North Dakota Immunization Program

2011 Vaccine Management Plan

Division of Disease Control

NORTH DAKOTA
DEPARTMENT *of* HEALTH

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Introduction

Congratulations! You have taken the first step to safeguarding your vaccine supply: reviewing (or at the very least, opening) the North Dakota vaccine management plan. This guide contains a great deal of information. For providers who have been enrolled in the Prevention Partnership program for many years, this information can seem dull and redundant. New providers or new staff in a provider office, however, might be overwhelmed by all of the details. All immunization providers in North Dakota are different, but everyone seems to have one thing in common—they're busy! The goal of the North Dakota Immunization Program is not to pile additional work onto providers. Unfortunately, vaccines are *extremely* fragile and require some extra time and diligence. Please let us help! Read through the material in this management plan once. If you find something that you think you'll use often or didn't know before, bookmark it! Highlight! Make notes! As always, contact the North Dakota Immunization Program with questions or concerns. Thank you for using safe and effective practices to contribute to the health and wellness of the people of North Dakota.

Vaccines for Children Program Background

The Vaccines for Children (VFC) Program is a federally funded program that provides vaccines at no cost to children who are VFC eligible. The VFC Program was created by the Omnibus Budget Reconciliation Act of 1993 as a new entitlement program to be a required part of each state's Medicaid plan. The VFC Program offers free vaccine only to individuals, 18 and younger, who are Medicaid eligible, American Indian or Alaska Native, without health insurance, or underinsured (a child whose health insurance benefit plan does not cover vaccines or a particular vaccine). The program was officially implemented in October 1994 as part of President's Childhood Immunization Initiative. Funding for the VFC Program is approved by the Office of Management and Budget and allocated through the Centers for Medicare & Medicaid Services (CMS) to the Centers for Disease Control and Prevention (CDC). CDC buys vaccines at a discount and distributes them to grantees—i.e., state health departments and certain local and territorial public health agencies—which in turn distribute them at no charge to those private physicians' offices and public health clinics registered as VFC providers. Children who are eligible for VFC vaccines are entitled to receive pediatric vaccines that are recommended by the Advisory Committee on Immunization Practices through passage of VFC resolutions.

Importance of Storage and Handling

Proper vaccine storage and handling is important in order to ensure the efficacy of vaccines in preventing vaccine-preventable diseases. Failure to store vaccines properly can lead to an inadequate immune response.

Good storage and handling practices are also important in order to prevent the wastage of increasingly expensive vaccines. In 2009, North Dakota providers reported wasting 5,154 doses of vaccine, which is approximately $115,991.83 worth of vaccine. This is only the reported wastage. There is no way to know how much vaccine was wasted and not reported.

Proper vaccine storage and handling is necessary in order to prevent having to repeat vaccinations in children that received improperly stored vaccine. Repeat vaccinations can lead to an increase in adverse reactions and wasted money spent on vaccinations that weren't needed.

It is important for providers to thoroughly review the North Dakota Department of Health Vaccines for Children Manual in order to understand the requirements of the VFC program and to prevent vaccine wastage in North Dakota.

VFC Program Requirements

- Providers must enroll annually with the Prevention Partnership Program to receive VFC or state-supplied vaccine. This enrollment must be signed by the **medical director** or equivalent (M.D. or D.O.), and list all the providers within the practice (hospitals do not need to list all providers).

  ☐ **Prevention Partnership Program enrollment materials submitted to NDDoH:**

  Date: _____

- A Provider Profile must be completed annually by each provider using data from the previous year. For guidance on how to estimate patient numbers from the previous year, contact the NDDoH Immunization Program.
- All patients must be screened for VFC eligibility at all immunization encounters.
- VFC vaccine must only be administered to children who are 18 years of age or younger who meet one or more of the following categories:
  - American Indian or Alaska Native.
  - Enrolled in Medicaid.

  - No health insurance.
  - Underinsured (a child whose health insurance benefit plan does not cover any or specific vaccines). Must be vaccinated at Federally Qualified Health Centers (FQHC) or Rural Health Clinics (RHC) or at providers with a Letter of Agreement with a FQHC.

