North Dakota

Immunization Program

2014

Vaccine

Management

Plan

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Division of Disease Control

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INTRODUCTION

It is important for providers to thoroughly review the North Dakota Vaccine Management Policy in order to understand the requirements of the Vaccines For Children (VFC) program and to ensure proper vaccine storage and handling. 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 vaccination practices to contribute to the health and wellness of the people of North Dakota.

VACCINES FOR CHILDREN PROGRAM BACKGROUND

The 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. OBRA was passed by Congress on August 10, 1993, and the VFC program became operational October 1, 1994.

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.

VFC PROGRAM REQUIREMENTS

All of the following requirements listed are included on the 2014 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 the following:

1. **I will annually submit a provider profile representing populations served by my practice/facility. I will submit more frequently if a) the number of children served changes or b) the status of the facility changes during the calendar year.**

   Providers and staff must understand:
   - The annual provider profile is auto-populated with NDIIS doses administered data based on the previous calendar year.
   - It is the provider's responsibility to notify the immunization program if client population size or status of the facility changes.

2. **I will screen patients and document eligibility status at each immunization encounter for VFC eligibility (i.e., federally or state vaccine-eligible) and administer VFC-purchased vaccine by such category only to children who are 18 years of age or younger who meet one or more of the following categories:**
    A. **Federally Vaccine-eligible Children (VFC eligible)**
        1. **Are an American Indian or Alaskan Native;**
        2. **Are enrolled in Medicaid;**
        3. **Have no health insurance;**
        4. **Are underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only). Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC), or Rural Health Clinic (RHC) or under an approved deputization agreement.**
    B. **State Vaccine-eligible Children**
        1. **In addition, to the extent that my state designates additional categories of children as "state vaccine-eligible", I will screen for such eligibility as listed in the addendum to this agreement and will administer state-funded doses (including 317 funded doses) to such children.**

Children aged 0 through 18 years that do not meet one or more of the eligibility federal vaccine categories (VFC eligible), are <u>not</u> eligible to receive VFC-purchased vaccines.

Providers and staff must understand:

- The eligibility requirements for the VFC program.
- The eligibility requirements for patients who are state vaccine-eligible. The vaccine coverage table can be found at www.ndhealth.gov/Immunize/Providers/Forms.htm.
- 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 charged to privately insured children.
- NDDoH staff will monitor the screening for eligibility requirements during the VFC compliance site visit by reviewing a random sample of charts for 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).

3. **For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedule, 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 for the child;**
    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.

4. **I will maintain all records related to the VFC program for a minimum of three years and upon request make these records available for review. VFC records include, but are not limited to, VFC screening and eligibility documentation, billing records, medical records that verify receipt of vaccine, vaccine ordering records, and vaccine purchase and accountability records.**

    Providers and staff must understand:
    - All records related to the VFC program must be maintained for the required time period.

5. **I will immunize eligible children with publicly supplied 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 and on the borrow/return form.

6. **I will not charge a vaccine administration fee to non-Medicaid federal vaccine eligible children that exceeds the administration fee cap of $20.99 per vaccine dose**. **For Medicaid children, I will accept the reimbursement for immunization administration set by the state Medicaid agency or the contracted Medicaid health plans.**

   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.
   - Medicaid may not reimburse the total administration fee charged to Medicaid.

7. **I will not deny administration of a publicly purchased vaccine to an established patient because the child's parent/guardian/individual of record 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.

8. **I will 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.

9. **I will comply with the requirements for vaccine management including:**
   a. **Vaccine ordering and maintaining appropriate vaccine inventories;**
   b. **Not storing vaccine in dormitory-style units at any time;**
   c. **Storing vaccine under proper storage conditions at all times. Refrigerator and freezer vaccine storage units and temperature monitoring equipment and practices must meet the North Dakota Department of Health storage and handling recommendations and requirements;**

d. **Returning all spoiled/expired public vaccines to CDC's centralized vaccine distributor within six months of spoilage/expiration.**

Providers and staff must understand:

- The need to comply with all requirements outlined in the NDDoH Vaccine Management Policy.
- NDDoH Vaccine Loss Policy.
- NDDoH Fraud and Abuse Policy.
- How to order vaccine using the North Dakota Immunization Information System (NDIIS) and how to submit monthly temperature logs.
- The procedure to return vaccines to the centralized distributor.

10. **I agree to operate within the VFC program in a manner intended to avoid fraud and abuse. Consistent with "fraud" and "abuse" as defined in the Medicaid regulations at 42 CFR §455.2, and for the purposes of the VFC Program:**

    Fraud: is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

    Abuse: provider practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid program, (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient); or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

    Providers and staff must understand:

    - The sections of the Vaccine Management Policy that explains the fraud and abuse and how it is detected, reported and followed up.
    - Activities that are deemed as fraudulent or abusive.

11. **I will participate in VFC program compliance site visits including unannounced visits, and other educational opportunities associated with VFC program requirements.**

12. **For providers with a signed deputization Memorandum of Understanding between a FQHC or RHC and the North Dakota Department of Health to serve underinsured VFC-eligible children, I agree to:**

    i. **Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit;**
    ii. **Vaccinate "walk-in" VFC-eligible underinsured children; and**

iii. **Report required usage data.**

Note: "Walk-in" in this context refers to any underinsured child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve underinsured patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations them the policy would apply to underinsured patients as well.

Providers and staff must understand:

- The 28 local public health units in North Dakota are the only VFC enrolled providers that are deputized to administer VFC vaccine to underinsured children.
- The NDDoH supplies 317 vaccine to private providers to vaccinated underinsured children.

13. **For pharmacies, urgent care, or school located vaccine clinics, I agree to:**
    a. **Vaccinate all "walk-in" VFC-eligible children and**
    b. **Will not refuse to vaccinate VFC-eligible children based on a parent's inability to pay the administration fee.**

Note: "Walk-in" in this context refers to any VFC-eligible child who presents requesting a vaccine; not just established patients. "Walk-in" does not mean that a provider must serve VFC patients without an appointment. If a provider's office policy is for all patients to make an appointment to receive immunizations them the policy would apply to VFC patients as well.

14. **I agree to replace vaccine purchased with state and federal funds (VFC, 317) that are deemed non-viable due to provider negligence on a <u>dose-for-dose</u> basis.**

Providers and staff must understand:

- The section of the Vaccine Management Policy covering vaccine loss and when replacement of doses may be necessary.
- How to report nonviable vaccine.

