NEW YORK STATE | Department of Health

NYS Vaccines for Adults (VFA) Program

Vaccine Management Plan

The New York State Bureau of Vaccine Programs requires providers enrolled in the Vaccines for Adults (VFA) Program to maintain a vaccine management plan for routine and emergency vaccine storage and handling situations. Completion and implementation of this vaccine management plan will ensure that vaccines are managed according to Centers for Disease Control (CDC) and Prevention and NYS Vaccine Program requirements.

- A hard copy of this document must be maintained at a location accessible to all staff handling vaccines and near our vaccine storage units.
- All staff handling vaccines at this practice must adhere to the protocols described in this document.
- The Vaccine Coordinator, Back-up Coordinator, and Medical Director (or equivalent) will review and update this plan at least once a year, **and when staff with designated vaccine management roles change** and/or when VFA Program requirements change.
- Staff designated in this plan will sign and acknowledge their roles and responsibilities in the signature log annually and whenever the plan is revised.

OFFICE/FACILITY INFORMATION

Office/Facility Name					
Office/Facility Address					
Office/ Facility Phone #		**PIN**		**DATE**	
Provider Agreement Signatory (Medical Director or equivalent)			**Phone Number**		

VACCINE STORAGE PRACTICES ARE THE PRIMARY RESPONSIBILITY OF:

Vaccine Coordinator	**Primary Phone Number**	**Secondary Phone Number**
Back-up Vaccine Coordinator	**Primary Phone Number**	**Secondary Phone Number**

VACCINE COORDINATOR AND BACK-UP COORDINATOR RESPONSIBILITIES

- ✓ Ordering vaccines
- ✓ Rotating stock at least weekly and using earliest expiration dates first
- ✓ Overseeing proper receipt and storage for vaccine deliveries
- ✓ Remove expired vaccines from storage units

- ✓ Managing physical inventory and the New York State Immunization Information System (NYSIIS) inventory module, documenting vaccine inventory information
- ✓ Respond to and report all temperature excursions (any out-of-range temperatures)
- ✓ Organizing vaccines within storage units
- ✓ Maintain all documentation (i.e., packing slips, temperature logs and data logger reports)
- ✓ Setting up temperature monitoring devices (digital data loggers)
- ✓ Organize vaccine related trainings/ensure completion by staff
- ✓ Checking and recording daily temps, including minimum/maximum temps at the start of each workday, and current temps at the close of the workday
- ✓ Monitor operation of vaccine storage equipment
- ✓ Analyzing temperature data for shifts in trends (i.e., changes in typically documented daily minimum/maximum readings)
- ✓ Oversee proper vaccine storage and handling in emergency situations (per this plan), including tracking inclement weather

Coordinator responsibilities may be completed by the coordinator or delegated to appropriate staff. The medical director (or equivalent) will ensure the coordinator has trained the delegate(s) and documented competency for the specific tasks assigned.

REQUIRED EQUIPMENT

VACCINE STORAGE UNITS

Use vaccine storage units that can maintain required vaccine storage temperatures and are large enough to hold the maximum vaccine needs (i.e. during flu and/or RSV season).

Only the following types of units meet the NYS Vaccine Program requirements:

1. Purpose-built or pharmaceutical/medical grade units, including doorless and dispensing units.
2. Stand-alone refrigerator and stand-alone freezer units. These units can vary in size and can be a counter-top model, under-the-counter style, or a large, pharmaceutical-grade storage unit.

Refer to the NYS Vaccine Storage Unit Purchasing Guidance:
www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/storage_unit_purchasing_guidance

NOTE:

- **Combination household style refrigerator/freezer units are not permitted by NYS Vaccine Program policy for storage of any vaccines, refrigerated or frozen.**
- **Dormitory-style refrigerators are not allowed for storage of any vaccines.** These units have a single exterior door and an evaporator plate/cooling coil, usually located in an icemaker/freezer compartment.
- **Convertible refrigerator/freezer units are not allowed for vaccine storage.** A convertible unit can change chilling modes, allowing it to be switched from a refrigerator to a freezer and vice versa. These units demonstrate fluctuating temperatures during transitions and like household combination units, they are not effective for storing temperature-sensitive items such as vaccines. There is also a risk of staff inadvertently adjusting the setting, rendering any stored vaccine non-viable.

