



Provider Quality Assurance (PQA) Unit
 Bureau of Immunization
 Department of Health and Mental Hygiene
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VACCINE MANAGEMENT PLAN

For Vaccines for Children (VFC) Program Providers

Directions:

- The primary person in charge of vaccines must review and complete this document annually.
- All staff handling vaccines at this practice must adhere to the protocols described in this document and must review it annually.
- This document must be maintained at a location accessible to all staff handling vaccines and close to the vaccine storage unit.

OFFICE / CLINIC: _____

VFC PIN #: _____ DATE: _____

THE VACCINE STORAGE PRACTICES LISTED BELOW ARE THE PRIMARY RESPONSIBILITY OF THE FOLLOWING:

VACCINE COORDINATOR: _____

WORK PHONE: _____ CELL PHONE: _____

BACK-UP VACCINE COORDINATOR: _____

WORK PHONE: _____ CELL PHONE: _____

Please note that _____ and _____ will be responsible for packing vaccines, contacting receiving location, and transporting vaccines to the new location in case of an emergency requiring the transfer of vaccines

EMERGENCY PLAN

LOCATION VACCINES WILL BE TRANSFERRED TO IF NEEDED:

CONTACT AT RECEIVING LOCATION (This person must have 24/7 access to where vaccines are stored and to the receiving location):

PHONE # OF CONTACT IN RECEIVING LOCATION:

1. DESIGNATION OF VFC VACCINE STAFF AND THEIR CONTACTS:

- The primary vaccine coordinator is _____. In the event that the primary person is unavailable, the back-up vaccine coordinator will be _____.
- The responsibilities of the primary vaccine coordinator and the back-up vaccine coordinator include the following vaccine management activities:
 - Adjusting the temperature of a vaccine storage unit as necessary to keep temperatures in range
 - Documenting the temperature on the temperature logs for each storage unit daily, preferably at the beginning of the clinic day
 - Guiding staff who are responsible for administering vaccines, or who may be required to transport vaccine in an emergency situation, to follow proper procedures for vaccine storage and handling
 - Reviewing temperature logs weekly to ensure proper temperature recording
 - Serving as VFC contacts for the site
 - Serving as an emergency plan coordinator
 - Managing routine vaccine storage and handling, including:
 - Ordering vaccines
 - Counting vaccine inventory at the time of ordering
 - Monitoring and documenting vaccine storage units daily
 - Minimizing vaccine wastage
 - Receiving and promptly storing vaccines shipped from McKesson
 - Packing and transporting vaccines as necessary in an emergency

2. VACCINE STORAGE & HANDLING BASICS

A. Vaccine Storage Units

Providers must have appropriate vaccine storage units and thermometers that will maintain proper conditions to keep vaccines viable. The minimum requirements for types of storage units are:

- **Pharmacy or biologic grade storage units specifically designed for vaccine storage**
or
- **Stand-alone refrigerators and freezers**

Dormitory style refrigerators are not acceptable for the storage of vaccines. As of April 1, 2013, the use of dorm-style or bar-style refrigerators or freezers was no longer allowed for ANY vaccine storage, even for temporary storage.

_____ (*name of practice*) has _____ (*number of storage units*). The type(s) of storage units that our practice has is/are: _____

These storage units are also compliant with the following requirements:

- Large enough to hold your maximum vaccine needs
- Large enough to store water bottles in the refrigerator and freezer to stabilize temperatures.
This recommendation does not apply to pharmaceutical units if the manufacturer indicates that water bottles negatively impact the functionality of the unit

B. Thermometer Requirements:

- Working certified and calibrated continuous digital data logger (DDL) thermometers with a buffered probe in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards. The certificates for the thermometers are located:

(write location of where the certificates are kept)

- An active temperature display that can be easily read from the outside of the storage unit
- The capacity for continuous temperature monitoring and recording; data can be routinely downloaded into a summary report which must be uploaded when ordering VFC vaccines
- Ability to maintain required vaccine storage temperatures
- Equipped with a temperature probe, preferably a buffered probe
- In addition, I must keep at least one back up DDL thermometer with a current certificate of calibration on hand not stored in a unit

Additional thermometer recommendations:

- Alarm for out-of-range temperatures
- Current, minimum, and maximum temperature display
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C)
- Memory storage of at least 4,000 readings
- User programmable logging interval (or reading rate) recommended at a maximum time interval of every 30 minutes
- Are able to maintain required vaccine storage temperatures
- Are large enough to hold your maximum vaccine needs
- Are large enough to store water bottles in the refrigerator and freezer to stabilize temperatures
- This recommendation does not apply to pharmaceutical units if the manufacturer indicates that water bottles negatively impact the functionality of the unit
- In addition, at least one back up DDL thermometer with a current certificate of calibration must be kept on hand and not stored in a unit

