



North Dakota Immunization Program



2012 Vaccine Management Plan



NORTH DAKOTA
DEPARTMENT of HEALTH

Division of Disease Control



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INTRODUCTION

Welcome to the wonderful world of vaccine management! You have taken the first step to safeguarding your vaccine supply: reviewing 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. 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!

It is important for providers to thoroughly review the North Dakota Vaccine Management Plan in order to understand the requirements of the VFC program and to prevent vaccine wastage in North Dakota. Vaccines are *extremely* fragile and require some extra time and diligence.

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 (OBRA) of 1993 as a new entitlement program to be a required part of each state's Medicaid plan. The VFC program offers free vaccine to individuals 18 and younger who are Medicaid eligible, American Indian or Alaskan Native, uninsured, or underinsured (a child whose health insurance benefit plan does not cover vaccines or a particular vaccine). 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.

Chances are good that you're familiar with the Vaccines For Children program. Here's your chance to learn about why it came about in the first place:

In 1989 – 1991, a measles epidemic in the United States resulted in tens of thousands of cases of measles and hundreds of deaths. Upon investigation, the CDC found that more than half of the children who had measles had not been immunized, even though many of them had seen a health-care provider. OBRA was passed by Congress on August 10, 1993, and the VFC program became operational October 1, 1994.

VFC PROGRAM REQUIREMENTS

All of the following requirements listed are included on the 2012 Prevention Partnership program enrollment form. It is important that all providers are familiar with the federal program requirements. Providers sign the enrollment form annually and agree to:

1. **Screen patients at each immunization encounter for VFC eligibility and administer VFC or state-supplied vaccine only to individuals who meet the following criteria:**
 - a. 18 years of age or younger
AND
 - b. Are VFC-eligible
 - i. American Indian or Alaskan Native
 - ii. Enrolled in Medicaid
 - iii. Does not have health insurance
 - iv. Underinsured (health insurance plan does not cover any vaccines, does not cover a specific vaccine or only covers vaccines up to a certain dollar amount)
 - OR
 - c. Are considered state-supplied vaccine-eligible based on the most current [North Dakota Vaccine Coverage Table](#).

Providers and staff must understand:

- The eligibility requirements for the VFC program
 - The eligibility requirements for patients who are state vaccine-eligible
 - The options for administering VFC or private vaccine for children that have Medicaid as secondary insurance
 - The VFC program does not have any authority over administration fees charge to privately insured children
 - NDDoH staff will monitor the screening for eligibility requirement during the VFC site visit by conducting a random sample of children 0 – 18 years
 - How and when to document the initial VFC screening appropriately
 - How to conduct VFC screening and document screening results at subsequent immunization visits for all children 0 – 18 years
 - How to document changes to VFC eligibility status
 - How to appropriately document VFC eligibility in the North Dakota Immunization Information System (NDIIS)
2. **Comply with immunization schedules, dosages and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:**
 - a. In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate; or

- b. The particular requirements contradict state law, including laws pertaining to religious and other exemptions.

Providers and staff must understand:

- The current ACIP recommendations and how to locate these recommendations and the VFC resolutions
- The process NDDoH uses to notify VFC-enrolled providers about changes to the VFC program
- The state laws related to vaccination requirements and acceptable vaccine exemptions
- The true contraindications for each vaccine

3. Maintain all records related to the VFC program for a minimum of three years and make these records available to public health officials upon request.

Providers and staff must understand:

- All records related to the VFC program must be maintained for the required time period
- These records include (but are not limited to) VFC screening forms, temperature logs, doses administered reports and borrow/return reports

4. Immunize eligible children with VFC vaccine at no charge to the patient for the vaccine.

Providers and staff must understand:

- Patients, Medicaid or private insurance companies cannot be billed for the cost of VFC vaccine or other state-supplied vaccine
- Providers must use the NDDoH [VFC Vaccine Borrow/Return Form](#) and follow NDDoH requirements related to the borrowing and returning of all state-supplied vaccine
- NDDoH will monitor the borrowing activities of VFC-enrolled providers during VFC compliance site visits
- Borrowing VFC vaccine to administer to a non-VFC-eligible patient may occur only in rare, unplanned situations (i.e., a delayed vaccine shipment, vaccine spoiled in-transit to the provider or new staff that calculated ordering time incorrectly)
- Providers are expected to maintain an adequate inventory of vaccine for their non-VFC-eligible patients
- VFC vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory
- Borrowing VFC vaccine must not prevent a VFC-eligible child from receiving a needed vaccination because VFC vaccine was administered to a non-VFC-eligible child
- Providers must document all borrow/return occurrences in the NDIIS

5. Not charge a vaccine administration fee to VFC-eligible children that exceeds \$13.90 per vaccine dose.

Providers and staff must understand:

- The maximum amount that can be charged to VFC-eligible children
- The administration fee is per vaccine and not per antigen in the vaccine

6. **Not deny administration of VFC or state-supplied vaccine to an established patient because the child's parent/guardian is unable to pay the administration fee.**

Providers and staff must understand:

- The only fee that must be waived is the administration fee; other visit or office fees may be charged as applicable and are beyond the scope of the VFC program

7. **Distribute the most current Vaccine Information Statement (VIS) each 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).**

Providers and staff must understand:

- How to obtain the most current VIS forms
- The use of VIS forms applies to all vaccines included in the NCVIA or purchased through federal contracts
- How to report adverse events to VAERS

8. **Comply with the requirements for ordering, vaccine accountability and vaccine management as outlined in the current North Dakota Immunization Program Vaccine Management Plan, Fraud and Abuse Policy, and Vaccine Loss Policy. Agree to operate within the VFC program in a manner intended to avoid fraud and abuse.**

Providers and staff must understand:

- The need to comply with all requirements outlined in the NDDoH Vaccine Management Plan
- [NDDoH Vaccine Loss Policy](#)
- [NDDoH Fraud and Abuse Policy](#)
- How to order vaccine and which documents to submit with vaccine orders [use the [Request for Vaccine](#) form or submit orders electronically here: www.ndhealth.gov/Immunize/Providers/Order.htm]

9. **Document demographic, VFC-eligibility and immunization information on a Vaccine Administration Record (VAR) or Patient Eligibility Screening Form and in the North Dakota Immunization Information System (NDIIS).**

10. **Allow NDDoH staff to conduct site visits for review of vaccine administration procedures, vaccine storage procedures and coverage level assessments.**

11. **Understand that the NDDoH may terminate this agreement at any time for failure to comply with these requirements, or you may terminate this agreement at any time for any reason. If you terminate, you agree to return all unused VFC and state-supplied vaccine.**

Providers and staff must understand:

- Situations that would terminate their participation in the VFC program
 - How to return unused VFC vaccine
 - How to discontinue enrollment from the VFC program
 - If a provider terminates their VFC enrollment, they must return all unused VFC vaccine within 30 days of the termination date
12. **Agree that all records, regardless of physical form, and the accounting practices and procedures of your facility relevant to this agreement are subject to examination by the North Dakota Department of Health, North Dakota State Auditor or the Auditor’s designee.**
13. **Be bound by CDC’s terms of use for interacting with the online ordering system should the staff, representative or provider access VTrckS. Agree to be bound by any applicable federal laws, regulations or guidelines related to accessing a CDC system and ordering publicly funded vaccines.**
14. **Identify each member of the provider’s staff or representative who is authorized to order vaccines on the provider’s behalf. In addition, maintain a record of each staff member who is authorized to order vaccines on the provider’s behalf. If changes occur, inform CDC within 24 hours of any change in status of current staff members or representatives who are no longer authorized to order vaccines, or the addition of any new staff authorized to order. Certify that the provider’s identification is represented correctly on the provider enrollment form.**

Providers and staff must understand:

- The provider must contact the Vaccine Order Management Contact Center at 877.878.6247 within 24 hours of a change in staffing related to vaccine ordering
- The provider must keep a copy of the Identity Voucher available for review
- The provider must keep a list of all users who are authorized to use VTrckS and order vaccine on behalf of a specific provider
- The provider must be able to use the VTrckS Access guide to assist in determining acceptable methods to verify the identification of staff who are authorized to order vaccines on the provider’s behalf
- The documents that discuss the regulations related to the federal CDC systems are on the National Institute of Standards and Technology website at:
<http://csrc.nist.gov/publications/PubsSPs.html>

BORROWING AND RETURNING VACCINE

Providers that care for VFC-eligible and privately insured children in North Dakota must maintain two separate inventories of vaccines: privately purchased vaccine for the privately insured children and publicly-supplied vaccine for those who are eligible. Borrowing between the two inventories of vaccines may occur but must be a rare occurrence. **Note: The only vaccine not eligible for borrowing is the**

seasonal influenza vaccine since there is no guarantee that the influenza vaccine can be replaced within the same season.

CDC's expectation is that VFC-enrolled providers maintain adequate inventories of vaccine to administer to both privately insured and VFC-eligible children. The borrowing of vaccine must be due to an unforeseen delay or circumstance surrounding the vaccine that was ordered. Scheduling a mass vaccination clinic without having appropriate amounts of both state and private vaccine available on hand for the expected participants would not be considered an unexpected circumstance.

All borrow/return occurrences must be documented in the NDIIS. These include any instances where privately purchased vaccine is used to immunize a VFC-eligible child or vice versa. The provider must document why the vaccine was borrowed and must document the date the vaccine was replaced. The [VFC Vaccine Borrow/Return Report](#) must be used in addition to the borrow/return functionality in NDIIS and be kept on hand for a minimum of three years.