OUR VFA VACCINE STORAGE UNITS:

	Grade (pharmaceutical, household or commercial)	Make	Model	Location
Refrigerator 1				
Refrigerator 2				
Freezer 1				
Freezer 2				

TEMPERATURE MONITORING DEVICES

www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/temp_monitor_device_guidance.pdf

1. Use a calibrated, continuous temperature monitoring device or Digital Data Logger (DDL) with a current Certificate of Traceability and Calibration Testing (also known as Report of Calibration), calibrated in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards, to monitor temperatures in each refrigerator or freezer used to store publicly funded vaccine.

2. In addition, have ***at least*** one back-up continuous temperature monitoring device with a current certificate of calibration in case of an emergency, when calibration testing of the current equipment is due, and if one of the primary device(s) malfunction.
    - The back-up temperature monitoring device should be stored outside of the storage unit until needed, and the calibration expiration date for the back-up device should be different than the one in use.
    - Purchase at least one back up data logger per site:
        - Regardless of storage conditions, there must always be continuous temperature monitoring, including during situations when the Emergency Plan is initiated.
        - Have a sufficient supply of both backup refrigerator and backup freezer data loggers (or programmable DDLs that can be set to read either refrigerator or freezer temperatures) for use during the emergency situations.
        - The primary storage units and backup storage (emergency location) units must have DDLs in them to monitor the temps:
            - of the primary storage unit(s) when the vaccine was removed and returned (must be able to document that the temperature was stable when vaccines were returned post emergency)
            - of the emergency backup storage unit(s) to determine that the unit is in the correct temperature range when vaccines are transported there, and to record temps daily while vaccine is stored at the backup location.
        - In addition, have DDLs to separately transport refrigerated and frozen vaccines, which are transported at different temperatures with different transport materials/conditions. Refer to the NYS VFC Program Guidance for Vaccine Transport: www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/guidance_vaccine_transport.pdf
        - Backup DDLs must be readily available during an emergency.

Required Data Logger Functionality

- Continuous temperature monitoring capability means temperature readings are recorded at preset intervals (at least every 30 minutes) and must have the capability to produce a data output (to be given to the NYS VFA program and/or vaccine manufacturer in the event of a temperature excursion)
- Accuracy or documented uncertainty of ±1° Fahrenheit (±0.5° Celsius)
- Digital display on outside of storage unit to allow reading temperatures without opening storage unit door.
- Display must indicate current as well as minimum and maximum temperatures
- Detachable probe in a bottle filled with a thermal buffer, like glycol, which more closely reflects vaccine temperature.
    - The thermal buffer should be placed centrally inside the storage unit away from ceilings, walls, vents, fans, and coils.
    - Please note: for accurate ultra-cold temperature monitoring, it is essential to use an air probe or a probe designed specifically for ultra-cold temperatures.

Recommended Device Features

Our data loggers have the following recommended features (check as applicable):

☐ Audible high/low alarm for out-of-range temperatures

☐ Low battery indicator

☐ Records continuously with memory storage of at least one month of data (no less than 4,000 readings)

☐ Data recording loops when memory is full (overwrites old data instead of stopping recording)

☐ Current minimum and maximum temperature display

Our Digital Data Loggers

	Make/Model	Serial #	Date Calibrated	Calibration Due Date
Primary Refrigerator DDL				
Backup Refrigerator DDL				
Primary Freezer DDL				
Backup Freezer DDL				

Our current calibration certificates are located here:

Enter instructions below for retrieving/recording the daily Minimum and Maximum (Min/Max) temperatures for the previous 24 hours. If the DDL needs to be reset after each Min/Max reading, include these instructions.

Enter instructions below for downloading the DDL data. Include where the data is saved/stored (preferably electronically in a folder on a computer, but paper copies are acceptable). Requirement is to download and review at least every 2 weeks, preferably weekly, and to maintain these records for a minimum of 3 years.

