

NH Immunization Program (NHIP) Vaccine Management Plan

OVERVIEW

The New Hampshire Immunization Program (NHIP) uses a combination of federal and state funds to purchase vaccines to administer, at no cost, to all children in NH from birth through the age of 18 years of age. Patients who are on or qualify for Medicaid, Uninsured, or American Indian/Native Alaskan are provided vaccine through the Federal Vaccine for Children's Program (VFC). Patients who are insured are provided vaccine through the State of NH Immunization Program.

NHIP also secures federal funding to purchase vaccines for providers who are enrolled in our adult program to administer to their uninsured/underinsured established adult patients .

All NHIP enrolled providers are required to develop, maintain and implement plans for routine and emergency vaccine management. These plans must be reviewed and/or updated annually (more frequently if changes occur). All information in the plan must be current and have a "review date" and signature to verify that the plan is up-to date. All providers and staff will comply with the NHIP guidelines and procedures related to the management and administration of the New Hampshire Immunization Program vaccines.

The Vaccine Management Plan must contain all of the following components:

- Names and contact information of the current Primary Vaccine Coordinator and at least one Assistant (back-up) Coordinator.
- Staff training requirements and documentation for vaccine management.
- Proper vaccine storage and handling practices, including temperature monitoring.
- Vaccine ordering procedures and vaccine accountability.
- Proper receiving procedures- maintaining the cold chain.
- Proper handling and inventory control to avoid wastage.
- Detailed emergency procedures that include how to properly pack vaccine.
- Review/Revised date and signature of person(s) responsible for its contents.

A practice may use all or parts of this document, adding specific information pertinent to your office, or develop its own plan as long as it meets or exceeds all of the components contained in this basic plan.

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**NH Immunization Program (NHIP)
Routine Vaccine Management Plan**

Practice Name: _____ PIN _____

Address: _____

Phone: _____ Fax: _____

Proper Vaccine Management is critical to keeping vaccine safe.
This plan will be kept easily accessible and available for all staff.

Vaccine Management - Important Numbers at a Glance

Designation/Responsibility of Vaccine Management Staff

Responsibilities Primary Vaccine Coordinator
Required Training

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VFC Billing
Adult Screening and Billing

Administration and Documentation

Vaccine Ordering, Accountability and Receiving

Ordering
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Receiving

Vaccine Inventory Control

Vaccine Storage and Handling

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Vaccine Transport

Notes and Date & Signature Page

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VACCINE MANAGEMENT

IMPORTANT NUMBERS AT A GLANCE

**PLEASE POST A COPY OF THIS INFORMATION
ON OR IN CLOSE PROXIMITY TO VACCINE STORAGE UNIT**

This information should be reviewed periodically and changes made as needed.
All changes in vaccine management staff should be reported to NHIP immediately
using an updated change of staff form. Please contact NHIP if one is needed.

PRACTICE NAME: _____ PIN# _____

VACCINE MANAGEMENT PLAN location: _____

DETAILED EMERGENCY PLAN location: _____

PRIMARY VACCINE COORDINATOR: _____

CONTACT NUMBER: _____

ASSISTANT VACCINE COORDINATOR: _____

CONTACT NUMBER: _____

POWER OUTAGE GUIDANCE

UTILITY COMPANY NAME: _____

UTILITY COMPANY PHONE: _____

VACCINE TRANSFER INFORMATION

LOCATION: _____

LOCATION PHONE: _____

LOCATION CONTACT: _____

OTHER IMPORTANT CONTACT OR INFORMATION INFO IN CASE OF EMERGENCY

QUESTIONS OR CONCERNS?

CALL

NH IMMUNIZATION PROGRAM

603-271-4482 OR 1-800-852-3345 X4482

**Proper
Vaccine
Management
is critical to
keeping
vaccine safe
and your
patients
protected.**

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DESIGNATION / RESPONSIBILITY of VACCINE MANAGEMENT STAFF

The practice will designate an individual to be the Primary Vaccine Coordinator and one to be an Assistant Vaccine Coordinator (to assume the duties in the absence of the Primary Coordinator). The practice must notify NHIP of any changes in key staff.