C. Vaccine Handling Practices

- Open vaccine shipments as soon as they arrive and store the vaccines immediately
- Maintain proper vaccine storage temperatures:
 - **Refrigerator: 36°F to 46°F (2°C to 8°C)**
 - **Freezer: -58°F to 5°F (-50°C to -15°C)**
- Place DDL thermometers in the central area of the vaccine storage units
- Record temperatures daily on the temperature log, preferably at the beginning of the day, even if you have a DDL thermometer
- Retain the temperature logs in your practice for at least 3 years
- Store vaccines in the middle of the refrigerator or freezer compartment
- **Do not** store vaccines against storage unit walls (or sides), doors, or vegetable bins, or in the bottom of the refrigerator/freezer unit, or under cold air vents
- Ensure stored vaccines have space around them for cold air circulation
- Store extra ice packs along the walls and in the door of the freezer
- Place water bottles labeled “DO NOT DRINK” on the refrigerator door
- Label “VFC” vaccines to differentiate them from your private stock of vaccines
- Check refrigerator/freezer doors to ensure they are closed at the end of each day
- Place “**Do Not Unplug**” signs near the vaccine storage unit’s electrical outlets and circuit breakers
- Store, rotate, and use vaccines with shortest expiration dates first
- If vaccines are within 6 months of expiration and will not be used, contact the VFC Program
- Conduct monthly inventory of your VFC vaccines to ensure a minimum 5-week supply of vaccines. This will prevent you from running out of the vaccines.
- **Do not** store food in the vaccine storage units
- **Never** use expired or “potentially spoiled” vaccines. If storage unit temperatures are out of range, immediately place a sign on the vaccines saying “**Do Not Use,**” maintain the vaccines in the storage unit, and call the vaccine manufacturers. If the manufacturers say the vaccines are spoiled, please report them in the CIR Vaccine Inventory Management (VIM) system and return them to McKesson Specialty. If the manufacturers say the vaccines are still viable, use them to vaccinate patients. Please notify the NYC Provider Quality Assurance (PQA) Unit at 347-396-2404 and document the temperature excursion on the *Temperature Excursion Report*.

3. VACCINE SHIPPING, RECEIVING AND COLD CHAIN FAILURES

A. Staff accepting deliveries must be available on site to receive vaccine at least one day a week other than Monday, for at least four consecutive hours during the day. Staff accepting deliveries must be aware of the importance of maintaining the cold chain and of the need to notify appropriate staff of the arrival of the vaccine so that it can be handled and stored appropriately and immediately. At this practice,

_____ (*vaccine coordinator*), or _____ (*back-up vaccine coordinator*) are responsible for the following procedures:

- Examining container and contents for physical damage upon receiving a vaccine shipment
- Looking at the packing list and verify if shipping time is either less than 48 hours or received by the specified date documented by the manufacturer (if the shipping time is greater than 48 hours, this can result in a cold chain failure)
- Checking the cold chain temperature monitors to see if temperatures were out of the recommended range
- Crosschecking contents and expiration dates with the invoice
- Checking that diluents are cold or room temperature, but not frozen
- Checking for the correct type and quantity of diluents

B. If there are any discrepancies with the invoice, concerns about the viability of the vaccine, or concern about cold chain failure and exposure of the vaccine to out of range temperatures, notify your clinic's vaccine coordinator _____ (*enter name*), mark the vaccine or diluents as "Do Not Use," store them under proper conditions, and contact the vaccine manufacturer and the NYC Bureau of Immunization Vaccine Management Unit (VMU) at 347-396-2405 immediately. In addition, if you believe that the vaccine shipment was compromised or there is a problem with the temperature monitors, you must contact VMU at 347-396-2405 on the same day the vaccine arrives.

4. EMERGENCY PLAN (RELOCATION)

A. In the event of refrigerator/freezer malfunctions, power failures, natural disasters, or other emergencies that might compromise appropriate vaccine storage conditions, vaccines may need to be transported to another location. The vaccine coordinator _____ (*enter name*) or the back-up vaccine coordinator _____ (*enter name*) will be responsible for making decisions about relocating vaccines. In addition, the following staff member _____ (*enter name*) will be available 24/7 as the point person to contact the emergency relocation site so it is prepared for the vaccine. This staff member will also be responsible to pack and relocate the vaccines. The staff member(s) to be contacted to allow access to the site other than business hours is/are _____ (*enter name*). The telephone number this staff member(s) can be reached at outside business hours are:

() _____ - _____; () _____ - _____; () _____ - _____.

B. Procedures for Packing Vaccine That Requires Refrigeration:

- Use properly insulated containers (e.g. the containers that arrive from McKesson, hard sided plastic insulated containers or Styrofoam coolers with at least 2-inch thick walls)
- Diluents should travel with their corresponding vaccines at all times
- Be sure to place an insulating barrier (e.g., bubble wrap, crumpled brown packing paper, Styrofoam peanuts) between the frozen packs and the vaccines to prevent accidental freezing
- Pack vaccines in their original packaging on top of the barrier (**do not remove vaccine vials from boxes**)
- Place a thermometer next to the vaccines to monitor temperature
- Pack enough frozen packs to maintain the cold chain
- The contents of the container should have:
 - frozen packs
 - barriers (bubble wrap)
 - vaccines
 - thermometer
- Attach labels to the outside of the container to identify the contents as valuable and fragile vaccines
- Place invoice in an envelope, outside the container, listing the name of office where the vaccine was transferred from, vaccine type(s), number of doses, lot numbers and manufacturers

Please note that frozen vaccines can only be transported with a portable freezer.