VACCINE STORAGE AND HANDLING

VACCINE MANAGEMENT

- Open vaccine shipments immediately upon delivery.
  - If the cold chain was not maintained during shipment, email nyvfc@health.ny.gov, or call 1-800-543-7468 immediately. Place in storage unit with a label “DO NOT USE” until response received.
- Check for broken vials or syringes or any other damage.
- Cross check content with packing slip to be sure they match.
- Place in correct storage unit immediately.
- “Accept Transfer” in the NYSIIS “Manage Orders” module*.
- Maintain proper vaccine storage temperatures
  - Refrigerator: 36°F to 46°F (2°C to 8°C)
  - Freezer: 5°F or below (-15°C or below)

        - Always refer to the vaccine product insert for specific storage and handling information, as some vaccines have a more limited storage range. For example, **when storing Mpox vaccine frozen, it must be stored between -15° and -25° Celsius.**
    - Ultra-cold freezer (**some** Pfizer COVID-19 vaccines): -90°C and -60°C (-130°F and -76°F)
- The digital data logger is placed in the center of each vaccine storage unit away from the coils, walls, floor and cold air vent.
- Store vaccines in the middle of the refrigerator or freezer compartment away from the coils, walls, floor and cold air vent.
- **Do not** store vaccines against the walls (or sides), in the doors, in the vegetable bin or in the bottom of the refrigerator or freezer unit.
- Ensure stored vaccines have space around their containers for cold air circulation.
- Place frozen water bottles in the door of the *freezer*. **
- Place water bottles labeled “DO NOT DRINK” in the *refrigerator* door to stabilize temperatures. **
- Physically separate VFA vaccines from private stock vaccines in separate, uncovered mesh/ventilated, containers in the refrigerator and freezer unit(s).
- AC” vaccines and “private stock” vaccines so that inventories are not mixed.
- Store diluents according to package insert instructions. If instructions are to store refrigerated, store next to the corresponding vaccine(s). **Do NOT interchange diluents**.
- Check the refrigerator/freezer doors to ensure they are closed at the end of each day.
- Place “**Do Not Unplug**” signs near the vaccine storage units’ electrical outlets and **“Do Not Break Circuit”** stickers on circuit breakers.
- Store and rotate vaccines according to expiration dates. Use vaccines with the shortest expiration dates first.
- Conduct an inventory of public vaccines at least once each month when not placing orders (this will prevent running out of vaccine and the need to borrow vaccine).
- **Do not** store food in the vaccine storage units

**Refer to the Vaccine Ordering and Inventory Management Section below.*
***If pharmaceutical/purpose-built unit, refer to user manual regarding use of water bottles, as they are not recommended for some units.*

TEMPERATURE MONITORING

- Option 1: Handwrite the temperature on a paper log. The log should be posted on each vaccine storage unit door or nearby in a readily accessible and visible location.
- Option 2: Use a continuous temperature monitoring and recording system that allows providers to electronically document temperature readings.

A printable temperature log can be found on the Immunization Action Coalition’s website: https://www.immunize.org. Search the website for the correct printable temperature log based on your needs:

- Temperature Log for Freezer - Celsius
- Temperature Log for Freezer - Fahrenheit
- Temperature Log for Refrigerator -- Celsius
- Temperature Log for Refrigerator -- Fahrenheit

- Download the DDL data at minimum every 2 weeks, preferably weekly, and any time there is an out-of-range temperature.
    - **Downloading DDL temperatures must not be used to replace daily manual review and recording of min/max temperatures**.
    - Review the DDL download report as a quality assurance measure and check for any possible missed excursions and temperature fluctuation trends.

- Save all DDL downloads to a folder on the computer, preferably, but paper copies are acceptable, for a minimum of 3 years.
- Save all temperature logs for a minimum of 3 years.

IDENTIFYING AND REPORTING TEMPERATURE EXCURSIONS

- **Any out-of-range temperature, regardless of duration or reason, is considered a temperature excursion!**
- ALL excursions involving publicly funded vaccines (anything ordered through NYSIIS) will be reported to the NYS VFA Program ***the day it is noted*** by filling out Part 1 of the Temperature Excursion Report (www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/excursion_reporting_form.pdf). Email the Temperature Excursion Report and the downloaded DDL report showing the excursion to vaccinetempexcursion@health.ny.gov.
- All publicly funded vaccine within a unit with an excursion will be labeled "DO NOT USE" and administration will be ceased until the NYS Vaccine Program determines if the vaccines are viable.

VACCINE TRANSPORT/EMERGENCY PLAN

- The emergency relocation site named below will grant us 24-hour access, if necessary.
- The emergency relocation site named below has dedicated or shared vaccine storage units that can maintain temperatures in the appropriate range.
- Certified, calibrated digital data loggers will be used to monitor vaccine temperatures while at the emergency relocation site named below.
- The emergency relocation site named below will be inspected at least once prior to an emergency to validate that proper storage conditions can be maintained.