Borrowing activities will be monitored as part of the VFC compliance site visit.

- Documentation must occur when any vaccine is borrowed regardless of inventory origin.
- Two-way borrowing can be used, after approval from the NDDoH, by a VFC-enrolled provider with a patient population that is mostly VFC-eligible and has only a small number of privately insured children in order to prevent loss of privately purchased vaccine due to expiring vaccine. Privately purchased vaccine that is short-dated may be borrowed and administered to a VFC-eligible child and replaced with a longer-dated VFC dose. This must be documented in the NDIIS.
- The NDDoH requires that providers return any borrowed vaccine (whether private or state supply) within four weeks of the occurrence.

BORROWING AND RETURNING FAQ

Q: We gave private vaccine to a child because the last time the child was seen here, the family had private insurance. After we submitted the claim, however, we found out that the family no longer had insurance coverage. What should we do in this situation?

A: VFC eligibility screening must be done at *every* immunization visit to prevent these mistakes from happening. Since this child does not have health insurance, he/she is considered VFC-eligible and should have been given VFC vaccine. In this situation, the private vaccine administered to the child should be borrowed to the state supply. State-supplied vaccine should be returned to the private supply. These borrow/return transactions must be documented, both on the [VFC Vaccine Borrow/Return Report](#) and in the NDIIS (see checklist below).

Q: At our clinic, we rarely borrow between state-supplied and private vaccine inventories. It does happen occasionally, but the nurses just know to replace the vaccine they've used with doses from the other inventory. Do we still need to document this in NDIIS?

A: Yes. It is very important that all borrow/return transactions are documented, both in NDIIS and on the VFC Vaccine Borrow/Return Report. Failure to document this information will result in inaccurate data entry; doses of VFC vaccine will appear as if they are being administered to children who are not VFC-eligible, for example. This could potentially lead to an investigation for fraud and abuse of the VFC program.

To appropriately document a borrow/return transaction, all of the following must be completed:

- VFC Vaccine Borrow/Return Report
- Borrow dose(s) in NDIIS
- Return dose(s) in NDIIS
- Correct patient's record in NDIIS (lot number and VFC eligibility)

VACCINE PERSONNEL

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

PRIMARY VACCINE COORDINATOR: _____

BACKUP VACCINE COORDINATOR: _____

BACKUP VACCINE COORDINATOR: _____

These people must be responsible for the following:

- Monitoring and recording twice daily (in the morning and evening) 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.

VACCINE STORAGE, HANDLING & DISPOSAL GUIDELINES

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 2011, North Dakota providers reported wasting 1,778 doses of vaccine excluding influenza, which is approximately \$59,305.40 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.

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/recs/storage/guide/vaccine-storage-handling.pdf>. 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. Providers who choose to use dorm-style fridges in this way must have a written policy addressing the daily procedures and identifying responsible personnel. 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.

STORAGE REQUIREMENTS FAQ

Q: We used a dorm-style fridge for years and never had issues with keeping stable temperatures. Because of the VFC program requirements, we purchased a small refrigerator-only unit and have had troubles keeping the temperatures within the acceptable range. Can we switch back to the dorm-style fridge to store our vaccines?

A: No. Problems with the small refrigerator-only unit should be addressed with either the product manufacturer or a refrigeration specialist.

Q: We are a birthing facility and use a dorm-style fridge on the OB unit to store only doses of state-supplied hepatitis B vaccine that will be given during that day's (or night's) shift. Is this practice acceptable?

A: Yes, if temperatures are being checked twice daily in the unit and any unused vaccine is being returned to its main storage unit after the shift's end. A written policy must be in place for these situations.

GUIDELINES FOR PROPER STORAGE

The information in this section is vital to the proper storage of vaccines. Items in **red bold font** are checked by NDDoH staff members on VFC compliance site visits.

INSIDE THE STORAGE UNIT

Do not store food or beverages in a refrigerator that contains vaccines. If other biologicals (i.e., medications, blood products, etc.) must be stored in the same storage unit, vaccine should always be stored above the other 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. 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.**

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.

Store vaccine products that have similar packaging or names (i.e. DTaP and Tdap) in different locations to avoid confusion and medication errors. Store all opened and unopened vials of vaccine in their boxes so that their contents and expiration dates are easily identifiable. Open only one vial or box of a particular vaccine at a time to control vaccine usage and allow easier inventory control.

Rotate vaccines in the refrigerator/freezer so that the shortest dated vaccine is used first.

Once a month, check vaccine inventory for expiring vaccine. **Remove expired vaccine from the storage unit as soon as possible after its expiration date to prevent administration errors.**

STORING DILUENTS

Most vaccine diluents may be stored either at room temperature or in the refrigerator. Diluent for Pentacel, Menveo and ActHIB must be stored in the refrigerator. The diluent component for Rotarix must be stored at room temperature.