15. **I will document demographic, VFC and state eligibility and immunization information in the North Dakota Immunization Information System (NDIIS) within four weeks of administration, in accordance with N.D.C.C 23-01-05.3.**

Providers and staff must understand:

- All demographic, VFC and state eligibility, vaccine funding source (private or public) and immunization information should also be documented on a Vaccine Administration Record (VAR), Patient Eligibility Screening Form or in the facility's Electronic Medical Record (EMR).

16. **I agree that all records, regardless of physical form, and the accounting practices and procedures of my 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 in accordance with N.D.C.C. 54-10-19.

17. **I understand this facility or the North Dakota Department of Health may terminate this agreement at any time. If I choose to terminate this agreement, I will properly return any unused federal vaccine as directed by the North Dakota Department of Health.**

    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.

VFC ELIGIBILITY

All patients should be screened for VFC eligibility at every immunization encounter. All demographic, VFC and state eligibility and immunization information should also be documented in the NDIIS AND on a Vaccine Administration Record (VAR), Patient Eligibility Screening Form or in the facilities Electronic Medical Record (EMR). **VFC vaccine should only be given to children who are 18 years of age or younger who meet one or more of the following categories:**

a. are an American Indian or Alaskan Native
b. are enrolled in Medicaid
c. have no health insurance
d. are underinsured OR

Persons who meet one or more of the following categories are considered state vaccine-eligible and are not eligible for VFC-purchased vaccine:

a. underinsured children at private clinics;
b. insured newborns immunized with the birth dose of hepatitis B at enrolled birthing hospitals;
c. insured children at participating health units;
d. uninsured and underinsured adults for Td, Tdap, HPV, PPSV23, MCV4 and MMR.

An updated vaccine coverage table can be found at www.ndhealth.gov/Immunize/Providers/Forms.htm.

Underinsured children may only be vaccinated with VFC vaccine at a rural health center (RHC), federally qualified health center (FQHC), or deputized local public health unit due to changes in federal policy regarding delegation of authority. Delegation of Authority Agreements from 2007 between Coal Country Community Health Center and private providers in North Dakota are no longer valid. Federal 317 vaccine may be used to vaccinate underinsured children at private provider offices in North Dakota.

Private providers should continue to vaccinate underinsured children with state-supplied vaccine and enter the doses into the NDIIS as underinsured.

For data entry in NDIIS the following VFC eligibility options should be chosen:

American Indian: Race of the child is American Indian and this child is receiving state-supplied vaccine. Privately insured American Indian children should be entered as "not eligible" at private provider offices. Universal local public health units must always enter "American Indian" for the VFC eligibility category for these children.

Medicaid: Medicaid enrolled or Medicaid-Eligible.

No Insurance: Child does not have health insurance.

Underinsured: A child who has health insurance, but the coverage does not include vaccines; a child whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only).

Not Eligible: Privately insured children receiving privately purchased immunizations. This status would also apply to privately insured adults or uninsured adults receiving privately purchased vaccines not included in the 317 program.

Other State Eligible: 1) Privately insured children receiving vaccinations at local public health units. 2) Privately insured infants receiving the birth dose of hepatitis B vaccine at enrolled birthing hospitals. 3) Uninsured or underinsured adults receiving vaccines through the 317 program (Td, Tdap, HPV, MCV4, MMR and PPSV23).

For further questions about VFC eligibility please consult the VFC Questions and Answers section or http://www.ndhealth.gov/Immunize/Providers/Forms.htm

VFC PROVIDER ENROLLMENT AND RECRUITMENT

Any provider who has the potential to vaccinate a VFC or state-eligible patient is eligible to participate in the VFC or state-supplied vaccine program.

In order to participate in the state-supplied vaccine program the provider must:

- Not employ anyone found to be on the Center for Medicare and Medicaid (CMS) List of Excluded Individuals and Entities (LEIE). The searchable database can be found here exclusions.oig.hhs.gov/.
- Enroll annually.
- Serve a VFC and/or state eligible population.
- Have a valid medical license in the state of North Dakota.
- Be able to adequately store vaccine and vaccine products.
- Safely administer vaccine.
- Follow the ACIP recommended immunization schedule.

- Follow all VFC program requirements for reporting.

The Immunization Program will check the LEIE database and verify state licensure each year with annual enrollment and quarterly for updated staff or staff turnover. Once a new provider enrolls the LEIE database and licensure will also be checked.

RECRUITMENT OF VFC PROVIDERS

The NDDoH Immunization Program will recruit any provider who expresses interest in participating in the VFC program and has the potential to vaccinate VFC or state-eligible patients. Through professional memberships, collaboration with other state agencies and active outreach the immunization program will try to identify and recruit at least 5 new providers each calendar year until 100% of North Dakota providers that see pediatric patients have been enrolled in the VFC program. Priority will be given to providers who see a large number of children, who see a largely VFC eligible population or a practice that is geographically located in an area with few or no other health care options.

ENROLLING IN THE VFC PROGRAM

Once a new VFC provider is identified and is eligible (see VFC eligibility) for providing VFC or state vaccine an enrollment visit is scheduled with the corresponding regional VFC coordinator. At the same time current enrollment documents are mailed to the provider to sign and return. Enrollment documents consist of the most recent CDC enrollment form, a provider profile and a storage certification form. The forms must be completed and originals mailed back to the immunization program. The new provider is also informed that they should begin monitoring temperatures as soon as possible. Before vaccine orders will be processed the immunization program must have one week of stable, in-range temperatures. The primary and secondary immunization contact should also view two modules produced by the CDC focusing on the VFC program and proper storage and handling. Once the two modules have been viewed a short post-test should be taken on the Immunization Program's website. Once the post-test is taken the Immunization Program will receive notification of the completed test.

VFC REENROLLMENT

Enrollment is done annually, generally in February. Every enrolled provider from the previous year will receive an enrollment packet in the mail with three required forms that must be completed and the originals returned to the immunization program. The required forms include:

- The enrollment form which is signed by the facility's medical director agreeing to all VFC program requirements.
- The provider profile outlines shipping information and a pre-populated estimate of VFC clients. This form is prepopulated with NDIIS data from the previous calendar year. Providers are asked to review the numbers and contact the Immunization Program with questions or concerns about

their estimated VFC population. The number of patients per provider will be determined using a formula based on the number of doses administered by VFC eligibility type:

Age Group	Vaccine	Criteria
<1 year	Pentacel or Pediarix	(# doses)/3
1 – 6 years	MMR and MMRV	# doses total
7 – 18 years	Td and Tdap	# doses total

- The third and final required enrollment document is the vaccine storage certification form. This lists what type of vaccine storage equipment a provider has as well as calibration dates for current thermometers.