Please note that a residence is not a sufficient first option for an emergency relocation site but may be a viable LAST resort ONLY.

Emergency Relocation Site Name	Emergency Relocation Site Address
Relocation Contact Name	**Relocation Contact Phone**

If the Vaccine Coordinator and Back-up Vaccine Coordinator are not available, the person(s) listed below will relocate the vaccine:

Staff Name	Primary Phone Number	Secondary Phone Number

- Vaccine transport will be limited to emergency transport (power failure, natural disasters, equipment or generator malfunction) or in the event of office relocation. Refer to the NYS VFC Program Guidance for Vaccine Transport:
  - www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/guidance_vaccine_transport.pdf
  - ***Exception for Local Health Departments ONLY when holding off-site clinics***

- Use a certified, calibrated DDL for ***each*** transport container.
- Ensure the cold chain is maintained by:
  - Not opening the containers
  - Placing containers out of direct sunlight
  - Bringing the vehicle to an acceptable temperature in advance (e.g., air conditioning or heat)
  - Not placing vaccine transport containers in the vehicle's trunk
  - Not placing vaccine transport containers in direct sunlight
  - Planning route to minimize travel time

- Following is/are our vaccine transport system(s) (check all that apply):

☐ CDC's Water Bottle Transport System

- *The conditioned water bottle system uses materials that can easily be found in a provider's office and tests have shown the system can maintain temperatures for up to eight hours if the package is not opened repeatedly. Refer to the NYS VFC Program Guidance for Vaccine Transport:* www.health.ny.gov/prevention/immunization/vaccines_for_children/docs/guidance_vaccine_transport.pdf

Required Materials:

- ✓ **Hard**-sided cooler or Styrofoam vaccine shipping containers, large enough for your typical supply of vaccines.
- ✓ Separate cooler for frozen vaccine transport.
- ✓ Conditioned frozen water bottles (refer to instructions linked above) for refrigerated vaccine transport.
- ✓ Frozen water bottles for frozen vaccine transport
- ✓ Insulating/cushioning materials
  - Bubble wrap, packing foam, or Styrofoam, at least one inch thick
  - Corrugated cardboard
- ✓ Backup digital data loggers

☐ Portable vaccine refrigerator and freezer units

- *Always the best option when transporting vaccine for any reason. Portable vaccine refrigerators have built-in temperature control and* ***do not require pack-out to maintain appropriate temperatures.***

☐ Qualified "Packout" System with *required* cooling and/or insulating materials

- *Are types of containers and supplies tested under laboratory conditions to maintain desired temperatures for short-term travel when a portable refrigerator is not available. These units do not have built-in temperature control but are able to maintain temperatures when paired with appropriate pack-out.*

Required Materials: The pack-out supplies and assembly should come with the qualified container when purchased.

- The selected emergency vaccine transport system must have the capacity to accommodate the largest annual supply of vaccine (i.e. flu season), and all required packing materials

- Maintain documentation of DDL temps before and during transport and upon arrival at the emergency location and document temperatures, vaccines and lot numbers on the Vaccine Transport Sheet located at the end of the NYS Bureau of Vaccine Programs Transport Guidance & Tracking Document.

CHECK ALL THAT APPLY:

☐ We have a generator and will only transport vaccines in case of equipment or generator failure.

- (If applicable) We will keep sufficient fuel on hand to continuously run the generator for at least 72 hours
- We will test the generator at least quarterly
- The generator will be serviced annually

☐ We have a backup battery power source in lieu of a generator

- We will test the battery system at least quarterly
- The battery system will be serviced annually

☐ All responsible staff have been trained on the proper packing and transport of vaccines in emergency situations.

☐ We certify that we have all necessary material, readily available on site, for the vaccine transport system as have indicated above, and will make available for review by NYS Vaccine Program staff upon request.

☐ We will test our emergency plan at least every 6 months, and every time new staff responsible for vaccine management are hired.