Responsibilities of the Primary Vaccine Coordinator include:

- ✓ Keeping the practice current with all guidelines, policies, procedures and recommendations
- ✓ Ordering, reporting, and accountability of state supplied vaccines
- ✓ Controlling inventory, including stock rotation, to minimize vaccine wastage
- ✓ Assuring proper storage of vaccines and monitoring storage conditions daily
- ✓ Implementing standard procedures in the event of storage temperature excursion and reporting the event to NHIP
- ✓ Transportation of vaccine including receiving, packing and transferring as necessary
- ✓ Ensuring that other designated staff is adequately trained to oversee the responsibilities in the absence of Primary Coordinator.

Required Training

Training dates and registration is located on the DHHS/Immunization website
<https://www.dhhs.nh.gov/dphs/immunization/providers.htm>

All Primary and Assistant Vaccine Coordinators are required to take some form of annual training that includes VFC protocols and proper storage & handling of vaccine and will attend a vaccine management training offered by NHIP.

New Primary Coordinators will attend training within 30 days of taking on their role as Primary Coordinator (and annually thereafter). If there is no NHIP training being offered within 30 days - he or she will complete the following 2 training modules offered by the CDC, You Call the Shots, *Vaccines for Children* and *Storage & Handling* modules. (<http://www.cdc.gov/vaccines/ed/youcalltheshots.htm>). Confirmation of completion will be submitted to NHIP.

New Assistant Vaccine Coordinators will attend training within 90 days of taking on their role as Assistant Vaccine Coordinator (and annually thereafter).

Vaccine Management staff needing access to the vaccine ordering system VOMS, must attend the required training offered by NHIP. Only fully trained staff will access the ordering system. No secure ID's or passwords will be shared among staff. This could be considered fraud and abuse.

All training and education relative to immunizations and vaccine management must be documented.

All changes in key staff will be reported to NHIP using an updated change of staff form. General vaccine management staff should be reported within 5 business days. Departing staff having secure access to VOMS should be reported to NHIP within 24 hours.

NHIP must be notified if any change that affects the business characteristics of the practice: name/address, closure, merger, new/departing physicians, etc.

PATIENT SCREENING and BILLING

VFC Eligibility Status

- All children will be screened for insurance status and will be documented appropriately in the patient's record at each immunization visit.
 - VFC eligibility criteria: 0 through 18 years of age, Medicaid eligible, uninsured, underinsured (FQHC only), and/or American Indian/Alaskan Native.
 - Fully insured or Underinsured (has health insurance but vaccines not covered or select vaccines only)

VFC Billing

- A fee will never be charged for federal and state supplied immunizations.
- The vaccine administration fee for non-Medicaid, VFC eligible children (self-pay) will not exceed the current state cap.
- No established patient through the age of 18 will be denied a vaccine due to the inability to pay the administration fee.
- No unpaid administration fees will be sent to collections

Adult Screening and Billing

- NHIP supplied adult vaccine will only be administered to patients 19 years of age and older who are uninsured or underinsured.
- Billing will mirror the VFC established guidelines.

ADMINISTRATION and DOCUMENTATION

- Vaccines will be prepared immediately before administration and will not be pre-drawn (exception: for mass vaccination clinics where one vaccine is being offered such as a flu clinic, up to 10 doses of vaccine may be pre-drawn).
- The most currently approved Vaccine Information Statement (VIS) for each dose of state supplied vaccine will be provided to the parent/guardian/patient prior to administering the vaccine.
- The package insert accompanying the vaccine will be reviewed for proper dose, route, site, and needle size.
- Immunization records will be maintained according to federal law and contain:
 - ✓ Name of the vaccine
 - ✓ Date the vaccine administered
 - ✓ Date the VIS was given
 - ✓ Publication date of the VIS
 - ✓ Manufacturer and lot number of the vaccine
 - ✓ Name and title of person administering the vaccine
 - ✓ Name and address of practice or clinic where vaccine was administered.
- All records related to the VFC/NHIP program will be kept for a minimum of three (3) years.
- Any adverse effects will be reported to the Vaccine Adverse Event Reporting System (VAERS).