- State-supplied vaccine must be administered only to those eligible according to the most recent Vaccine Coverage Table.
- Screening information must be documented on the Vaccine Administration Record (VAR) or on the Patient Eligibility Screening Form **and** in the NDIIS.
- The immunization schedule, dosage and contraindications that are established by the ACIP and included in the VFC program must be followed unless:
  - In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate. This determination must be made on a case-by-case basis.
  - The particular requirements contradict state law, including those pertaining to religious and other exemptions.
- Distribute the most current Vaccine Information Statements (VIS) every time a vaccine is administered and maintain records in accordance with the National Childhood Vaccine Injury Compensation Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - VIS forms can be ordered from the NDDoH and are also available at http://www.cdc.gov/vaccines/pubs/vis/default.htm and http://www.immunize.org/vis/.
  - If the NDDoH vaccine administration record is not used, the following information about VISs must be kept in the patient's permanent medical record:
    - Which VIS was given
    - Date of publication of the VIS
    - Date the VIS was given
  - VAERS forms should either be submitted in the NDIIS or faxed to the NDDoH at 701.328.2499 **(See Appendix 1 for a VAERS form)**.

- Maintain all records (including patient screening forms, temperature logs, etc.) related to the VFC program for a minimum of three years and make these records available to public health officials including the North Dakota Department of Health (NDDoH) or U.S. Department of Health and Human Services (DHHS) upon request.
- The maximum vaccine administration fee that may be charged for VFC or state-supplied vaccine is $13.90.
- The reimbursement for immunization administration set by the state Medicaid agency for vaccine administered to children enrolled in Medicaid must be accepted.
- Immunize eligible children with VFC or state-supplied vaccine at no charge to the patient for the vaccine.
    - Patients or Medicaid cannot be billed for the cost of VFC or state-supplied vaccine.
    - Do not administer VFC vaccine to patients not eligible for the VFC program.
    - Borrowing VFC vaccine to administer to a non-VFC eligible patient can occur only in rare, unplanned situations (i.e., outbreaks, shortages, etc.).
        - Replace the vaccine as soon as possible with privately-purchased vaccine.
        - Record all borrows/returns in the NDIIS.
- Do not deny administration of a VFC or state-supplied vaccine to a patient because the child's parent or guardian or the patient is unable to pay the administration fee**.**
    - Other visit or office fees may be charged.
- Operate within the VFC program in a manner intended to avoid fraud and abuse.
- Comply with the NDDoH requirements for ordering, vaccine accountability and vaccine management according to the Vaccine Loss Policy, Vaccine Fraud and Abuse Policy and the Vaccine Management Plan.

Vaccine Personnel

- Providers should designate a primary vaccine coordinator and at least one backup.

  PRIMARY VACCINE COORDINATOR: _____

  BACKUP VACCINE COORDINATOR: _____

  BACKUP VACCINE COORDINATOR: _____

  BACKUP VACCINE COORDINATOR: _____

- These people must be responsible for the following:
  - Monitoring and recording twice daily the temperatures on the temperature logs for each storage unit containing state-supplied vaccine.
  - If necessary, adjusting the temperature of a vaccine storage unit.
  - The primary vaccine coordinator should review temperature logs weekly if daily monitoring is being conducted by a backup person to ensure proper temperature recording. The backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
  - Checking expiration dates of vaccine and ensuring the earliest outdates are placed in the front of the freezer/refrigerator.
  - Receiving all state-provided vaccine shipments or ensuring that others who may receive the order are aware of the procedure for receiving vaccine.
- Training of other staff who are responsible for administering vaccine should be the responsibility of the vaccine coordinator.
- The coordinator can be the same person who orders vaccine.

Vaccine Storage, Handling & Disposal Guidelines

Providers must follow recommendations and general guidelines for handling, storage and disposal of vaccines from *Vaccine Management: Recommendations for Handling and Storage of Selected Biologicals*, a publication from the U.S. Department of Health and Human Services. This guide is available online at http://www.cdc.gov/vaccines/pubs/vac-mgt-book.htm. Information in addition to these recommendations is listed below. These recommendations are NOT a substitute for the package insert included with each biological.