OUTSIDE THE STORAGE UNIT

Place a warning sign by the electrical outlet to prevent unplugging the refrigerator/freezer to help ensure that the refrigerator/freezer is not turned off ([see Appendix 1](#)). Also place a warning sign on the circuit breaker for the refrigerator/freezer.

Install PLUG GUARDS/PROTECTORS in outlets. This serves as an additional visual reminder to prevent power loss.

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).

STORAGE FAILURES

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(s) for efficacy of vaccine not stored properly ([see Appendix 3](#)).

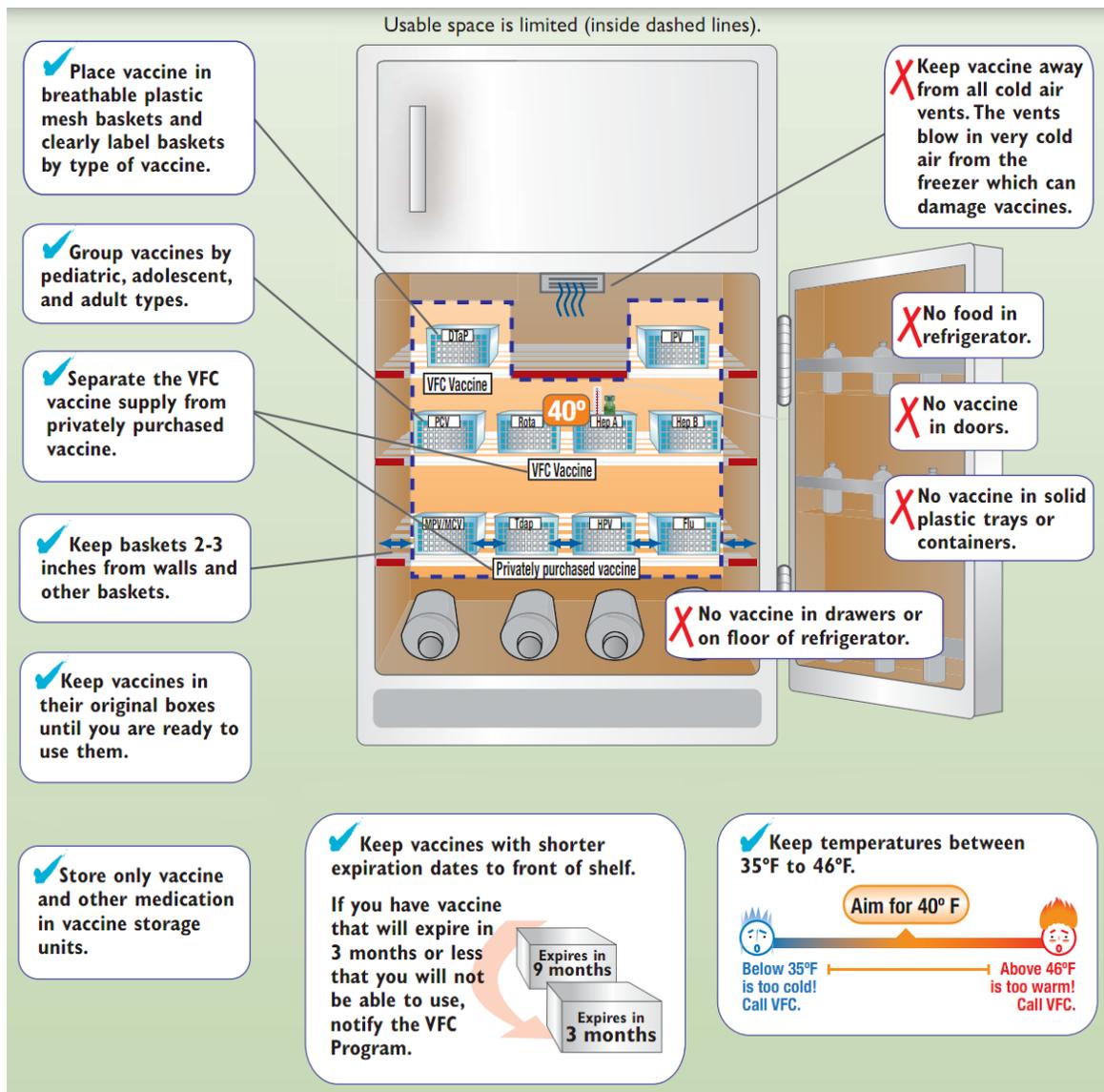
When a storage unit failure is identified or anticipated (such as a planned power outage) vaccine should be moved to an alternative location or storage unit if possible. Temperatures in the alternate storage unit must be monitored and documented. It is very important to document all actions taken for situations involving a storage unit failure, including the temperatures, times and vaccines potentially affected.