VACCINE ORDERING, ACCOUNTABILITY, and RECEIVING

Ordering

- An adequate supply of all routinely recommended vaccines will be maintained for the populations served.
- Vaccine will be ordered through the Vaccine Ordering Management System (VOMS) of NH's Immunization Information System (IIS) - *VaxNH*.
- Only trained staff will be given access to the system. Contact NHIP at 603-271-4482 or email vaxnh@dhhs.state.nh.us for information on training.
- Vaccine orders for this practice will be completed approximately every _____ weeks.
- Call NHIP distribution staff at 603-271-4463 for information on emergency ordering.

Reporting

- Doses administered and accurate current inventory must be reported with each order.
- Proper reconciliation will be completed at least monthly whether vaccine is being ordered or not.
- All expired, wasted or transferred vaccine will be reported in VOMS as soon as possible and returns will be completed as required.

Receiving

- The Vaccine Coordinator or Assistant Coordinator will be notified immediately when a shipment of vaccine arrives.
- The vaccine order will arrive either by Fed Ex or UPS. Trained vaccine management staff will immediately open the shipment and check the temperature monitors. If the vaccine has been "out of range", NHIP will be contacted (or the number located on the vaccine temperature monitor in shipment) within 2 hours of delivery to determine if the vaccine is viable.
- Quantities and lot numbers of each vaccine will be compared to the McKesson packing list. If there are any discrepancies, they will be noted in VOMS and NHIP contacted.
- **All** vaccine, including any vaccine in question, will be stored at appropriate temperatures immediately after the package is delivered and checked in. Any vaccine in question will be marked "DO NOT USE" until manufacturer and/or NHIP have determined viability.
- The receiving process will be completed by confirming in VOMS the amount received for each presentation within 3 business days.

VACCINE INVENTORY CONTROL

- Vaccines will be stored and rotated according to expiration dates with vaccines having the shortest expiration dates used first.
- When vaccines are within **90 days of expiration** and will not be used, there will be the attempt to administer the vaccine to patients who are due for it, transfer the vaccine to another VFC Provider in the area, or contact NHIP for assistance. All transfers will be reported to NHIP according to the Vaccine Transfer Procedures.
- All vaccine that is compromised (e.g. expired or deemed non-viable due to temperature excursion) will be immediately removed from the storage unit and clearly labeled. This vaccine will be returned to McKesson by following the NHIP Vaccine Return Procedures.
- All vaccine that is wasted due to malfunction of syringe, broken vial, pre-drawn and not used, or any other situation where the vaccine *cannot* be returned to McKesson, will be reported to NHIP according to the Vaccine Wastage Procedures.
- All returns/wastage/transfers will be reported in VOMS.
- Vaccine in multi-dose vials that do not require reconstitution will be used through the expiration date printed on the label as long as the vaccine is not contaminated, unless indicated otherwise by the manufacturer.
- To be sure accurate vaccine accountability, inventory will be done at least monthly whether a vaccine order is being placed or not.
- Vaccine inventory will be completed in this office Weekly Monthly Other _____

VACCINE STORAGE AND HANDLING

Storage Units

- Any refrigerator or freezer unit used for vaccine storage must be able to maintain proper vaccine storage temperatures year-round and be large enough to hold the year's largest inventory including influenza vaccine.
- Refrigerator units must be maintained between 2.0°C-8.0°C. Freezer units must be maintained between -15°C to -50°C.
- As of July 1, 2019, any newly acquired storage unit will be a single-standalone unit.
- Current in-use combination storage units must meet the minimum requirements of having a separate freezer compartment with a separate exterior door and containing two separate thermostat controls.
- Dorm style refrigerators (small combination refrigerator/freezer units with one exterior door and a small ice maker/freezer compartment contained inside) are not permitted at any time.
- Any NEW storage unit must have at least 3 days of stable temperatures recorded and submitted to NHIP before vaccines can be moved into the new refrigerator or freezer. NHIP will be contacted for more information when obtaining a new storage unit.