Vaccine Storage

Storage Requirements

All VFC providers are required to have appropriate equipment that can store and assist with the maintenance of proper conditions of vaccines. Refrigerators without freezers and stand-alone freezers may be better at maintaining the required temperatures. However, combination refrigerator/freezer (household) units are acceptable for vaccine storage if the refrigerator and freezer components each have a separate external door.

Refrigerators and freezers used for vaccine storage must comply with the following requirements:

- Be able to maintain required, stable vaccine storage temperatures year-round.
- Be large enough to hold the year's largest inventory.
- At minimum, have a working certified thermometer inside each storage compartment.
- Be dedicated to the storage of vaccines. Food and beverages must not be stored in a vaccine storage unit because this practice results in frequent opening of the door and destabilization of the temperature.

The Centers for Disease Control and Prevention (CDC) no longer allows VFC vaccine to be stored in dorm-style fridges, and these types of units are not considered acceptable storage units for VFC vaccine. A dorm-style refrigerator is a small combination refrigerator/freezer unit that is outfitted with one external door, an evaporator plate (cooling coil) which is usually located inside an ice-maker compartment (freezer) within the refrigerator and is void of a temperature alarm device. Its temperature control sensor reacts to the temperature of the evaporator rather than the general air in the storage compartment. When the compressor is on, the evaporator cools to lower the temperature in the refrigerator, in most cases to below 0°C. Dorm-style fridges are not adequate for long-term or permanent storage of vaccine because they do not maintain proper temperatures and pose a high risk of freezing vaccine. The only acceptable use of dorm-style fridges is to store a clinic's single-day supply of refrigerated (never frozen) vaccine, and these vaccines must be returned to the main refrigerator storage unit **at the end of each clinic day**. Temperatures must still be monitored and recorded twice daily for any dorm-style fridges used for storing single-day supplies of vaccine. These logs must be submitted to the NDDoH monthly with the main storage unit's logs.

