pennsylvania
DEPARTMENT OF HEALTH

Division of Immunizations
Vaccine Storage and Handling

All enrolled providers must have the necessary equipment to maintain proper conditions and enough room to store the largest inventory they may have at the busiest point in the year.

For vaccine to be shipped, Vaccines for Children (VFC) Program providers must have appropriate storage units that meet the requirements below. This ensures the provider's ability to maintain stable in-range temperatures and vaccine viability.

VFC Storage and Handling Equipment Requirements

To ensure the viability of VFC vaccines, providers must have:

- Storage units that maintain correct temperatures at all times
    - Refrigerator temperature between 2°C and 8°C (36°F and 46°F)
    - Freezer temperature between -50°C and -15°C (-58°F and +5°F)
- Digital data loggers (DDLs) with continuous monitoring capabilities and a current, valid Certificate of Calibration Testing for each unit, as well as at least one back-up unit.

The use of dormitory or bar-style refrigerator/freezers is **prohibited** for VFC Program providers. (These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment.)

CDC recommends the following units, in order of preference, for the storage of VFC vaccines:

- Purpose-built or pharmaceutical/medical-grade units, including doorless and dispensing units.
- Stand-alone refrigerator and freezer units—these units can vary in size from a compact under-the-counter style to a large stand-alone, pharmaceutical-grade storage unit.
- Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines. A separate stand-alone freezer should be used to store frozen vaccines.

VFC Program providers are required to ensure:

- Food and beverages will not be stored in a unit with vaccines.
- Vaccine will not be stored in the deli, fruit, or vegetable bins (remove bins if possible), in the doors or on the floor of the unit, or under or near cooling vents.
- Place water bottles throughout units—against walls, in the back, on the floor, and in the doors—to help stabilize temperatures unless the manufacturer provides specific guidance for vaccine storage and handling.
- Place vaccines and diluents in the center of the unit, two to three inches away from walls, ceiling, floor, and door.
- Store vaccines in their original packaging with lids closed until ready for administration.
- Before ordering vaccine, providers must rotate vaccine inventory and update inventory in Pennsylvania's IIS.
- Vaccine storage units are plugged into separate outlets and on separate circuits if possible.
- Providers must protect the power source for all storage equipment, usually by means of "Do Not Disconnect" warning labels at the electrical outlet and circuit breaker.

- Implement an emergency back-up plan to safeguard vaccine in the event of a power outage and/or equipment failure.

Digital Data Loggers (DDLs)*

VFC Program providers must use a DDL with continuous temperature monitoring capability and a current, valid Certificate of Calibration Testing (also known as a Report of Calibration) in each unit storing public vaccines. DDLs must be used during routine, on-site vaccine storage, vaccine transport, and mass vaccination clinics.

To meet VFC Program requirements, the DDL must be equipped with:

- A temperature probe or sensor (a buffered probe is recommended);
- An active temperature display outside the unit that can be easily read without opening the storage unit's door;
- Continuous temperature monitoring and recording capabilities.

Providers must download and review the data logger temperature file a minimum of once per month.**

**Providers with purpose-built or pharmaceutical-grade equipment (e.g., doorless or dispensing units) with temperature monitoring capabilities may be as reliable as a DDL in monitoring vaccine temperature. Not all these units are capable of digitally logging temperatures. When in doubt, consult Division of Immunizations on whether the unit is capable of meeting VFC Program temperature monitoring requirements.*

***Division of Immunizations recommends the download and review of the data logger temperature file once per week and anytime there is suspicion of a power outage or equipment failure.*

Additional recommended DDL features include:

- Alarm for out-of-range temperatures
- Temperature display showing current, minimum, and maximum temperatures
- Low battery indicator
- Accuracy of +/-1°F (0.5°C)
- User-programmable logging interval (or reading rate) recommended at a maximum time interval of no less frequently than every 30 minutes

Certificates of Calibration Testing must include:

- Model/device Number
- Serial Number
- Date of Calibration (report or issue date)
- Confirmation the instrument passed testing (or instrument in tolerance)

A back-up DDL must be readily available in case a DDL fails, or calibration testing is required. The back-up DDL should have a different calibration testing date than other DDLs to avoid requiring all DDLs to be sent out for recalibration at the same time. If the back-up DDL has the same calibration testing date as other DDLs, providers must have the unit retested prior to expiration ensuring that a valid DDL is

available for required temperature monitoring. Back-up DDLs must maintained on-site. Extra batteries needed for the DDLs should also be available on-site.

Providers should have on site readily available vaccine transport devices with currently calibrated DDLs to relocate vaccine in response to a power outage, equipment failure, or DOH approved vaccine redistribution. It is recommended a flashlight, along with transport documents for vaccine inventory and temperature monitoring, be kept with the vaccine transport devices.