Set up of Storage Unit

- Water bottles (for refrigerators) and frozen water bottles (for freezers) will be placed throughout the unit to (1) act as a thermal buffer to stabilize temperatures and extend temperatures longer during a power outage or unit failure and (2) serve as physical barriers preventing the placement of vaccines in areas of the unit that are at a higher risk for fluctuation of temperatures. The water bottles will be marked "Do Not Drink", "Not for Human Consumption" etc.
- State vaccines will be stored on a separate shelf from practice purchased vaccines, or placed in separate baskets that are clearly labeled.
- All state supplied vaccine will be labeled to distinguish "state" from private supply.
- Vaccines will be stored in the middle of the shelf in such a way that air can circulate freely and will not be stored near the cooling fan or vent of the unit.
- Vaccines will be stored in the original packages and, because several vaccines are light sensitive, tops of boxes will not be removed.
- Vaccines will be stored in a separate refrigerator from food or drink.
- Vaccines will not be stored in the door, in vegetable bins, or against the sides or the back of the refrigeration/freezer unit.
- Merck vaccine diluent may be stored in the door or outside the refrigerator. Diluents that contain an antigen must be stored with their corresponding vaccine.

Other Safety Points

- Refrigerator/freezer doors will be checked to assure they are closed and, if possible, locked at the end of each day. Velcro strips help assure the door has been properly closed.
- Steps will be taken to protect the power source for all vaccine storage equipment by means of warning labels, back-up generators, and/or developing appropriate policies/protocols.
 - Storage units will not be plugged into surge protectors or GFI outlets.
 - A "**Do Not Unplug**" sign will be placed near the outlet (or on the unit if outlet is not accessible) and a notice on the circuit box indicating breaker switch connected to storage units.
 - Safety outlet covers will be placed on open area/exposed outlets to avoid accidental unplugging of units (NHIP recommendation).
 - Maintenance and cleaning personnel will be informed not to unplug storage units at any time. (NHIP recommendation)

TEMPERATURE MONITORING and EXCURSIONS

Temperature Monitoring Devices/Systems

- Refrigerator units will be maintained between 2.0°C-8.0°C.
 - Freezer units will be maintained between -15°C to -50°C
 - Each refrigerator and freezer unit will have a certified calibrated continuous monitoring device or system that meets or exceed the following specifications:
 - **Detachable Bio safe glycol-probe** or similar buffered solution, that remains in the refrigerator or freezer.
 - **Continuous Monitoring.** The ability to record and save temperature information 24 hours a day. Measures at least one reading every 15 minutes.
 - **A digital display on the outside of the unit.**
 - **The ability to display the minimum and maximum temperatures** between readings.
 - **A Hi/Lo alarm**, audible or visual for out- of- range temperatures.
 - **The ability to download and transmit** temperature information by email or fax.
 - **Low battery indicator.**
 - **A current certificate of calibration** that is traceable to the National Institute of the Standards and Technology (NIST).
 - **Accuracy of +/- 1°F (0.5°C).** This information should be contained in the Certificate of Traceability and Testing (aka the Report of Calibration). A copy of this certificate should be readily available for any NHIP staff during a site visit.
 - The buffered probe/glycol bottle will be placed/fastened in the center of the storage unit.
 - The practice will have a certified calibrated data logger available to serve as a backup should the main monitoring device fail.
 - The practice will use a certified calibrated data logger to monitor the vaccine temperature during transport of vaccine at any time.
 - The Certificate of Calibration for each monitoring unit/system must be issued either by an ILAC-accredited laboratory or, if not ILAC-accredited, certificate must contain measurement results and a statement indicating that it meets ISO 17025 standards. All certificates must contain:
 - ✓ name of device (optional),
 - ✓ model number,
 - ✓ serial number, and
 - ✓ date of calibration
- Certificates of calibrations are located:**

Back-up Thermometer is located:

- The temperature of each storage unit will be read and recorded at the beginning and end of every workday.
 - The minimum and maximum temperatures will be recorded each morning.
 - The temperature readings, along with the time taken and the initials of the person taking the temperatures, will be recorded on the NHIP supplied temp log.
 - The temperature log for each storage unit will be faxed to NHIP at the end of every month.
 - If it is not received by NHIP by the 10th of the month, a reminder will be sent to the practice.
 - If it is not received by NHIP by the 15th of the month, ordering privileges will be suspended until compliance is met.
 - Acceptable temperatures/logs must be submitted before an order can be placed
 - A report from the 24/7 monitoring device will be reviewed at the end of every month. If the information can be downloaded, it should be saved electronically or printed/saved. If the monitoring is done by a *system*, confirmation of review must be documented.
 - NHIP will be notified immediately of any temperature excursion.