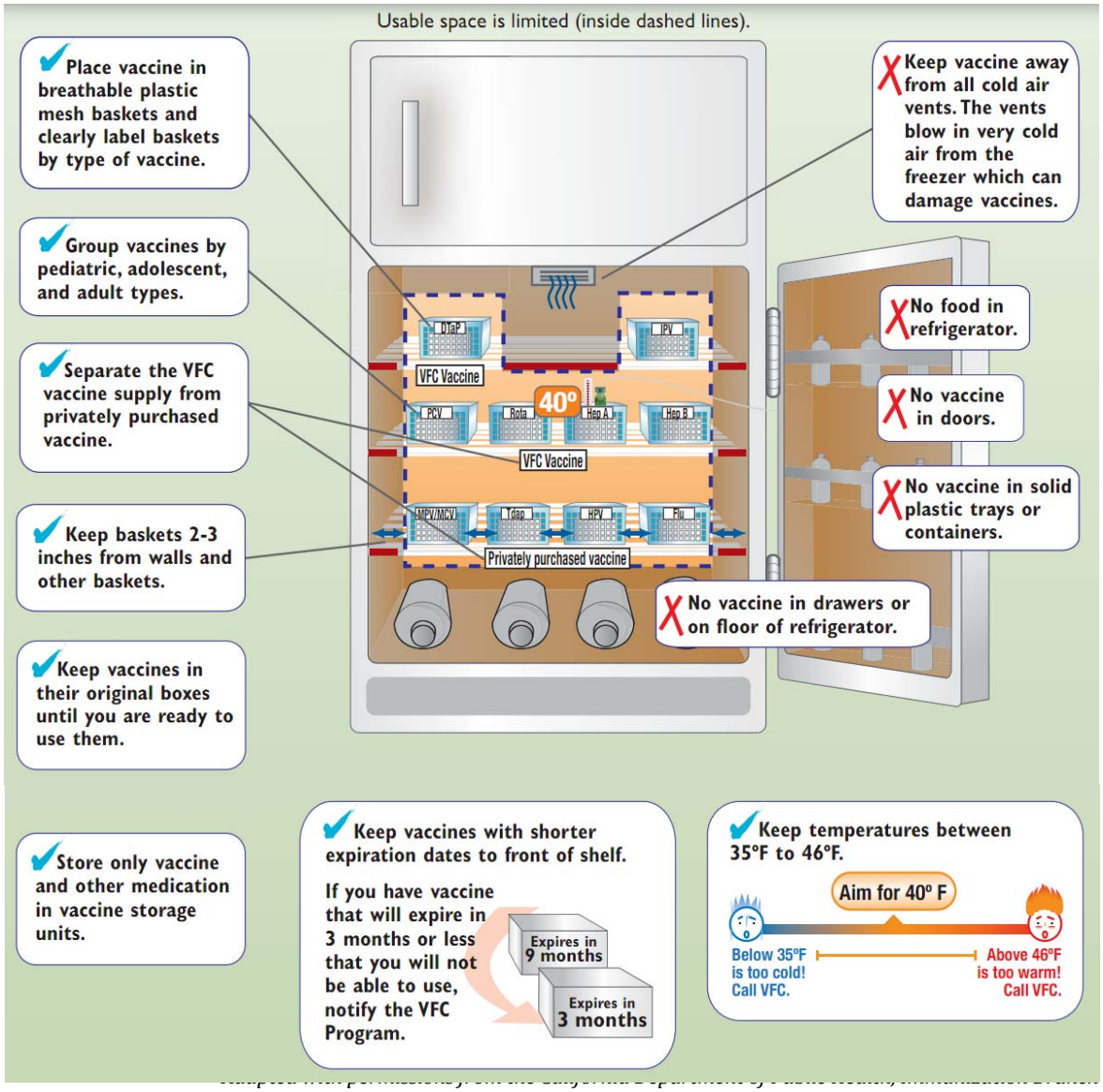
Refrigerated Vaccines

These vaccines **MUST** be stored at temperatures of 2°–8° C or 35°– 46° F:

DT	**Influenza**
DTaP	**IPV**
DTaP/HBV/IPV	**Live attenuated influenza vaccine**
DTaP/Hib/IPV	**MCV-4**
DTaP/IPV	**PCV-13**
Hepatitis A	**PPV-23**
Hepatitis B	**Rotavirus**
Human Papillomavirus	**Td**
Hib	**Tdap**

The above vaccines must **NOT** be stored in the freezer.

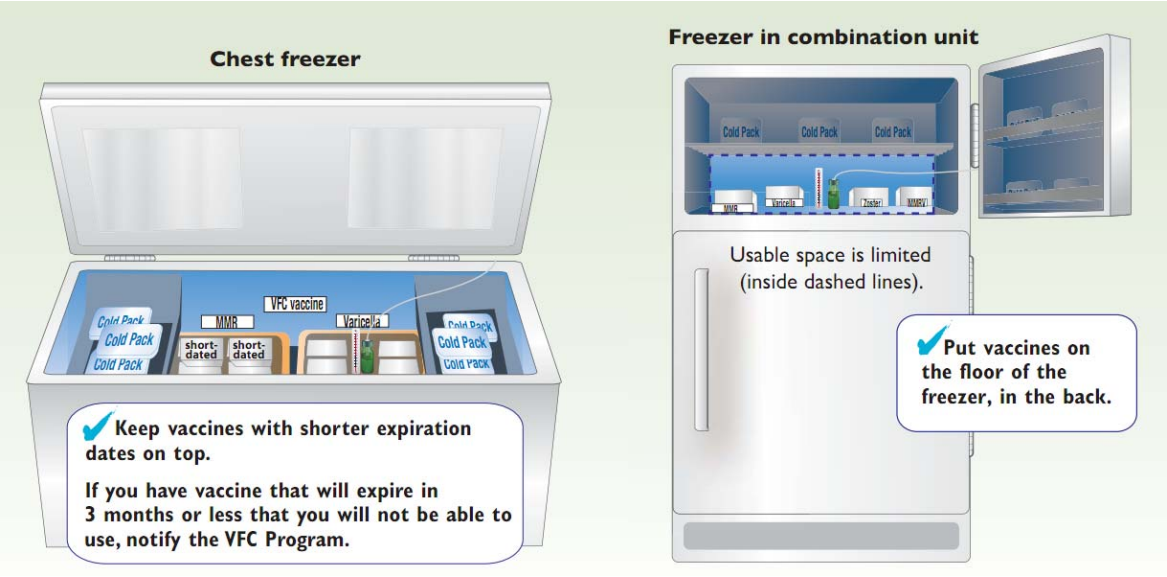
- Vaccine diluents may be stored at room temperature.
- MMR vaccine may be stored in the refrigerator or the freezer. Storing MMR in the freezer prevents vaccine wastage due to power failures because the vaccine will take longer to warm to out-of-range temperatures when frozen.
- MMRV, varicella and zoster vaccines **MUST NOT** be stored at refrigerator temperature at any time.