C. Procedures for Transporting Vaccine

It is critical that vaccine potency is protected by maintaining the cold chain at all times during relocation and transport. Always Inform the PQA Unit at 347-396-2404 about your intentions to transport VFC vaccines, the location where the vaccines were transferred to, and the amount of vaccines transferred. If it is necessary to move the vaccines to protect their viability outside normal business hours, please proceed transporting vaccines and contact the PQA Unit as soon as possible. The vaccine coordinator _____ (*enter name*) or back-up vaccine coordinator _____ (*enter name*) will be responsible for arranging the transportation of vaccines in case of an emergency to _____ (*name of site*). The person in charge of receiving the vaccines at this site will be _____ (*enter name*).

D. Guidelines for Transporting Vaccine:

During vaccine transportation, the following guidelines must be followed:

- A thermometer or a cold chain monitor must be placed in the vaccine transport container
- If vaccines are maintained in an insulated cooler, the temperatures must be checked and recorded hourly
- Stay with the vaccines at all times during transport and promptly place the vaccines into appropriate storage units upon arrival
- When transporting vaccines in vehicles, use the passenger compartment not the trunk. **For additional guidelines on Maintaining the Cold Chain, please visit <http://www.immunize.org/catg.d/p3049.pdf>.**

5. VACCINE ORDERING BASICS

- A. Order vaccine in accordance with actual vaccine need. Avoid stockpiling or build-up of excess vaccine inventory. At the time of ordering, vaccine inventory should not exceed a 5-week supply.
- B. Depending on volume of patients reported to the Citywide Immunization Registry (CIR) and order history, practices have been placed on either a monthly, bi-monthly, or quarterly ordering frequency. This practice orders vaccines _____ (*monthly/bi-monthly/quarterly*).
- C. Develop and maintain complete, accurate, and separate records for both public and private vaccine stock. The requirement to keep separate records does not necessitate having separate storage units for public and private vaccines. Providers must be able to distinguish between their public and private vaccine stock. The practice is able to differentiate public from private vaccine stock by:

6. INVENTORY CONTROL GUIDELINES

- A. The vaccine storage practices listed below are the responsibility of the following staff member:
_____ (*this staff member can be the vaccine coordinator or it can be delegated to another staff member; however, if these practices are delegated to a staff member, the vaccine coordinator should monitor the activity weekly*).
- Conduct physical count of vaccines monthly and assess need
- Always place vaccines with shorter expiration dates in front of those with later expiration dates so that they can be used first (“first-in, first-out”). Short-dated vaccines should be checked at least every 4 weeks just in case expiration dates get out of order.
 - Vaccines are checked for expiration dates every _____ week(s)
 - Vaccines are rotated every _____ week(s)

7. VACCINE EXPIRATION AND SPOILAGE GUIDELINES

A. If you experience spoiled or expired vaccine, the vaccine coordinator _____ (*enter name*), or back up person _____ (*enter name*) will be responsible for reporting these vaccines to the NYC VMU. This staff member will:

- Enter expired/spoiled VFC vaccine information through the CIR Online Registry. Once logged in, click on the VIM icon and on the “VFC Vaccine Returns” tab
- Review/confirm expired/spoiled VFC vaccine information
- Receive “VFC Vaccine Return Receipt.” This receipt should be inserted in a shipping box
- A return label will be emailed to you from **McKesson Specialty** after reporting the spoiled or expired vaccine to NYC VMU
- Do not include ice packs or cold packs
- Give the packed and labeled box to UPS the next time a delivery is made to your site
- Please **DO NOT** call McKesson Specialty, UPS, or Federal Express to arrange a pickup or else you will be charged for the pickup.

For questions, contact the NYC VMU at: 347-396-2405.

The VFC Program receives excise tax credit for vaccine that is returned. Excessive spoilage or expiration of VFC vaccines may require the VFC provider to replace the publicly funded vaccines with privately purchased vaccines.

B. NEVER return the following:

- Vaccine drawn-up into the syringes but not administered
- Multi-dose vials from which some vaccine has already been withdrawn
- Broken vials
- Used syringes with or without needles

The items listed above should be reported in the CIR as “Wastage” and must be properly disposed of as medical waste.

8. UPDATE VACCINE-RELATED DOCUMENTS ANNUALLY (OR AS STAFF CHANGES)

A. At a minimum, the entire Vaccine Management Plan must be reviewed and updated annually or as necessary or when there is a change in staff who have responsibilities specified in this plan.

Last reviewed on _____	by _____			
Date		Name	Title	Signature
Last reviewed on _____	by _____			
Date		Name	Title	Signature
Last reviewed on _____	by _____			
Date		Name	Title	Signature
Last reviewed on _____	by _____			
Date		Name	Title	Signature