If original copies are not received by the due date providers will be unable to order VFC and state vaccine until they have been returned. All providers must also complete an educational component each year. There are two modules produced by the CDC focused on storage and handling and the VFC program. For each facility the primary and secondary vaccine contact must complete the trainings along with a posttest provided by the immunization program. If this is not done prior to enrollment the provider will not be able to reenroll or receive VFC or state vaccine until this is completed.

All providers who do not return enrollment paperwork or complete the required annual training component will be contacted to determine the reason for not meeting the requirements and whether they will continue in the VFC program.

VACCINE ORDERING AND DISTRIBUTION

VACCINE ORDERING

Providers submit all vaccine orders using the NDIIS. No paper or online orders are accepted. Providers may still place material orders online at: www.ndhealth.gov/Immunize/Providers/Order.htm.

Vaccine orders will not be processed until the NDDoH has received monthly temperature logs from the provider. The NDIIS vaccine ordering module populates doses administered and current inventory on hand. Providers have the capability to manually enter doses on hand in case there is a discrepancy from what NDIIS has for on hand inventory. Providers should note that by changing the inventory on hand in the NDIIS ordering module does not change the actual inventory in NDIIS. Providers must still adjust inventories in NDIIS provider lot distribution.

Before proceeding to the vaccine ordering section of the ordering module providers must verify that contact information and business hours are correct. This will determine who should be contacted when the vaccine arrives as well as when it can be delivered.

The vaccine ordering module will automatically calculate a suggested order minimum and maximum based on doses administered and current inventory on hand. The suggested order minimum will be enough vaccine to immunize one month of clients. The suggested order maximum will be enough for

three months. Providers are required to leave a comment if ordering over the order maximum. Providers are not guaranteed to receive anything over a three month inventory. 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 not place more than one order per month except in the case of an emergency. Please call the Immunization Program 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 up to 2-3 weeks for delivery.

There is a different process for ordering influenza vaccine from other vaccines. The Immunization Program will request providers to pre-book influenza vaccine for VFC or state eligible children in the spring of the year prior to the following influenza season (example: pre-book in February 2014 for distribution of influenza vaccine in October 2014). Once influenza vaccine is available for distribution, the NDDoH will allocate doses to providers based on their pre-book and vaccine availability. For example, if 20% of the total state's Flumist pre-book is available, then each provider will be allocated approximately 20% of their prebook (some variability may exist due to rounding). After all of the pre-booked vaccine has been allocated, the NDDoH will then allow for additional orders of influenza vaccine.

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 month. 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 allowing for a three month inventory on hand. So, for example, if your clinic reported having 10 doses of MCV4 on hand and administering eight 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 vaccine ordering module.

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. Varicella and MMRV vaccines are shipped directly to providers from Merck.

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

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. To further separate private lot numbers they are also highlighted in green when adding a lot number to a patient record. State-supplied lot numbers appear with a "-State" at the end of the lot number. Providers should make sure that data entry staff choose the correct lot number (private vs. state-supplied) in NDIIS when entering doses.

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: Each time you place an order in the NDIIS vaccine ordering module you are required to enter the days your clinic is open as well as business hours. If you know that you will be closed on certain days or times please note this in this section of the ordering screen. 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).

VACCINE MANAGEMENT

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 weekly.
- Receiving all state-supplied vaccine shipments or ensuring that others who may receive the order are aware of the procedure for receiving vaccine.
- Training of other staff that are responsible for administering vaccine should be the responsibility of the primary vaccine coordinator.
- A log sheet should be kept with the vaccine management plan noting which staff have participated in immunization related training.
- Contacting the immunization program as soon as there is a change in vaccine coordinators.
- Utilizing and maintaining proper vaccine storage equipment and temperature monitoring devices.
- Performing vaccine management practices through proper ordering and inventory management.
- Developing and maintaining an organizational system to distinguish between public and private stock.
- Post appropriate signs in order to protect vaccine supply from loss of power.

Each year the primary and secondary VFC contact from each enrolled facility will be required to complete two online modules produced by the CDC. One module contains information on vaccine storage and handling and the other on requirements of the Vaccines for Children program. All staff who work with vaccines should attend the training, but at least two contacts from each facility are required. The online training will be posted on the immunization program webpage and will need to be completed by each facility prior to enrollment or other specified date by the immunization program. After viewing the module providers will need to fill out a post-test found on the immunization program website. This is separate from the CDC post-test for nursing credit. The information from this page will be sent to the immunization program and will provide documentation that the facility has met this requirement.

IMPORTANCE OF STORAGE AND HANDLING

Proper vaccine storage and handling is important to ensure the efficacy of vaccines in preventing vaccine-preventable diseases. Failure to store vaccines properly can lead to an inadequate immune response resulting in the potential for disease outbreaks and the public's mistrust of vaccines.

Good storage and handling practices are also important in order to prevent the wastage of increasingly expensive vaccines. In 2013, North Dakota providers reported wasting 3,258 doses of vaccine, excluding influenza, which is approximately $149,156.70 worth of vaccine. This is only the reported wastage for publicly purchased vaccine. 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 Storage and Handling Toolkit* published by the CDC. The toolkit can be found at www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf

Information in addition to these recommendations is listed below. These recommendations are NOT a substitute for the package insert included with each biological.

Due to findings by the Office of Inspector General showing that many providers' offices in the United States have unacceptable storage and handling procedures, the CDC is now requiring each state to conduct unannounced storage and handling visits. These visits will contain the same basic elements as other VFC visits, but the provider offices will not be notified beforehand. Storage and handling procedures will be the main point of the visit, along with chart reviews. Providers will receive corrective actions for items that are not being done in accordance with VFC policy. Providers will then be required to be compliant within four weeks of notification of corrective actions.

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. The CDC recommends stand-alone, self-contained units that only refrigerate or only freeze. The use of stand-alone units is considered a best practice. However, combination refrigerator/freezer (household) units are acceptable for vaccine storage if the refrigerator and freezer components each have a separate external door. The use of the freezer component in combination units is not recommended for frozen vaccine. When purchasing new equipment, providers should look for refrigerators and freezers that have frost-free or automatic defrost cycle units. Providers are encouraged to contact the North Dakota Immunization Program for guidance prior to purchasing new refrigerators or freezers. Providers may find tools to help them decide which refrigerators, freezers, thermometers and transport equipment to purchase on the immunization program website at http://www.ndhealth.gov/Immunize/Providers/Forms.htm. After purchasing a new refrigerator or freezer, providers should monitor and document temperatures in the unit twice daily for one week prior to storing vaccine in the unit.