Frozen Vaccine

Varicella, MMRV and Shingles

- Varicella, MMRV, and shingles vaccines are required to be stored at a temperature of -15° C or +5° F or below.
- Discard reconstituted varicella, MMRV and shingles vaccine after 30 minutes.
- Do not freeze reconstituted varicella, MMRV or shingles vaccine.
- Protect varicella, MMRV and shingles vaccine from light before and after reconstitution.



Adapted with permissions from the California Department of Public Health, Immunization Branch

<u>Providers must monitor the temperature of their refrigerator/freezer with certified thermometers.</u>

- Thermometers must be calibrated and certified in accordance with National Institute of Standards and Technology (NIST) or the American Society for Testing and Materials (ASTM) standards. Calibrated, certified minimum/maximum thermometers are available from the NDDoH for storage units containing state-supplied vaccine.
- The optimal system for monitoring refrigerator/freezer temperatures is an automated temperature-sensing device. If a sensing device is not feasible, a min/max thermometer is recommended. Thermometers should be placed in the center of the refrigerator, next to the vaccine.
- Monitor and document temperatures at least twice per day (beginning and end). **Only the current temperature reading(s) should be recorded.** Post a temperature-recording chart on your refrigerator/freezer to record the temperatures. Copies of temperature recording charts must be sent in to the NDDoH at the end of every month <u>for each unit containing state-supplied vaccine</u>. **(For temperature recording charts, see Appendices 2 – 4)**
- Temperature logs must be kept on hand for a minimum of three years.
- **Actions must be taken and <u>RECORDED</u> on every out-of-range temperature.** If refrigerator or freezer temperatures are out-of-range, record the temperature on a temperature log and immediately isolate the affected vaccine. Mark "do not use" until the vaccine manufacturers and the NDDoH have been contacted. Do not assume that the vaccine is not viable and do not discard any state-supplied vaccine until the

NDDoH has been contacted. Recorded actions should be sent monthly to the NDDoH along with the temperature logs.

- Do not store food or beverages in a refrigerator that contains biologicals.
- Stack vaccine with enough air space between stacks to allow cold air to circulate around the vaccine.
- Do not stack vaccine next to coils in the refrigerator. The coils are extremely cold and could result in the vaccine being inadvertently frozen.
- Never store vaccine in the refrigerator door. The temperature of the refrigerator door is unstable because of opening and closing of the unit.
- Rotate biologicals in the refrigerator/freezer so that the shortest dated vaccine is used first.
- Once a month, check vaccine inventory for expiring vaccine.
- Place ice packs in the freezer and filled plastic water jugs in the refrigerator to help maintain temperature stability. This helps keep temperatures uniform and provides additional cold mass, both of which are particularly useful if there is a power failure.
- Unofficial studies have indicated some biologicals will retain their potency when left at room temperature for short periods of time. In the event of a vaccine storage mishap, contact the vaccine manufacturer for efficacy of vaccine not stored properly.
- Place a warning sign to prevent unplugging the refrigerator/freezer by the plug/outlet to help ensure that the refrigerator/freezer is not turned off **(See Appendix 5).** Also place a warning sign on the circuit breaker for the refrigerator/freezer.

