these marks.

- Manually input twice daily temperatures within Florida SHOTS at least once during a seven calendar period.* If data is manually entered into Florida SHOTS a physical **Fahrenheit** or **Celsius Temperature Log** must be posted and completed on the storage unit door (see **Appendix 3**).

**Florida SHOTS will freeze ordering capabilities and require a provider to contact the VFC Office for assistance if a provider does not input temperatures for their VFC storage units into Florida SHOTS at least once during each seven day period.*

Please note: Beginning on March 1, 2016, providers will be required to use a continuous temperature monitoring device with a probe buffered material in all of their VFC vaccine storage units. The temperature readings are required to be uploaded into Florida SHOTS. The VFC Program is supplying providers with a Log Tag for each of their VFC vaccine storage units to meet this new requirement. If a provider would like to purchase their own continuous monitoring device they will need to contact the VFC Program for more information.

Record the following information if maintaining a paper temperature log daily:

- Staff initials of the individual recording the information.
- Room temperature when recording the unit temperature.
- Unit temperature and exact time/date of recording first thing in the morning.
- Unit Temperature and exact time/date of recording last thing at the end of the day
- Minimum and Maximum temperature of the unit for the previous 24 hours first thing in the morning.
- Record refrigerator/freezer temperatures on the **Temperature Log for Vaccines Form** twice a day (beginning and end), ensuring that refrigerator temperature ranges are between 35° to 46°F (2° to 8°C). Keep the freezer temperature 5°F or lower (-15°C or colder).
- Monitoring and recording temperatures twice a day is required, even if a continuous graphing/recording thermometer or a digital data logger is used.
- Correct improper vaccine storage conditions immediately, including inappropriate exposure to light or storage temperatures outside the recommended ranges. Document the actions taken on the **Emergency Response Plan Form** (see **Appendix 5**).
- Maintain and store three years' worth of completed **Temperature Log for Vaccines Forms** or data logger data files on your computer. The Florida Immunization Section Field Staff will review this information when they conduct VFC Compliance site visits.

- Monitor vaccine storage temperatures by using a centrally located, certified, calibrated thermometer or continuous recording thermometer both in the refrigerator and freezer. Follow the manufacturer’s recommended schedule for recalibration of the thermometers.

Vaccine Shipments

- Immediately check the vaccine cold chain monitors when vaccine arrives at the office or clinic.
- If upon the arrival of the vaccine shipment there is a vaccine viability concern (i.e., if the monitor is not activated or if there is damage to the package), contact a McKesson Specialty representative at 1-877-836-7123 or VFC Program representative at 1-800-483-2543 within the contractual two-hour window.
- Develop a policy with protocols and procedures for maintaining the vaccine cold chain during transport to off-site clinics or emergency storage locations. You can access the CDC storage and handling guidelines, *Maintaining the Cold Chain during Transport*, at: <http://www.immunize.org/catg.d/p3049.pdf>.

Action Plan/Vaccine Wastage

What to do if a power failure occurs, staff left the refrigerator door open, the temperature was too cold or too hot, the refrigerator plug was pulled, or in any other situation that would cause improper storage conditions:

- Transfer and store the vaccines at appropriate temperatures in a refrigerator/freezer that is working properly. Do not throw out the affected vaccines. Ensure the exposed vaccines are separated to prevent inadvertent administration, and label with “DO NOT USE”, until the provider receives a response from the vaccine manufacturer indicating that the vaccine is still potent.
- Do not discard any vaccine, unless directed to do so by the VFC Program Office.
- Close the door and/or plug in the refrigerator/freezer.
- Record the current temperature of the refrigerator/freezer on the ***Temperature Log for Vaccines Form***. Return refrigerator/freezer to acceptable temperature ranges and monitor temperatures on an hourly basis.
- Contact the VFC Program Office to report the potential vaccine loss and obtain the VFC Incident Checklist (See **Appendix 5A** or http://www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vfc-incident-checklist.pdf) which provides the steps providers take to

address the situation.

- Contact the manufacturer(s) (phone numbers located on the VFC Incident Checklist) to obtain letters specific to each vaccine's viability.
- If directed to by the VFC Program Office, return the vaccines (except syringes that you filled but did not use, syringes with or without needles, open vials or any multi-dose vial from which any dose has been withdrawn) to McKesson Specialty in the recyclable insulated vaccine containers in which the vaccines were originally shipped.
- To ensure accountability for expired or unserviceable vaccines, adjust out the spoiled doses from your VFC inventory and document these vaccines within Florida SHOTS under **Report Returns/Waste**.
- Include a copy of the Florida SHOTS **Vaccine Return and Waste Form** with all expired or unserviceable vaccines in the shipping container.
- Request a shipping label when completing the Return and Waste Form within Florida SHOTS. This information will be submitted to McKesson who will then send the provider a return label.

Vaccine Security and Equipment Maintenance

Safeguard the electrical supply to the VFC storage units and post warning notices at both the electrical outlet and the circuit breaker to prevent accidental disconnection of power.

- Plug the storage units into an outlet in a restricted access area.
- DO NOT plug a VFC storage unit into a surge protector. If the power goes out, anything plugged into a surge protector will not turn on when power is restored.
- Label the refrigerator, electrical outlets, fuses, and circuit breakers on the power circuit with information that clearly identifies the perishable nature of vaccines and the immediate steps the provider will take in case of interruption of power. Contact the VFC Program at 1-800-483-2543 to request "**DO NOT UNPLUG**" stickers or print them here:
<http://www.immunize.org/catg.d/p2090.pdf> and
<http://www.immunize.org/catg.d/p2091.pdf>.
- Limit access to the vaccine supply to authorized personnel only.
- Install locks on refrigerators and, if possible, the electrical plug.
- Safeguard public vaccines by providing facility security, such as temperature alarms and restricted access to vaccine storage and handling areas.
- Provide a source of back-up power (generators) and a security system to

alert appropriate personnel in the event of a power outage. If the provider's building has auxiliary power, use the outlet supplied by that system.

- Test back-up generators quarterly and maintain back-up generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).