Refer to CDC's Vaccine Storage & Handling Toolkit Section: Emergency Transport: Vaccine Storage and Handling. ***https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf***

VACCINE ORDERING AND INVENTORY MANAGEMENT

Every dose of publicly funded vaccine must be accounted for. Following the steps below ensures accountability requirements set forth by the VFA Program and will prevent vaccine loss (expiation, spoiled or missing doses)

VACCINE ORDERING

- Conduct a physical inventory of all public vaccine supply within 14 days of placing an order and confirm the inventory in NYSIIS.
- Order at least a two-month supply of publicly funded vaccine, and up to a 3-month supply if storage space allows, via the NYSIIS "Manage Orders" module. Routine vaccines may be ordered every 30 days.
- When shipments are received, inventory must be added to NYSIIS via the "Manage Orders" or "Manage Transfers" module. By clicking "Accept Transfer" the order is automatically added to the inventory to NYSIIS "Manage Inventory" module. All orders must be accepted into inventory **BEFORE** administering any of the lot numbers in the order. Failure to do so timely may cause doses to not decrement each time a publicly funded vaccine is administered.

INVENTORY MANAGEMENT (Refer to the NYSIIS User Manual)
https://www.health.ny.gov/prevention/immunization/information_system/docs/user_manual.pdf)

- Physical vaccine inventory must be checked and reconciled in NYSIIS at least once per month, and each time an order is placed.
- Publicly funded vaccine lots ***will be carefully data-entered in the electronic medical record*** for data transfer (if applicable), so that all fields, including trade name, expiration dates, and lot numbers are an **exact** match to the orders received. Mismatches will cause doses to end up in the NYSIIS "Inventory Not Deducted" module.
- Do **not** use the "Error Correct" function in NYSIIS to make our NYSIIS inventory and physical inventory match, unless under the direction of the NYS Department of Health. Using this function *does not* account for where the publicly funded doses went.

- To account for each dose of publicly funded vaccines:

1. "Accept Transfers" upon receipt of each order and not administer these lot numbers until they are accepted into NYSIIS inventory.

2. Select the correct funding type and corresponding VFA eligibility: "317" for all uninsured and underinsured adults (19+ years), "Not VFC Eligible" for privately insured/private funding type, otherwise they will not decrement from publicly funded inventory.

3. Use the NYSIIS "Manage Returns & Wastage" module to:
    - ***Return*** unopened vaccine vials or pre-filled syringes that are expired, spoiled, or recalled by the manufacturer at least monthly. A **return** label is generated through this process. CDC requires this vaccine to be returned to McKesson (distributor) to receive excise tax credits.
    - ***Report Waste:*** Waste includes open or damaged intact vials and pre-filled syringes, including used syringes (with or without needles), syringes that were drawn up but not administered, non-vaccine products (IG, HBIG, PPD), expired and viable diluent, expired or spoiled multi-dose vials that are open (e.g., IPOL with < 10 doses remaining). No return label will be generated. These doses must be discarded as medical waste (i.e., sharps container). **NEVER return these doses!**

4. If data exchanging with NYSIIS, regularly check the NYSIIS "Inventory Not Deducted" Module to identify any inventory that is not decrementing. This allows the immunization to be deducted from inventory by assigning a trade name and vaccine lot to the listed immunizations. It also assists in identifying potential data transfer issues.

REVIEW AND UPDATE VACCINE MANAGEMENT PLAN

At minimum, the entire vaccine management plan must be reviewed and updated annually. The plan must also be reviewed and updated when there is a change in personnel who have responsibilities specified in the plan.

Date Vaccine Management Plan Revised/Reviewed	Revised/Reviewed By (Print Name)	Revised/Reviewed By (Signature)

STAFF TRAINING AND DOCUMENTATION

At minimum, the staff designated on this plan and in the Provider Agreement (Medical Director, or equivalent, Primary Coordinator and Back-up coordinator, and substitute vaccine transport staff) must complete the required trainings annually: www.health.ny.gov/prevention/immunization/vaccines_for_children/vaccine_personal.htm#training

In addition, any new staff must complete the required trainings. All trainings must be documented in this section.

CHECK ALL THAT APPLY:

- ☐ All staff designated on the provider agreement and in this plan will complete the required trainings annually, and the completed trainings will be documented below.
- ☐ Training completion certificates for all staff will be maintained and made available upon request from the NYS Vaccine Program,
- ☐ All newly hired staff involved in vaccine management will complete the required trainings and we will notify the NYS VFA Program of the new staff members' training completion by emailing: nyvfc@health.ny.gov

Fill out date, name, role, and place a check in the box for the training type completed.

Date	Staff Name	Role	Annual Renewal	New Staff/ Enrollment
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