<u>Other suggestions</u>

- Install **PLUG GUARDS/PROTECTORS** in outlets. This serves as an additional visual reminder to prevent power loss.
- Lock storage facilities and equipment. This prevents unauthorized removal of vaccine and use of storage for other purposes.
- Diluent should be stored outside the refrigerator. It takes up space and does not need to be refrigerated.
- Remove vegetable bins from the refrigerator; replace with cold water jugs or bottles. **DO NOT STORE VACCINE IN THE SPACE FORMERLY OCCUPIED BY VEGETABLE BINS.**

- Store all opened and unopened vials of vaccine in their boxes inside the appropriate storage unit so that their contents and expiration dates are easily identifiable.
- Keep vaccines organized (place opened vials of vaccine in a tray so they are readily identifiable).
- Indicate on the label of each vaccine vial the date and time it was reconstituted or first opened.
- Open only one vial or box of a particular vaccine at a time to control vaccine usage and allow easier inventory control.
- Store vaccine products that have similar packaging or names (i.e. DTaP and Tdap) in different locations to avoid confusion and medication errors.
- Follow manufacturer's recommended schedule for recalibration of the certified thermometers. If using state-supplied thermometers, request replacement thermometers before recalibration is due.
- Conduct a monthly inventory to monitor vaccine use, anticipate needs and remove expired vaccines.
- In larger clinics, provide a source of backup power (generator) and a security system to alert the appropriate personnel in the event of a power outage.
- If applicable, test backup generators quarterly and maintain backup generators at least annually (check manufacturer specifications for test procedures and maintenance schedules).

Vaccine Handling

- **It is recommended that vaccines not be drawn up until immediately prior to administration.**
- Biologicals may lose efficacy if drawn up and stored in syringes for any period of time.
- If vaccines are drawn up prior to administration because of large clinics or limited staff, observe the following guidelines:
    - NO vaccine should be administered if drawn up in syringes for more than 8 hours.
    - NEVER return vaccine to a multiple dose container.

- MMR may be kept up to 8 hours in a dark, cool place after reconstitution.
- Varicella, MMRV and shingles must be administered within 30 minutes after reconstitution. Discard reconstituted vaccine if not used within 30 minutes.
- MMRV MUST NOT be stored at refrigerator temperature at any time.
- Properly stored vaccines are valid up until expiration date. If the expiration date is listed as a month and year only, vaccine is valid until the end of that month (e.g. July 2012 -- valid until July 31, 2012). **Vaccines must be utilized until the expiration date**.

Emergency Vaccine Storage and Handling

In the event of a freezer/refrigerator failure, power failure, natural disaster or other emergency which may compromise the storage condition of vaccines, each provider must have a written emergency vaccine storage and handling plan as part of their vaccine management plan. A plan template is included in the Prevention Partnership enrollment packet and can also be accessed at http://www.ndhealth.gov/Immunize/Providers/Forms. This should be reviewed and updated as needed and at least annually. NDDoH staff making site visits will ask to see this. At a minimum, this plan must include:

- Designation of primary vaccine coordinator and at least one backup
- Guidelines for proper routine storage and handling
- Procedures for vaccine shipping (including receiving and transporting)
- Procedures for emergency vaccine relocation in the event of a power failure, mechanical difficulty or emergency situation. Necessary components for the emergency plan include:
  - ✓ Person(s) responsible for preparing and transportation including contact information
  - ✓ How this person will be notified that vaccine needs to be moved
  - ✓ Location that will receive vaccine
  - ✓ How receiving location will be notified of transport
  - ✓ How to pack vaccine for transport
  - ✓ Worksheet to document vaccine involved in power or equipment failure

- Appropriate plan for vaccine ordering
- Guidelines for proper inventory control (i.e. stock rotation)
- Procedure for returning or wasting nonviable vaccine

Vaccine Return and Wastage

Immediately notify the NDDoH if any vaccine is exposed to temperatures outside of the normal storage condition for that vaccine. Failure to report wasted vaccine to the NDDoH may result in your facility no longer being able to receive state-supplied vaccine.

Return all unopened vials and manufacturer's pre-filled syringes of non-viable vaccine to McKesson. Vaccine provided by the NDDoH should never be discarded. The one exception would be open vials or syringes, including multi-dose vials from which doses have already been withdrawn. These can no longer be sent back to McKesson. A wastage form must still be filled out and sent to the NDDoH, and the open vials and syringes should then be discarded per your facility's policy.