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 CDC no longer allows VFC vaccine or other vaccine purchased with public funding to be stored in dorm-style fridges under any circumstance. 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 any storage of vaccine because they do not maintain proper temperatures and pose a high risk of freezing vaccine.

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 near the walls or the top of the refrigerator. Coils in the walls or the air vent in the top of the refrigerator might be colder than the rest of the refrigerator and could freeze vaccines. Immunizations should be stored as centrally in the storage unit as possible.

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. Label pediatric and adult versions of the same

vaccine clearly to avoid confusion. Attach labels directly to the shelves on which the vaccines are placed or by labeling containers in which packages for the same vaccine type are placed. 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.

Store VFC vaccines separately from private pediatric and adult vaccines. Label VFC vaccines, so they won't accidentally be administered to non-VFC eligible children or adults.

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

Remove expired vaccine from the storage unit as soon as possible after its expiration date to prevent administration errors. Weekly, check vaccine inventory for expiring vaccine and rotate stock so the shortest outdates are located in the front.

STORING DILUENTS

Most vaccine diluents may be stored either at room temperature or in the refrigerator but there are a few exceptions for vaccine diluent that must be stored in the refrigerator.

Must be refrigerated: ActHib, Menomune (MPSV4), Menveo (MCV4), Pentacel (DTaP-IPV/Hib).

Refrigerate or room temperature: Hiberix (Hib), MMR, MenHibrix, ProQuad (MMRV), Rotarix (RV1) Varivax (Var), and Zostavax (HZV).

OUTSIDE THE STORAGE UNIT

Place a warning sign by the electrical outlet to prevent the refrigerator/freezer from being unplugged or turned off (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 (**Appendix 2**).

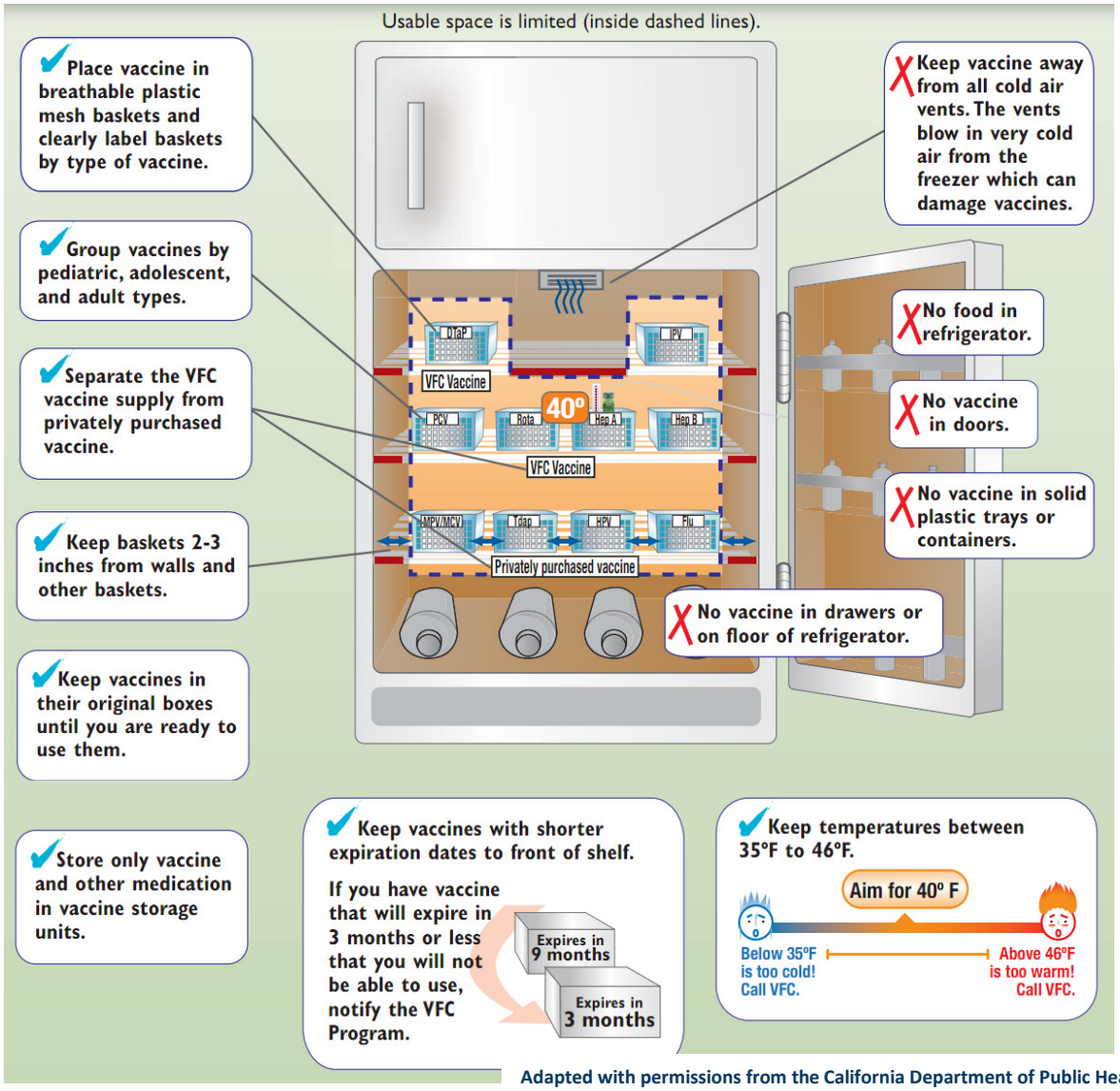
When a storage unit failure is identified or anticipated (such as a planned power outage) vaccine should be moved to an alternative location or storage unit if possible. Temperatures in the alternate storage unit must be monitored and documented. It is very important to document all actions taken for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

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.