REFRIGERATED VACCINE

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

DT or DTaP	Hepatitis A	Influenza	PPV-23
DTaP/HBV/IPV	Hepatitis B	IPV	Rotavirus
DTaP/Hib/IPV	Human Papillomavirus	MCV-4	Td
DTaP/IPV	Hib	PCV-13	Tdap

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



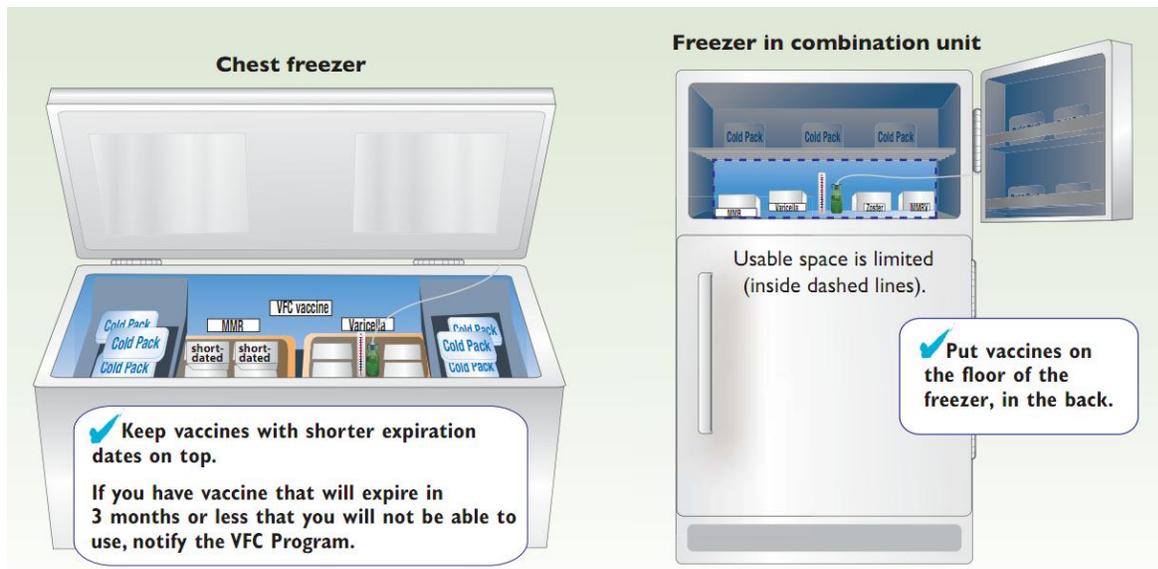
Adapted with permissions from the California Department of Public Health, Immunization Branch

FROZEN VACCINE

Varicella, MMRV, and shingles vaccines are required to be stored at a temperature of -15°C or $+5^{\circ}\text{F}$ 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

THERMOMETERS

Providers must monitor the temperature of their refrigerator/freezer with certified thermometers. **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.** See [Appendix 2](#) for guidance on purchasing new thermometers or calibrating current thermometers. Follow manufacturer's recommended schedule for recalibration of the certified thermometers.

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.

THERMOMETERS FAQ

Q: In the past, we received thermometers from the state health department. If we find that our thermometers are past their calibration date, can we request a replacement thermometer from the NDDoH?

A: No. Effective January 1, 2012, the North Dakota Department of Health no longer supplies thermometers to providers. Providers must either purchase acceptable thermometers or recalibrate the previously-supplied NDDoH thermometers.

Q: We recently had a VFC compliance site visit, and the reviewer told us that our thermometer is past its calibration date. Can we use the outdated thermometer as long as it is still working?

A: No. Providers are required to use certified, calibrated thermometers for all units storing state-supplied vaccines.

TEMPERATURE MONITORING

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 for each unit containing state-supplied vaccine.

Temperature logs must be kept on hand for a minimum of three years.

Actions must be taken and RECORDED 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.

INAPPROPRIATE OR UNKNOWN STORAGE ENVIRONMENTS

The North Dakota Immunization Program reviews temperature logs submitted by enrolled providers. The following situations may prompt action by the NDDoH:

- Temperatures not being documented twice per day when the clinic/practice is open.
- Out-of-range temperatures are recorded, and no documentation regarding any actions taken to correct or explain the temperature is provided.
- Out-of-range temperatures are recorded, but the documented actions taken are inadequate for the specific situation.

Verbal reporting of temperatures or actions taken for out-of-range temperatures is not acceptable. The NDDoH may contact the clinic/practice staff to obtain proper documentation and/or the vaccine manufacturers to determine the vaccines’ safety and efficacy following exposure to unknown or inappropriate temperatures.