Procedure for returning non-viable vaccine to McKesson:

- Complete a Non-viable Vaccine Return and Wastage Form before returning unopened non-viable vaccine **(See Appendix 6)**.
- Make two copies of the form, one for your records and one for McKesson.
- Prior to shipping non-viable vaccine, fax the form to the NDDoH Immunization Program at 701.328.2499.
- Contact the NDDoH for a return label. Ship via UPS.
- Ship non-viable vaccine and a copy of the completed return form to McKesson in a shipping container that you received from previous vaccine shipments.
- Providers should not directly contact UPS to schedule a pick-up, as this may result in the provider being charged for the shipping fees. Providers can either give the package to a UPS driver who is already there for another pick-up or delivery, or contact the Immunization Program, who will schedule a pick-up through McKesson.
- **DO NOT** ship viable vaccine to McKesson.
- **DO NOT** ship viable or non-viable vaccine to the NDDoH.

Vaccine Transfer

- Providers who have state-supplied vaccine that will not be able to be used before expiration should transfer the vaccine to other enrolled providers. This process should be started 3-6 months before the vaccine expires. It is the provider's responsibility to find another provider willing to take the vaccine and to pack and ship the vaccine to the provider following standard cold-chain procedures. Contact information for other enrolled providers can be found in the NDIIS under the "Provider Search" tab.
- Providers must either transfer the vaccine in NDIIS or submit a completed Vaccine Transfer Form to the NDDoH when vaccine is transferred from one enrolled vaccine provider to another enrolled vaccine provider **(See Appendix 7).** This process removes the doses from the inventory of the transferring provider and adds them to the inventory of the receiving provider.
- Cold chain procedures must be used during the transfer of vaccine, even if the distance between providers is minimal.
- Frozen vaccine can only be transferred on dry ice or in a portable freezer designed for this purpose. Frozen vaccine must stay at +5° F or -15° C or below**.**

Vaccine Disposal

Dispose of all materials properly:

- Syringes, needles, empty vials and material containing biologicals should be disposed in sharps containers, designated waste containers, etc. and burned, boiled or autoclaved before disposing in landfills.
- Unused or expired vaccines are considered hazardous if they contain mercury (such as thimerosal) or cresol-based preservatives. These are most commonly found in multi-dose vials and some pre-filled syringes. Any vial that is not empty and contains vaccine with a mercury or cresol-based preservative must be managed as hazardous waste per North Dakota's Pharmaceutical Waste Guidance. This can be accessed at www.ndhealth.gov/wm/Publications/NorthDakotaPharmaceuticalWasteGuidance.pdf. For information about vaccines that contain thimerosal visit www.vaccinesafety.edu/thi-table.htm.
- Hazardous waste should be kept separate and should be disposed of properly. A list of hazardous waste disposal companies can be found at www.ndhealth.gov/WM/Publications/HazardousWasteManagementCompanies.pdf.

Most health systems already have policies and procedures for handling hazardous waste.

- You can assume that preservative-free vaccines (most commonly single-use vials) and single-dose pre-filled syringes are non-hazardous.
- Other disposable items such as cotton balls, gauze, etc. should be secured in garbage bags for disposal.

Vaccine Ordering and Distribution

Vaccine Ordering

- Vaccine requests are accepted by the NDDoH by mail, fax or online. Requests are not accepted by telephone. This is to ensure accuracy in filling provider requests. **(See Appendix 8 for the Vaccine/Materials Order Form).** Providers may also place vaccine and material orders online at: www.ndhealth.gov/Immunize/Providers/Order.htm
- Vaccine order forms should be filled out completely, including provider's doses on hand or an accurate inventory. **The NDDoH will not fill the order if this data is not provided.**
- **Vaccine orders cannot be processed until the NDDoH has received a Monthly Doses Administered Report and temperature logs from the provider. (A Monthly Doses Administered Report can be found in Appendix 9)**. Doses administered reports may also be obtained from the North Dakota Immunization Information System (NDIIS). Doses administered reports should reflect only the number of state-supplied doses given, and not doses given to insured children with private vaccine. Orders may be adjusted by the NDDoH if a provider has ordered too much vaccine based on provider inventory and doses administered reports.
- Providers may only order enough vaccine to last one month beyond their Tiered Order Frequency (TOF) as follows:
    - High volume clinics who can order monthly – 2 month supply
    - Medium volume clinics who can order bi-monthly – 3 month supply
    - Low volume clinics who can order quarterly – 4 month supply
    - Very low volume clinics who can order as needed – as needed

- Providers may only order vaccine according to their TOF as listed above. No provider may place more than one order per month except in the case of an emergency. Please call the NDDoH for approval prior to placing a second order.
- Providers should notify clinic staff that vaccine is being shipped to their clinic after they have ordered vaccine. This is to prevent vaccine wastage.
- Providers should allow 2-3 weeks for delivery.