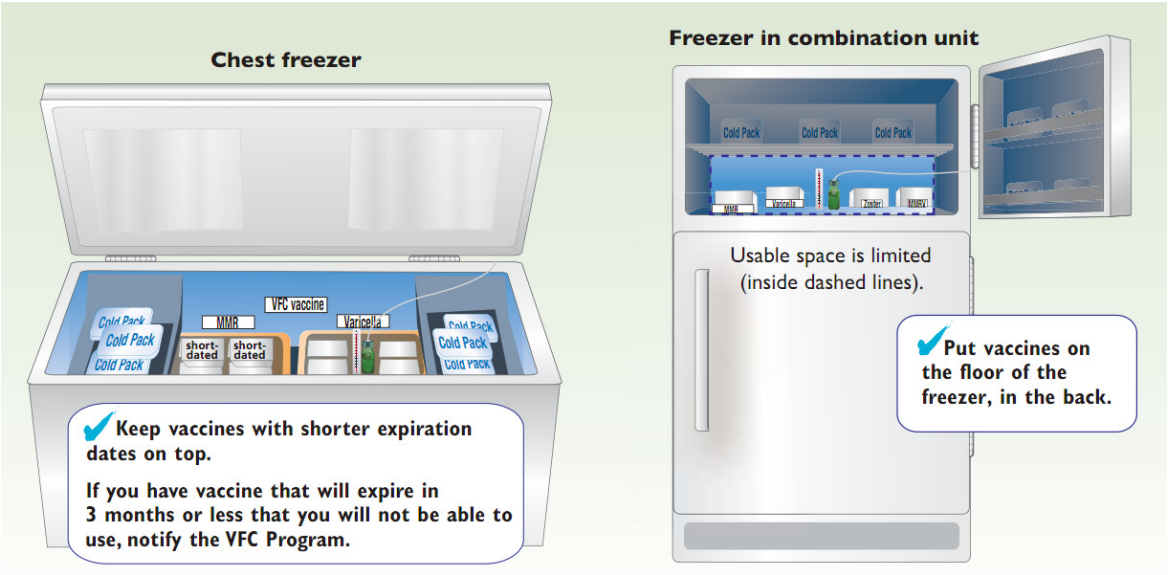


Adapted with permissions from the California Department of Public Health, Immunization Branch

FROZEN VACCINE

Varicella, MMRV, and zoster vaccines are required to be stored at a temperatures between -58° F and +5° F (-50° C and -15° C). Discard reconstituted varicella, MMRV and zoster vaccine after 30 minutes. Do not freeze reconstituted varicella, MMRV or zoster vaccine.

Protect varicella, MMRV and zoster 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. For guidance on purchasing new thermometers or calibrating current thermometers please visit www.ndhealth.gov/Immunize/Providers/. Providers are encouraged to contact the North Dakota Immunization Program for guidance prior to purchasing new thermometers. Follow manufacturer's recommended schedule for recalibration of the certified thermometers.

Providers must keep certificates of calibration for vaccine storage thermometers on hand, as the certificates will be reviewed during VFC site visits. Certificates of calibration must meet certain criteria in order to be considered acceptable. They must meet all criteria from lists A **OR** B to meet the requirement.

A: Come from an ILAC-accredited laboratory and contain all of the below items:

- Name of the device.
- Model number.

- Serial number.
- Date of calibration (report or issue date).
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/-1 F (0.5 C).

B: If from a non-ILAC-accredited laboratory it must contain all of the below items:

- Name of device.
- Model number.
- Serial number.
- Date of calibration.
- Measurement results for the device.
- Measurement results indicate unit passed test and the documented uncertainty is within suitable limits (recommended uncertainty = +/-1 F (0.5 C).
- A statement that calibration testing conforms to ISO 17025.

If the certificate of calibration does not have an expiration date, the date of expiration will be one calendar year from the date of calibration or issue date. There must always be a certified, calibrated thermometer in a refrigerator or freezer that contains vaccine. Providers should have a back-up certified, calibrated thermometer to use when the primary thermometer is sent back to be recalibrated. Starting in 2015 a back-up certified, calibrated thermometer will be required.

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. The CDC recommends the use of a digital thermometer with a biosafe glycol-encased probe that is able to provide continuous data monitoring information in an active display and is placed on the outside of the unit door, allowing for reading temperatures without opening the unit door. The data stored in the thermometer should be easily downloadable for review. The probe should be detachable to allow the downloading of information without removing the probe from the storage unit. The digital data logger should also include:

- Alarm for out of range temperatures
- Current temperature as well as minimum and maximum temperatures
- Reset button
- Low battery indicator
- Accuracy of +/- 1°F (0.5°C);
- Memory storage of at least 4000 readings, devices will not rewrite over old data and stops recording when memory is full;
- User programmable logging interval (or reading rate)

THERMOMETERS FAQ

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). It is also recommended to review and record minimum and maximum temperature readings at the beginning of the work day ensuring that refrigerator and freezer temperatures have been in the appropriate range. Twice-daily temperature monitoring and recording is required even if a continuous graphing/recording thermometer or a digital data logger is used. Post a temperature-recording chart on your refrigerator/freezer to record the temperatures. For copies of refrigerator and freezer temperature-recording charts please visit www.ndhealth.gov/Immunize/Providers/Forms.htm. Copies of temperature recording charts must be submitted to the NDDoH monthly **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 effected 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. The description of actions taken should include the date and time of occurrence, ambient room and storage unit temperatures, description of the problem, action taken, outcome, and the initials of the person documenting the information.

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 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 zoster must be administered within 30 minutes after reconstitution. Discard reconstituted vaccine if not used within 30 minutes.

Vaccine Information Statements (VIS) should be given at each immunization encounter and for every immunization given. The immunization program does not provider copies of VISs for provider offices. The immunization program does notify providers of where to find VISs and when VISs change. This notification occurs through the quarterly immunization newsletter and through the immunization list-serve. On each compliance site visit all VIS dates are checked to ensure provider offices have the most recent copy. If a provider is using an old version or not supplying VISs they will receive corrective actions and must demonstrate that they have corrected the issue.

By North Dakota law all immunizations administered to those 18 and younger must be entered into NDIIS within 4 weeks of administration. VFC eligibility is a required field in NDIIS and is entered at the dose level. All required fields must be completed in NDIIS, so therefore the vaccine administration record or electronic health record must contain all fields that NDIIS requires.