Following investigation, the North Dakota Immunization Program reserves the right to invalidate any doses of vaccine that were administered after being exposed to unknown or inappropriate temperatures. The NDDoH will notify the clinic/practice of the changes made to the doses in the North Dakota Immunization Information System (NDIIS) and will recommend that a letter explaining the situation be sent to affected patients. If necessary, the NDDoH may send out this communication.

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. Indicate on the label of each vaccine vial the date and time it was reconstituted or first opened.

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 2014 -- valid until July 31, 2014).

Vaccines must be utilized until the expiration date.

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.

PROVIDER VACCINE MANAGEMENT PLANS

Providers are required to have a written vaccine management plan. All staff members should be familiar with both routine and emergency policies and procedures. Posting the plan on or near the vaccine storage unit would help staff members to know what to do in the event that primary or back-up vaccine coordinators are unavailable.

A plan template is included in the Prevention Partnership enrollment packet and can also be accessed at www.ndhealth.gov/Immunize/Providers/Forms. This should be reviewed and updated as needed and at least annually. NDDoH staff making compliance site visits will be reviewing provider vaccine management plans. 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

Notify the NDDoH if any vaccine must be wasted as a result of exposure to temperatures outside of the acceptable range. 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

1. Complete a [Non-viable Vaccine Return and Wastage Form](#) before returning unopened non-viable vaccine. This form can also be completed electronically: www.ndhealth.gov/Immunize/Providers/Wastage.aspx.
2. Make two copies of the form or confirmation page, one for your records and one for McKesson.
3. Prior to shipping non-viable vaccine, fax the form to the NDDoH Immunization Program at 701.328.2499.
4. If needed, a return label will be sent to you via mail. McKesson will send a return label along with UPS to pick up the return for providers who do not have a regularly scheduled pickup.
5. 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. Expired or otherwise wasted vaccine does not need to be shipped in a refrigerated state.
6. Providers should not directly contact UPS to schedule a pick-up, as this may result in the provider being charged for the shipping fees.
7. **DO NOT** ship viable vaccine to McKesson.
8. **DO NOT** ship viable or non-viable vaccine to the NDDoH.

VACCINE TRANSFER

Providers who have state-supplied vaccine that will not be used before expiration should attempt to 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. VFC or state-supplied vaccine must not be sent to providers who are not enrolled in the Prevention

Partnership program. If you have questions about whether a provider is enrolled, contact the Immunization Program.

Providers must transfer the vaccine in NDIIS when vaccine is transferred to another enrolled vaccine provider. 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 in a portable freezer designed for this purpose. Dry ice is no longer recommended for the transport of frozen vaccines. 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. 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. **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. 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 VFC-eligible population, provider inventory and doses administered reports.

Providers may only order according to their Tiered Order Frequency (TOF) as follows:

- High volume clinics – monthly
- Medium volume clinics – every other month
- Low volume clinics – quarterly
- Very low volume clinics – as-needed basis

Providers who are unsure of their TOF should contact the Immunization Program for assistance. Providers may not 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.

To prevent unnecessary vaccine wastage, providers should notify clinic staff that vaccine is being shipped to their clinic after they have ordered vaccine. Providers should allow 2-3 weeks for delivery.

VACCINE ORDERING FAQ

Q: We just received our VFC vaccine order and the person responsible for ordering the vaccines forgot to order rotavirus vaccine. Can we place an additional order for only rotavirus vaccine?

A: This type of situation can be prevented by making sure an inventory of the vaccines is done prior to the vaccine order being placed. Providers should attempt to determine whether their current supply is sufficient to last until the next order is received. If not, contact the Immunization Program to explain the situation and place an additional order of vaccine. Providers who frequently place multiple orders per month will receive follow-up education regarding proper inventory management.

Q: We ordered 80 doses of MCV4 and only received 20. Why?

A: Orders are approved based on the reported inventory and the previous month's number of doses administered. So, for example, if your clinic reported having 10 doses of MCV4 on hand and administering 8 doses of MCV4 in the previous month, only 20 additional doses would be necessary for an adequate three-month supply. When ordering for special situations (i.e., a planned mass

immunization clinic or anticipation of increased demand for back-to-school vaccinations), make a note in the Comments section of the order form.

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 and MMRV vaccines are shipped directly to providers from the vaccine manufacturer.

Vaccine shipments from the NDDoH via McKesson are recorded in the NDIIS, which includes the lot number, expiration date, doses sent and the provider to whom the vaccine is sent.

Since the NDDoH does not receive shipping information on direct-ship vaccines (varicella and MMRV), providers must notify the NDDoH when a frozen shipment is received so the information can be entered into the NDIIS. [Email Teri Arso](mailto:tarso@nd.gov) (tarso@nd.gov), including your provider number and the lot number, expiration date and number of doses received.

