

Pennsylvania Immunization Program Vaccine Storage and Handling Requirements

Providers must have the necessary equipment that will maintain proper conditions and have enough room to store the largest vaccine inventory a provider might have at the busiest point in the year without crowding vaccine. For vaccine to be shipped, VFC providers must have appropriate storage units that meet the requirements below to maintain stable in range temperatures to maintain vaccine viability.

Storage and Handling Equipment Requirements

To ensure the viability of vaccines, providers must have:

- Storage units that maintain correct temperatures at all times as follows:
 - 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.

The use of dormitory or bar-style refrigerator/freezers is prohibited at all times, including emergencies. These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment.

The use of the freezer compartment of combination household refrigerator/freezer units is prohibited.

CDC recommends the following units, in order of preference, for the storage of 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 then be used to store frozen vaccines.

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.
- Water bottles are placed 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.
- Vaccines and diluents are placed in the center of the unit, two to three inches away from walls, ceiling, floor, and door.
- Vaccines are stored in their original packaging with lids closed until ready for administration.
 - In circumstances that require redistribution of vaccine, providers must store vaccines removed from original packaging in pharmaceutical vaccine storage bags.
- Before ordering vaccine, providers must rotate vaccine inventory by bringing the oldest vaccine to the front of the storage unit to be used first and placing newer vaccine behind existing stock. Providers must also update inventory in PIERS (Pennsylvania Immunization Electronic Registry System).

- Vaccine storage units are plugged into separate outlets and on separate circuits if possible.
- The power source for all storage equipment is protected, usually by means of “Do Not Disconnect” warning labels at the electrical outlet and circuit breaker.
- An emergency back-up plan is in place to safeguard vaccine in the event of a power outage and/or equipment failure.

Digital Data Loggers (DDLs)*

Providers must use a DDL with continuous temperature monitoring capability and a current 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 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 are required to 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 of these units may be capable of digitally logging temperatures. When in doubt, consult Pennsylvania Immunization Program staff on whether the unit is capable of meeting VFC temperature monitoring requirements.*

***It is strongly recommended that the data logger temperature file be downloaded and reviewed 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 retesting 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 retesting date, awardees/providers must have the unit retested prior to expiration ensuring that a valid DDL is

available for required temperature monitoring. Back-up DDLs are usually maintained on site. Extra batteries needed for the functionality of the DDLs should 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.