Vaccine Distribution

- The NDDoH will act as the central contact for VFC and state-supplied vaccine distribution and ordering.
- McKesson Specialty, Ltd. will act as the distributor for VFC and state-supplied vaccine.
- Vaccine is shipped on Mondays, Tuesdays and Wednesdays only. This ensures the vaccine will arrive at the provider site before the weekend.
- The method of shipping vaccine is a commercial shipping company (usually FedEx).
- Varicella, MMRV and shingles vaccine is shipped on dry ice directly to providers from the vaccine manufacturer.
- Vaccine shipments from the NDDoH via McKesson are recorded in the NDIIS database, which includes the lot number, expiration date, doses sent and the provider to whom the vaccine is sent.
- The NDIIS will record and account for vaccine distributed to providers.
- Providers are responsible for entering privately-purchased vaccine lot numbers into NDIIS.

Receiving Vaccine

- It is the responsibility of the provider to arrange for someone to be available in your office to immediately receive and properly store the vaccine. This employee must be trained in proper vaccine storage and handling. A back-up employee should also be trained. The National Immunization Program created a Vaccine Storage and Handling Toolkit that is available online at

http://www2a.cdc.gov/nip/isd/shtoolkit/splash.html. The NDDoH recommends that all clinic staff involved in vaccine storage and handling view this toolkit online.

- Providers should have written protocols in place for receiving vaccine.
- Immediately upon arrival of a vaccine shipment, the temperature monitor contained in the shipment should be checked to determine that the vaccine has remained at proper storage temperature. Notify the NDDoH **immediately** if the temperature monitor indicates that proper temperatures were not maintained during shipment of vaccine.
    - If compromised vaccine is received, the NDDoH will contact McKesson to arrange for a pick-up of the compromised vaccine and for a replacement shipment to be sent as soon as possible.
    - All contents of the shipment (including the compromised vaccine, packing slip and thermometers) should be returned to the cooler. McKesson will arrange for FedEx to pick up the vaccine.
- Compare the vaccine received with the information on the invoice. Notify the NDDoH **immediately** if there are any discrepancies in the order, including lot numbers or expiration dates.
- All vaccines, except varicella, MMR, MMRV and shingles, must be refrigerated immediately at 2 – 8° C or 35 – 46° F.
- Varicella, MMRV and shingles vaccine must be immediately stored in the freezer at a temperature of -15° C or +5° F or colder.

Vaccine Packaging/Shipping

There are a variety of materials available to ensure that vaccines are protected and are kept at the appropriate temperature during shipment. Vaccines other than varicella, MMRV and shingles need to be kept cool, but not frozen, during the shipping process. Varicella, MMRV and shingles vaccines on the other hand, need to be kept frozen while being shipped.

- Varicella, MMRV and shingles vaccines must remain frozen during shipping. Use dry ice in block form to ship varicella, MMRV and shingles vaccine. Do not handle the dry ice with your bare hands! Wear gloves while handling dry ice so you do not burn your hands. It is recommended to use no less than 5 lb. of dry ice per package.
- Do not ship vaccine if the daytime temperature is expected to exceed 90° F.

- Do not ship vaccine if the nighttime temperature is expected to be below 0° F unless it is vaccine which should be frozen.
- Vaccines must stay adjacent to the cold packs in order to maintain the desired internal temperature range when the outside temperature is extremely high.

Consider outside temperatures when traveling with biologicals. Do not leave vaccine in a vehicle for extended periods of time in either very cold or very hot temperatures.

Appendix

1 VAERS Form

2 Temperature Log (Fahrenheit)

3 Temperature Log (Celsius)

4 Temperature Log (Fahrenheit and Celsius)

5 "Do Not Unplug" Warning Signs

6 Non-viable Vaccine Return & Wastage Form

7 Vaccine Transfer Form

8 Vaccine/Materials Order Form

9 Vaccine Administration Monthly Report for all Providers