Required NDIIS fields include:

- First, middle and last name
- Race
- Ethnicity
- Date of Birth
- Gender
- Address
- City
- State
- Zip code
- Birth State/Country
- Phone Number
- Parent's Name (if under 18 years of age)
- Date of vaccine administration
- Vaccine administered
- Vaccine Manufacturer
- Lot Number
- Whether lot number was public or private
- VFC eligibility

Other fields that must be documented at the time of vaccine administration:

- Publication date of VIS
- Date VIS given
- Name and title of person who gave the vaccine
- Address of clinic where vaccine was given

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 will help staff members to know what to do in the event that the 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.htm. 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:

- Current primary vaccine coordinator and at least one back-up.
    - The primary vaccine coordinator should be in charge of providing education to all staff responsible for storing and administering vaccines.

- Proper vaccine storage and handling practices.
- Vaccine shipping and receiving procedures.
- Vaccine emergency plan.
- Vaccine ordering procedures.
- Inventory control (e.g., stock rotation).
- Staff training (and documentation of training) on vaccine management including storage and handling.
- How to pack vaccine for transport.
- Procedure for returning or wasting nonviable vaccine.
- 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.

BORROWING AND RETURNING VACCINE

Private and non-universal local public health units 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 adults and publicly-supplied vaccine for those who are eligible. Borrowing between the two inventories of vaccines may occur, but must be a rare occurrence (outbreak, vaccine shipment delayed etc.). Accidentally administering a dose of vaccine from the wrong inventory (i.e., giving a dose of VFC MMR vaccine to a not-eligible child) is considered borrowing. **Note: For seasonal influenza vaccine, providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available. As a caution, due to the nature of influenza vaccine supply, providers may borrow private vaccine to VFC stock at their own risk, as replacement VFC doses are not guaranteed. VFC influenza vaccine must NEVER be borrowed. This one-directional borrowing exception is unique to seasonal influenza vaccine.** All borrowing regardless of direction must be documented in NDIIS and on the VFC Vaccine Borrow/Return Form which can be found here www.ndhealth.gov/Immunize/Providers/Forms.htm**.**

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. The form must be kept on hand for a minimum of three years. Providers are able to run reports in NDIIS, which show the status of borrow and return balances and patient-level borrow and returns. For more information on borrowing and returning vaccine in NDIIS go to: www.ndhealth.gov/Immunize/NDIIS/Training/Borrow_Return.pdf.

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.
- To generate a borrow or return in NDIIS the provider should enter the immunization exactly as it was given (i.e., private vaccine inadvertently given to a Medicaid-eligible child. The private lot number should be chosen and the VFC eligibility should be set to "Medicaid"). This will then borrow a private dose of vaccine.
- The NDDoH requires that providers return any borrowed vaccine (whether private or state supply) within four weeks of the occurrence.
- Monthly NDIIS data is pulled and examined for data inconsistencies. If errors are discovered they are reported to the provider to follow up and either investigate the reason for the error or correct the data entry if a mistake was made.

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.

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.

Q: In the old NDIIS we could borrow a box of vaccine at a time and I noticed that this is no longer an option. How do I borrow doses in the NDIIS and can I borrow more than one dose at a time?

A: In the old system providers had to go in and change the lot number from state-supplied to privately-purchased before it could be entered in an immunization record if a borrow occurred. This method did allow for borrowing more than one dose at a time. The current system in NDIIS no longer allows this. In order to borrow a dose the vaccine should be entered in a patient record exactly as it was administered. For example if a "Not Eligible" child received a state-supplied lot number it would be entered as VFC "Not Eligible" and the state lot number. When it is entered in NDIIS this way the system will generate a borrow. In this circumstance a privately-supplied vaccine given to a VFC eligible child would pay back the borrowed dose. Borrows and returns are now patient based so therefore several doses cannot be borrowed in one transaction. They must all be done individually and entered exactly as was administered.

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

VACCINE RETURN AND WASTAGE

Vaccine Return: All non-viable vaccine that needs to be returned to McKesson because it has expired, spoiled because of a temperature excursion or due to a vaccine recall. Multi-dose vials (MDVs) can only be returned if no doses have been drawn from the vial. Partially used MDVs must be documented as vaccine wastage.

Vaccine Wastage: All non-viable vaccine that is not able to be returned to McKesson. This includes broken vaccine vials or syringes, vaccine drawn into a syringe but not administered, lost or unaccounted for vaccine and partially used MDVs.

Notify the Immunization Program 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 Immunization Program 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 completed and submitted to the NDDoH, and the open vials and syringes should then be discarded per your facility's policy.

All spoiled/wasted/expired state-supplied vaccines must be returned to McKesson within six months of spoilage/expiration. When returning vaccine it should be placed in a shipping container from a previous shipment of vaccine from McKesson. Packing material should be used so that the vaccine cannot move

around in the container. The vaccine does not need to be kept at refrigerator or freezer temperatures therefore no temperature monitoring devices or cool packs need to be used. All containers returned to McKesson should have a packing slip created by the immunization program. A McKesson shipping label should be attached to the outside of the container and all old shipping labels or bar codes should be removed or crossed out.

PROCEDURE FOR RETURNING NON-VIABLE VACCINE TO MCKESSON

1. Complete a Non-viable Vaccine Return and Wastage Form and fax to the NDDoH Immunization Program at 701.328.2499. This form can also be completed electronically: www.ndhealth.gov/Immunize/Providers/Wastage.aspx.
2. McKesson will send a return label in the mail. If a pickup needs to be scheduled please contact the Immunization Program. Otherwise the shipment can be sent anytime UPS is at your facility. Providers should not contact UPS directly to schedule a pickup, as this may result in the provider being charged for the shipping fees.
3. Prior to shipping unopened, non-viable vaccine, you must have a packing slip from NDDoH AND a shipping label from McKesson.
4. Ship unopened non-viable vaccine and a copy of the packing slip in a shipping container received from previous vaccine shipments.
5. **DO NOT** ship viable vaccine to McKesson.
6. **DO NOT** ship viable or non-viable vaccine to the NDDoH.

VACCINE TRANSFER

All vaccine transfers of VFC or state-supplied vaccine must be approved by the Immunization Program prior to the physical transfer of any vaccine. The immunization program reserves the right to not approve vaccine transfers. Data on vaccine transfers can also be analyzed in NDIIS to determine the frequency with which vaccine is transferred.

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. Refer to the CDC's *Vaccine Storage and Handling Toolkit* www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf for further guidance on transporting vaccine. If vaccine is being shipped, providers must use a qualified pack out container that guarantees proper temperatures can be maintained for the transport of vaccine. If the vaccine is driven it should be packed in a cooler so that appropriate temperatures can be maintained and never placed in the trunk of a car or left for long periods of time. Whenever transferring or transporting vaccine, a continuous recording thermometer should be placed in the package. When the vaccine arrives at its destination the thermometer should be checked to ensure that vaccines have stayed within the appropriate temperature range.