Temperature Excursions

Any temperature below 2.0°C or above 8.0°C (refrigerator) or above -15°C (freezer) will be immediately addressed and reported to the NH Immunization Program. The only exception to reporting any temperature excursion is when stocking vaccine and when performing monthly inventory. NOTE- If the temperature in the storage unit rises above the recommended temperature for 10 minutes or more during stocking or inventory; it must be reported as a temperature excursion.

If temperatures are found to be out of range:

1. The temperature monitoring report will be reviewed as soon as the excursion is discovered.
2. Vaccines will be secured in correct storage temperature and label as “Do Not Administer” until viability of vaccines has been determined by the manufacturer or NHIP.
3. Vaccines will not be assumed viable or compromised until confirmation has been fully determined.
4. NHIP will immediately be contacted. If after hours, emergency plan will be enacted for temporary storage.
5. A Cold Chain Incident Report will be completed and submitted to NHIP for every excursion incident.
6. Vaccine that had been involved in a cold chain incident and has been deemed non-viable by the manufacturers must be returned to McKesson. NHIP will, on the provider’s behalf, enter the return into VOMS based on the information documented on the Cold Chain Incident Report. NHIP will email the packing slip to the provider contact and a pre-paid shipping label will be emailed from UPS within 24- 48 hours after packing slip has been sent.

EMERGENCY ACTION PLAN

For the protection and safety of all vaccines and to minimize potential monetary loss in the event of refrigerator and/or freezer malfunction, power failures, natural disasters, or other emergencies that might compromise vaccines, a *written Emergency Action Plan* for an alternative storage of vaccine must be readily available to ALL STAFF. Generators should be tested quarterly & serviced annually (plan is required even with a generator on site).

The *written* Emergency Action Plan must be created by the practice and include the following components:

- ✓ Updated current emergency contact information for key practice staff
- ✓ Specific action steps to take for unit failure or power outage
- ✓ Steps during “working hours” & “after hour” emergencies
- ✓ Electric company contact information
- ✓ Designation of site(s) with storage availability
- ✓ Inventory of materials needed for proper pack-out of vaccines
- ✓ Proper vaccine pack-out and transport guidelines

Emergency Action Plan is located

Vaccine Transport

Vaccine potency will be protected by maintaining the cold chain at all times during relocation and transport. Proper procedures will be followed if vaccines must be transported due to a power failure, short expiration date, or other reasons that require moving of vaccine. Every transport container will contain a continuous temperature monitoring device. When relocating large quantities of vaccine due to impending storm or power/unit failure, inventory of vaccine will be taken prior to transfer and upon its return once the emergency has been resolved. Frozen vaccine will be packed out last and unloaded first at designated site. Shipping containers will be labeled appropriately based on contents—VACCINE Refrigerate Immediately or Freeze Immediately.

Vaccine will be delivered directly to and/or from back-up site. Never place container in trunk of vehicle. If vaccine is transferred to another facility for reasons other than emergency or temporary storage, the transfer will be documented and completed in VOMS by the end of the day.

THIS PLAN WILL BE KEPT EASILY ACCESSIBLE AND AVAILABLE FOR ALL STAFF

OTHER IMPORTANT VACCINE MANAGEMENT NOTES:

It is a CDC/NHIP requirement that this document be reviewed annually and updated as necessary.

Last review/revision date _____

Practice Manager/Clinical Coordinator _____

Print

Signature

New staff and all staff who administer vaccine should review the Vaccine Management plan.

Staff member reviews:

Name:

Date:

