

**New York State Department of Health (NYSDOH) Bureau of Immunization
Pharmacy Vaccine Storage and Handling Plan:
Influenza ONLY**

Primary Provider/Practice Name: _____ PIN # (if renewal) _____

Vaccine must be properly stored and administered to ensure maximum efficacy and safety. All Vaccines for Children (VFC) sites must attest to their compliance with routine and emergency storage and handling procedures. Each section of this agreement includes required elements for an effective storage and handling plan. For guidance, refer to:

https://www.health.ny.gov/prevention/immunization/vaccines_for_children.htm Storage & Handling Requirements.

Review this storage and handling plan with all staff annually and with new staff, including temporary staff, as part of their orientation.

EQUIPMENT and TEMPERATURE MONITORING

Provide the following information for each VFC vaccine refrigerator and temperature monitoring equipment in use:

Refrigerator Unit:

Unit Location/ ID#:	Refrigerator Type: <input type="checkbox"/> Stand alone refrigerator <input type="checkbox"/> Other, specify: _____
Use: <input type="checkbox"/> Primary <input type="checkbox"/> Backup/Overflow	Grade: <input type="checkbox"/> Commercial <input type="checkbox"/> Med/Lab/Pharmaceutical <input type="checkbox"/> Household/Consumer <input type="checkbox"/> Other, specify: _____

Thermometer: Digital data logger
Brand: _____ Calibration Expiration Date: ____/____/____

Notes: Pharmacy providers are required to have stand alone refrigerator units and digital data loggers for every unit storing VFC vaccine. Dormitory style refrigerator/freezer and household combination refrigerator/freezer units are not acceptable.

Additional VFC Refrigerator Unit:

Unit Location/ID #:	Refrigerator Type: <input type="checkbox"/> Stand alone refrigerator <input type="checkbox"/> Other, specify: _____
Use <input type="checkbox"/> Primary <input type="checkbox"/> Backup/Overflow	Grade: <input type="checkbox"/> Commercial <input type="checkbox"/> Med/Lab/Pharmaceutical <input type="checkbox"/> Household/Consumer <input type="checkbox"/> Other, specify: _____

Thermometer: Digital data logger
Brand: _____ Calibration Expiration Date: ____/____/____

Backup Thermometer:

Digital data logger:
Brand: _____ Calibration Expiration Date: ____/____/____

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Carefully review all the following required elements. Each element is a VFC requirement.

1. Refrigerator temperatures are maintained at 36°F- 46°F (2°C-8°C), with an optimal temperature of 40°F (5°C).
2. Vaccine storage units are not connected to an outlet with a ground-flow circuit interrupter (GFCI) or an outlet activated by a wall switch. "Do Not Unplug" signs are next to the electrical outlets for the refrigerator and freezer and "Do Not Stop Power" warning labels are placed by the circuit breaker for the electrical outlets. All staff and any maintenance and custodial staff are instructed to never turn off the power to the vaccine storage units.
3. Each VFC refrigerator contains a calibrated temperature monitoring device that has a Certificate of Traceability and Calibration in accordance with National Institute of Standards and Technology (NIST) standards.
4. At least one back-up temperature monitoring device with a current certificate of calibration is on hand in case a temperature monitoring device in use is no longer working properly or calibration testing of the current equipment is required.
5. Temperature monitoring devices are re-calibrated at least every two years and a valid certificate is available for NYSDOH review at the time of a site visit. Temperature monitoring devices with Certificates of Calibration that do not specify a recalibration date will be recalibrated annually.

All temperature monitoring devices are digital data loggers with an alarm or alarm system that indicates when the temperature may be out of a preset range. All temperature monitoring devices can display minimum/maximum * temperatures.

Temperature monitoring device probes are located in the center of the storage compartment.

Temperature monitoring devices are inspected monthly for signs of breakage or wear.

6. Temperatures are recorded for each VFC refrigerator at the beginning and end of each clinic day. The minimum and maximum temperatures for each vaccine storage unit are also recorded daily to ensure round-the-clock temperature monitoring. **Twice daily temperatures and minimum and maximum temperatures are entered in the New York State Immunization Information System (NYSIIS) within 7 days of the date the temperature was read.**

*Minimum and maximum temperatures are defined as the coldest (minimum) and the warmest (maximum) temperatures recorded in the storage unit for the specified period.

REFRIGERATOR SET-UP

1. Vaccines are stored in the appropriate storage unit throughout the clinic day.
2. Vaccines are stored in the center of the storage unit stacked with air space between the vaccine containers and the sides and the back of the unit to allow cold air to circulate around the vaccine.
3. Vaccines are not stored on the top shelf of the refrigerator directly under a fan because it could cause the vaccine to freeze.
4. Expiration dates are monitored and stock is rotated to ensure short-dated inventory is used first.
5. All publicly-funded vaccine is labeled and can be distinguished from private stock.
6. Filled water bottles are placed in doors and the bottom of the refrigerator and the freezer to maintain the temperature in the event of a power outage.
7. No food, drink, lab specimens, or radioactive materials are kept in a refrigerator where vaccines are stored.
8. Vaccines are stored in their original packaging in clearly labeled and uncovered containers with slotted sides that allow air to circulate.
9. Vaccines are not stored on the door or in the vegetable bins as these are areas where the temperature can deviate from the rest of the storage unit (these are good places for water bottles to help stabilize temperatures).

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VACCINE DELIVERIES

1. The office/facility is open at least one day other than Monday to receive vaccine shipments. On this day, the office/facility is open for at least 4 consecutive hours.
2. All shipping containers are examined for any evidence of damage during transport.
3. Cold-chain monitor cards are examined for any evidence of exposure to out-of-range temperatures.
4. Shipments are not accepted if reasonable suspicion exists that the delivered product may have been mishandled.
5. The manufacturer is contacted when circumstances raise questions about the efficacy of a delivered vaccine.
6. Expiration dates are checked to be sure vaccine has not expired.
7. Vaccine is immediately placed in an appropriate storage unit.

VACCINE INVENTORY MANAGEMENT

1. A physical inventory of all public vaccine supply is done within 14 days of placing an order and the inventory is confirmed in NYSIIS.
2. Vaccine is ordered using the NYSIIS vaccine ordering module. The quantity ordered is enough for at least one month as the VFC Program cannot accept greater than one order per PIN# within 30 days. Providers are encouraged to order 2-3 months' quantity if storage units can accommodate the quantity.
3. All immunizations, including VFC eligibility, are documented using the New York State Immunization Information System (NYSIIS) (required under Section 2168 of the Public Health Law).
4. Reasonable efforts are made to prevent over ordering of vaccine and to prevent expiration of unused doses, including transfer of vaccine to an alternate facility.
5. The VFC Program is notified between 60 to no later than 90 days prior to the expiration date of the vaccine (via [survey monkey link](#)) if the product will not be used.
6. Any vaccine that needs to be returned or reported wasted is reported in the NYSIIS Returns/Wastage module.

VACCINE ADMINISTRATION

1. Reconstituted vaccines are discarded if not used within the interval allowed on the package insert.
2. Only one multi-dose vial of a specific vaccine is opened at a time.
3. Vaccines are drawn immediately before administration. Large quantities of vaccines are not predrawn as this can lead to waste and/or administration errors.
4. Single-dose vials with cap or dust cover removed are discarded. Any active manufacturer-filled syringes (i.e. syringe cap removed or needle attached) that are not used by the end of the workday are discarded.
5. The appropriate vaccine manufacturer will be contacted and the VFC Program notified if there is any question about the storage or handling of any vaccine.

VACCINE EMERGENCY PLAN

VFC providers may, with approval from the VFC Program, use an internally developed emergency plan or must otherwise adhere to the NYS Vaccine Program guidance for any emergency situation which may necessitate vaccine transport. All practices must either have an emergency plan or adhere to the NYS Vaccine Program guidance. Practices adopting their own vaccine emergency plans must submit plans with this application and include the key elements of the vaccine emergency plan below (#1 - 4), and include signatures of key vaccine personnel at the end of this document.

Failure to adhere to this guidance will result in the practice providing restitution for lost vaccine.

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- i. Open affected units only when necessary and only after all preparations for packing and moving vaccine have been made.
- ii. Condition frozen water bottles by placing in a sink filled with several inches of cool or lukewarm water until a layer of water forms near the surface of the bottles. The ice block spins freely when rotated.
- iii. Line bottom of the cooler with a single layer of dried, conditioned water bottles.
- iv. Place one sheet of corrugated cardboard over the water bottles to cover completely.
- v. Place a one inch layer of bubble wrap, packing foam, or Styrofoam™ on top to cover the cardboard completely.
- vi. Place boxes of vaccine and diluents on top of insulating materials.
- vii. Place DDL buffered probe in center of the vaccines. Keep DDL display outside cooler until finished packing.
- viii. Cover vaccine with another inch of insulating material.
- ix. Place another layer of corrugated cardboard on top of the insulating material.
- x. Place another layer of dried, conditioned water bottles on top.
- xi. Close and secure the lid and attach the DDL display.
- xii. Document transfer information on Refrigerated Vaccine Transport Tracking Sheet and affix to transport container. Temperatures are to be maintained between 36°F and 46°F (2°C and 8°C).

4) Procedures for Transporting Vaccine:

A) Staff responding to vaccine emergency must stay with the vaccine during transport and promptly place in appropriate storage unit(s) upon arrival.

B) If transporting vaccine in a vehicle, use the passenger compartment, never the trunk.

C) Before opening cooler:

- i. Record time, temperature of vaccine, and temperature of receiving storage unit on the Refrigerated Vaccine Transport Tracking Sheet.
- ii. Immediately transfer vaccine to alternate storage units.
- iii. Contact the VFC program (800-543-7468) if vaccine temperatures were out of normal range at any time during the vaccine emergency. Any potentially affected vaccine should be quarantined until viability is determined.

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REQUIRED SIGNATURES

We agree to implement the storage and handling plan outlined in this document. In the event of any situation which could potentially compromise the efficacy of VFC vaccine we will comply with the emergency procedures provided.

Pharmacy Director or Equivalent:

Name (Print) Title (Print) Email Address (Print)

Pharmacy Director or Equivalent Signature Date

Primary Vaccine Coordinator:

Name (Print) Title (Print) Email Address (Print)

Pharmacy Director or Equivalent Signature Date

Back-up Vaccine Coordinator:

Name (Print) Title (Print) Email Address (Print)

Pharmacy Director or Equivalent Signature Date