Frozen vaccine can only be transferred or transported in a portable freezer designed for this purpose. Dry ice is no longer allowed to be used for the transport of frozen vaccines. Frozen vaccine must stay between -58° F and +5° F (-50° C and -15° C).

The immunization program has developed a short tips guide on transporting vaccine and can be found on our website at www.ndhealth.gov/Immunize/Providers/Forms.htm.

PROVIDER-TO-PROVIDER TRANSFER OF VACCINES

Providers who have excess vaccine on hand that will not be used before expiration are encouraged to transfer this vaccine to other providers to utilize, and thus avoid being charged for wasted vaccine. Providers should begin this process within 3-6 months of the vaccine expiring. **It is the provider's responsibility to find another provider willing to accept the vaccine, and also to properly pack and ship the vaccine to that provider following standard cold-chain procedures.** While the NDDoH is willing to assist when possible, it is very difficult to match odd numbers of vaccines with other provider orders and to try to arrange for shipments between providers. Providers can find contact information for other VFC providers in their area in the NDIIS under the "Provider Lookup" box (the list can be sorted by city, provider name, etc., by clicking on the headings). Providers must also transfer the doses in NDIIS.

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 zoster vaccine need to be kept cool, but not frozen, during the shipping process. Varicella, MMRV and zoster vaccines on the other hand, need to be kept frozen while being shipped. 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 specifically 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 use the trunk of a vehicle to transport vaccines. 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. When transporting vaccine temperatures should be checked every 30 minutes to ensure vaccine is being stored in appropriate temperatures.

Vaccines must stay adjacent to the cold packs in order to maintain the desired internal temperature range when the outside temperature is extremely high.

For more specific information about transporting vaccines, visit CDC's Storage and Handling Toolkit at www.cdc.gov/vaccines/recs/storage/toolkit/default.htm. The Immunization Program has also developed a short tips guide on transporting vaccine and can be found on our website at www.ndhealth.gov/Immunize/Providers/Forms.htm.

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 http://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.

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. When you receive your vaccine shipment, it should be examined immediately:

- Examine the shipping container and its contents for any signs of physical damage.
- Determine if the shipping time was less than 48 hours (3 days for varicella-containing vaccines). If the interval between shipment from the supplier and arrival of the product at the facility was more than these time frames, the vaccines could have been exposed to excessive heat or cold that may have altered their integrity. Shipment information can be found on the packing slip.
- Cross-check the contents with the packing slip to be sure they match.
- Check the vaccine expiration dates to ensure that you have not received any vaccines or diluents that have already expired or will expire soon.
- Check that lyophilized (freeze dried) vaccines have been shipped with the correct type and quantity of diluents for reconstitution.

- Examine the vaccines and diluents for heat or cold damage:
    - Check the vaccine cold chain monitor(s), if present, to determine if the vaccines or diluents have been exposed to temperatures outside the recommended range(s) during transport. Vaccines that require reconstitution and their corresponding diluents will arrive in the same shipping container. For varicella-containing vaccines, the diluents should be in a separate compartment, usually in the lid of the shipper.
- Check that the vaccines were packed properly. There should be an insulating barrier (such as bubble wrap, Styrofoam pellets, or some other barrier) between the vaccines and the refrigerated or frozen coolant packs.
- All vaccines, except varicella, MMRV and zoster vaccines, must be refrigerated immediately at 35 – 46°F (2 – 8 °C).
- Varicella, MMRV and zoster vaccines must be immediately stored in the freezer at a temperature between -58° F and +5° F (-50° C and -15° C). MMR can be refrigerated or frozen upon receipt.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately notify the primary vaccine coordinator (or alternate coordinator). Label the vaccines "DO NOT USE" and store the vaccines under appropriate conditions separate from other vaccine supplies. Then contact the Immunization Program and/or vaccine manufacturer(s) for guidance.

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 Immunization Program immediately to report any discrepancies between the packing slip and your actual shipment. The Immunization Program 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 (**Appendix 2**) 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. In certain circumstances providers may be required to replace doses of lost state or VFC vaccine due to improper storage of vaccine upon arrival.

VACCINE LOSS

Current state and federal vaccine contracts stipulate that spoiled or expired vaccines cannot be returned to the manufacturer for replacement. Such vaccine losses are absorbed directly by the North Dakota Immunization program's budget.

Prevention Partnership Providers are required to report all wasted, expired, spoiled or lost vaccine to the North Dakota Immunization Program and must be physically returned to McKesson within six months of expiring or wasting. Please reference the Vaccine Return and Wastage section for directions on how to report and return nonviable vaccine. This document serves as the NDDoH Immunization Program's policy for management of incidents that result in loss of state-supplied vaccine. Replacement of state-supplied vaccine will be requested if wastage was due to the provider's failure to properly store, handle or rotate vaccine inventory.

Doses replaced per this policy must be administered to VFC or state-eligible patients.

DEFINITIONS

Wasted: Any vaccine that cannot be used. This includes expired, spoiled and lost vaccines.

Expired: Any vaccine with an expiration date that has passed.

Spoiled: Any vaccine that exceeds the limits of the approved cold chain procedures or is pre-drawn and not used within acceptable time frames. Always consult with the Immunization Program before determining that the vaccine is non-viable.

Lost: Commercial carrier (FedEx or UPS) or United State Postal Service (USPS) does not deliver the vaccine or does not deliver in a timely manner.

SITUATIONS THAT REQUIRE FINANCIAL RESTITUTION

Expired Vaccine

- Failure to rotate or attempt to transfer vaccine that results in expired vaccine amounting to **greater than 20 doses of any one vaccine in a 30-day period.**

Spoiled Vaccine

- Pre-drawn vaccine that is not used. Please note the North Dakota Immunization Program strongly discourages the practice of pre-drawing vaccine.
- Handling and storage mishaps by provider staff.
- Vaccine that is left out of the refrigerator or freezer and becomes non-viable. Call the vaccine manufacturer first to help you determine the stability/viability of vaccine left out of the refrigerator/freezer.