Providers are responsible for entering privately-purchased vaccine lot numbers into NDIIS. The NDIIS automatically differentiates privately-purchased lot numbers entered by providers from state-supplied lot numbers by adding “– Private” to the private lot number. State-supplied lot numbers appear as-is.

VACCINE DISTRIBUTION FAQ

Q: Our office days and hours vary from week to week. How can we make sure that the shipment will arrive when we're in the office?

A: If your practice has irregular hours, make sure to note this on the order form when placing an order for vaccines. Note the days and times that you will be available to accept your vaccine delivery within the next two weeks. Providers who anticipate being unavailable at the time of vaccine delivery should make alternative arrangements for the vaccine being delivered (i.e., having the vaccine delivered to another VFC-enrolled provider who agrees to accept your shipment).

RECEIVING VACCINE

It is the responsibility of the provider to arrange for someone to be available 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.

Providers should have written protocols (included in the vaccine management plan) 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.

RECEIVING VACCINE FAQ

Q: Our packing slip states that we received 10 doses of Hib vaccine, but we didn't receive any. What should we do?

A: Contact the NDDoH immediately to report any discrepancies between the packing slip and your actual shipment. The NDDoH will work with McKesson to make sure that a replacement shipment is sent as soon as possible.

Q: The vaccine shipment was delivered on a day when the primary vaccine contact was out. The other staff members in the office that day were unsure of what to do with the vaccine, so the vaccine wasn't unpacked until the following business day. What should we do?

A: First, keep the potentially spoiled vaccine separate from the other vaccines in the refrigerator. Clearly mark the vaccine with a "DO NOT USE" sign until the vaccine's viability can be confirmed. Call all vaccine manufacturers ([see Appendix 3](#)) to determine vaccine viability. They will need to know specifics surrounding the situation, including what time the delivery was received, the room temperature and the time the vaccine was stored in a proper environment.

To prevent this situation from happening in the future, all staff members should be trained on how to properly receive vaccine shipments.

VACCINE PACKAGING/SHIPPING

There are a variety of materials available to ensure that vaccines are protected and are kept at the appropriate temperature during transport. 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. Because the use of dry ice is no longer recommended for transporting frozen vaccines from provider offices, the North Dakota Immunization Program does not allow shipping or transporting of frozen vaccines unless a portable unit designed for frozen vaccine storage is used.

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. 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.

APPENDICES

1. **“Do Not Disconnect” Warning Signs**
2. **Guidance for Purchasing and Calibrating Thermometers**
3. **Vaccine Manufacturers’ Quality Control Phone Numbers**

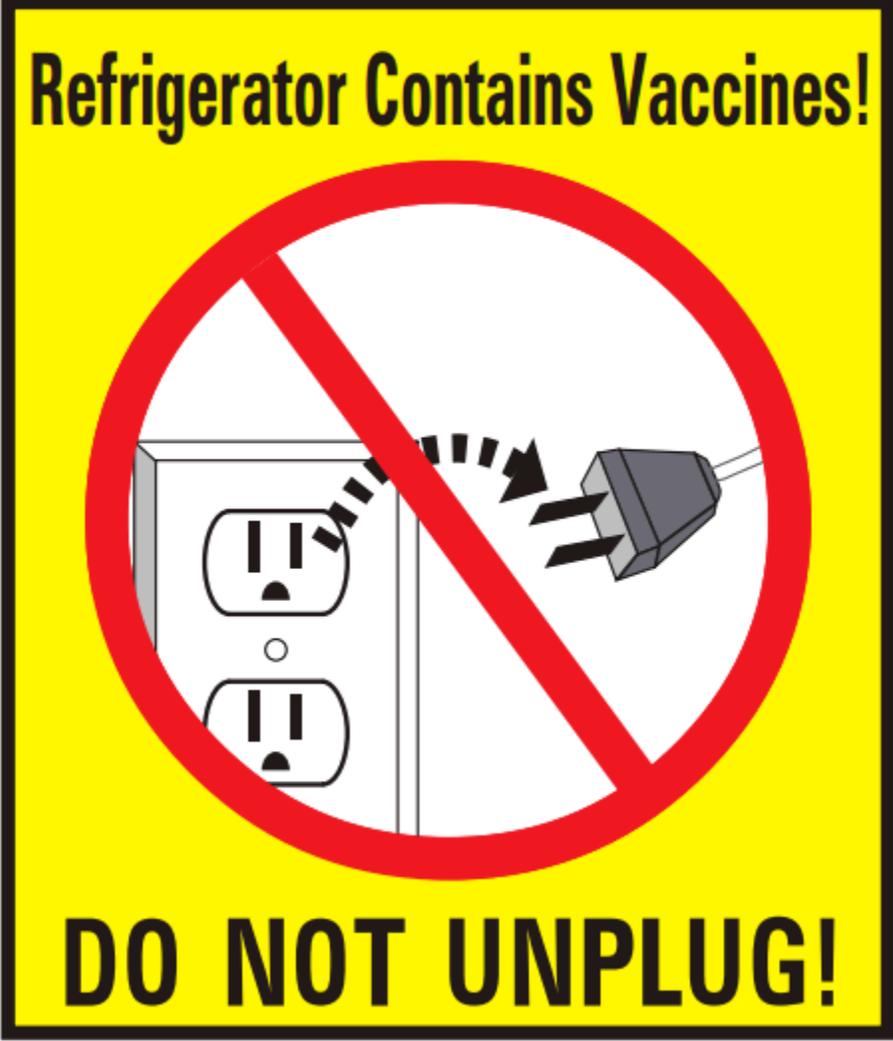
WARNING
**Do not unplug the refrigerator/freezer
or break circuit.
Expensive vaccine in storage.**



DO NOT UNPLUG!

In event of electrical problem, immediately contact:

Refrigerator Contains Vaccines!



DO NOT UNPLUG!

GUIDANCE FOR PURCHASING AND CALIBRATING THERMOMETERS

Providers are required to have certified and calibrated thermometers in all refrigerator and freezer compartments used for VFC and other publicly-funded vaccine storage in order to monitor temperatures. Certified and calibrated thermometers are available in a variety of types including digital, bio-safe liquid, continuous and minimum/maximum. The NDDoH recommends providers use continuous tracking thermometers when possible.

Instead of purchasing new thermometers, providers may choose to recalibrate previously supplied NDDoH thermometers as needed. The blue sticker on the back of NDDoH-supplied thermometers lists the calibration expiration date and the contact information for the company. As of November 2011, the cost to recalibrate NDDoH-supplied thermometers is \$17.50 and an additional \$16.00 in shipping and handling.

The VFC Program requires a second calibration process that is documented with a certificate that comes with the product. Each device is to be covered by a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are traceable to an ISO/IEC 17025 accredited testing laboratory, to National Institutes of Standards and Technology (NIST) or to another internationally recognized standards agency.

Providers are responsible for ensuring that thermometers are recalibrated as needed based on expiration dates. Recalibration means the thermometer was tested and adjusted to keep its accuracy after purchase. Most manufacturers recommend recalibration every one or two years. Providers should contact the manufacturer of the thermometer for instructions regarding recalibration procedures.

Certified and calibrated thermometers are available from a number of suppliers and manufacturers. A chart follows giving a sample list of suppliers/manufacturers that currently offer certified and calibrated thermometers with valid documentation. The NDDoH does not recommend or endorse products or manufacturers. This list is a courtesy and is not inclusive of all manufacturers. Providers may purchase thermometers not manufactured by companies on this list but that also have certificates of calibration that meet program requirements. When choosing a certified and calibrated thermometer, be sure to consider the cost and frequency of required recalibration.

COMPANY	WEBSITE	PHONE
Fisher Scientific	www.fishersci.com	1-800-766-7000
DeltaTrak	www.deltatrak.com	1-800-962-6776
Control Solutions	www.vfcdataloggers.com	1-888-311-0636
Dickson	www.dicksondata.com	1-800-323-2448
Streck	www.streck.com	1-800-228-6090
Control Company	www.control3.com	1-281-482-1714

Vaccine Manufacturers' Quality Control Phone Numbers

<p>GlaxoSmithKline 800.806.9364</p> <ul style="list-style-type: none"> • Infanrix® • Kinrix® • Pediarix® • Cervarix • Boostrix® • Havrix® • Engerix-B® • Twinrix® • Rotarix® 	<p>Merck 877.829.6372</p> <ul style="list-style-type: none"> • PedvaxHIB® • VAQTA® • GARDASIL® • MMR-II® • PNEUMOVAX 23® • RECOMBIVAX® • RotaTeq® • VARIVAX® • ZOSTAVAX® • ProQuad® 	<p>sanofi pasteur 800.822.2463</p> <ul style="list-style-type: none"> • DAPTACEL® • DECAVAC® • Pentacel® • ADACEL® • ActHIB® • I-POL® • Menactra®
<p>Massachusetts Biological Labs 617.474.3000</p> <ul style="list-style-type: none"> • Td 	<p>Novartis 800.244.7668</p> <ul style="list-style-type: none"> • Menveo® 	<p>Wyeth 800.999.9384 (opt 1)</p> <ul style="list-style-type: none"> • Prevnar 13®
		<p>MedImmune 877.633.4411</p> <ul style="list-style-type: none"> • FluMist®

When a temperature in a vaccine storage unit is discovered outside of the recommended ranges, it is vital to contact the vaccine manufacturers to determine the viability of the vaccines. If vaccine must be wasted or an expiration date for a vaccine must be changed, contact the North Dakota Immunization Program.