- Freezing vaccine that is supposed to be refrigerated.
- Refrigerating vaccine that is supposed to be frozen.
- Refrigerator/freezer left unplugged.
- Refrigerator/freezer door left open or ajar.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is not provided to the North Dakota Immunization Program within 30 days from the date you became aware of the situation.
- Non-weather related power outages in which the provider fails to take precautions.
- Vaccine that is considered spoiled due to the provider not checking and/or reviewing refrigerator and freezer temperatures twice daily.
- Vaccine that is considered spoiled because a provider did not take immediate or appropriate action on out-of-range temperatures.
- Replacement vaccine: health care providers who must re-vaccinate due to negligence in failure to keep vaccine viable (temperatures out of acceptable range) or improper administration will be responsible for the current CDC cost of the vaccine needed to re-vaccinate.

Wasted Vaccine

- State-provided vaccine given to children or adults who are not eligible to receive it based on the most recent NDDoH Vaccine Coverage Table which can be found here www.ndhealth.gov/Immunize/Providers/Forms.htm.
- Discarding vaccine before the manufacturer's expiration date (includes multi-dose vials).

SITUATIONS THAT DO NOT REQUIRE FINANCIAL RESTITUTION

Below is a list of situations that are NOT considered "provider negligence." This list is not exhaustive. In these situations, the provider is deemed not to be at fault. You may be required to produce a letter from the alarm/alert company or the power company.

- A commercial carrier or USPS does not deliver to the provider in a timely manner. Before making the determination that the vaccine is non-viable, first call the vaccine manufacturer.
- A provider who has a contract with an alert/alarm company has a refrigerator that malfunctions, and the alarm/alert company does not notify the provider.

- A provider moves vaccine to a nearby hospital due to anticipated inclement weather, the hospital experiences a power failure, and the North Dakota Immunization Program later deems the vaccine not viable.
- Power was interrupted or discontinued due to a storm, and after consultation with the vaccine manufacturer and the North Dakota Immunization Program, it is determined that vaccine is not viable.
- A vial that is accidentally dropped or broken by a provider.
- Vaccine that is drawn at the time of the visit but not administered due to parental refusal or a change in physician orders.
- Expired vaccine amounting to less than 20 doses in a 30-day period that is not due to provider negligence.
- Expired influenza vaccine that is not due to provider negligence.
- Extraordinary situations not listed above which are deemed by the North Dakota Immunization Program to be beyond the provider's control.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the North Dakota Immunization Program within 30 days from the date you became aware of the situation.

PROCEDURES FOR FINANCIAL RESTITUTION

The vaccine replacement policy applies to any vaccine received as wasted by the North Dakota Immunization Program on or after January 1, 2014. Financial reimbursement will be expected for doses wasted prior to December 31, 2013.

- The provider will receive an invoice from the NDDoH for vaccine reported as wasted to the North Dakota Immunization Program.
- The invoice will reflect the number of doses that must be replaced by purchasing private vaccine. Replacement vaccine must be the same brand and type as the state-supplied vaccine that was lost.
- Replacement of the vaccine is **due within 60 days** of receiving the invoice.
- If replacement is not completed within 60 days, the North Dakota Immunization Program will not supply vaccine to the negligent provider until proof of replacement is received.
- A copy of the purchase order for private vaccine must be submitted to the VFC Manager within 60 days. The NDDoH must be notified immediately when the purchased vaccine arrives so that the lot numbers can be entered into the NDIIS as state-supplied vaccine. Replaced doses must

not be administered to VFC or state-eligible children until the NDDoH converts the private lot numbers to state-supplied lot numbers in NDIIS.

FRAUD AND ABUSE

DEFINITIONS

Fraud and Abuse as defined in the Public Health Code of Federal Regulations 455.2:

www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=d79098ee26f348a1ab87837a3cd89e5d&rgn=div5&view=text&node=42:4.0.1.1.13&idno=42#42:4.0.1.1.13.0.132.3.

Fraud: An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law.

Abuse: Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, [and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or a patient]; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program.

All cases of suspected fraud and abuse will be handled according to this policy and the Centers for Disease Control and Prevention's (CDC) Vaccines for Children (VFC) Operations Guide: Module 10 Fraud and Abuse.

Suspected VFC fraud or abuse may be reported to one of the following individuals:

Abbi Pierce, VFC Manager, is designated as the primary contact.
2635 E. Main Ave., P.O. Box 5520
Bismarck, ND 58506-5520
(P) 701-328-3324 (F) 701-328-2499
apierce@nd.gov

Molly Howell, Immunization Program Manager, is designated as first back-up.
2635 E. Main Ave., P.O. Box 5520
Bismarck, ND 58506-5520
(P) 701-328-4556 (F) 701-328-2499
mahowell@nd.gov

Stacy Lovelace, VFC/AFIX Coordinator, is designated as second back-up.

2635 E. Main Ave., P.O. Box 5520
Bismarck, ND 58506-5520
(P) 701-541-7226 (F) 701-328-2499
slovelace@nd.gov

FRAUD AND ABUSE HOTLINE

Suspected cases of fraud and abuse should be reported immediately to the North Dakota Immunization Program at 800.472.2180.

ALLEGATION AND REFERRAL DATABASE

A database will be maintained to monitor and document all actions taken on allegations related to fraud and abuse of VFC program requirements, including actions taken to address identified situations. The following information must be collected:

- Provider's name (Medicaid ID, if known)
- Address
- Source of allegation
- Date allegation reported to NDDoH Immunization Program
- Description of suspected misconduct
- Specific VFC requirements violated
- Value of vaccine involved, if available
- Success of educational intervention
- Disposition (closed, referred, entered into educational process) of case and date of disposition

FRAUD AND ABUSE DETECTION AND MONITORING

Fraud or abuse can occur in many ways, and some types of fraud and abuse are easier for the Immunization Program to prevent or detect than others, depending on how the VFC program is implemented. The Immunization program uses provider profiles, ordering patterns, monthly error reports, VFC site visits, temperature logs and doses administered reports to monitor provider compliance with VFC program requirements. The Immunization Program will try to differentiate between intentional fraud and abuse and unintentional abuse or error due to excusable lack of knowledge.

Some examples of potential fraud and abuse that VFC staff might encounter are:

- Providing VFC vaccine to non–VFC-eligible children;
- Selling or otherwise misdirecting VFC vaccine;

- Billing a patient or third party for VFC vaccine;
- Charging more than the established maximum regional charge for administration of a VFC vaccine to a federally vaccine-eligible child;
- Not providing VFC-eligible children VFC vaccine because of parents' inability to pay for the administration fee;
- Not implementing provider enrollment requirements of the VFC program;
- Failing to screen patients for VFC eligibility, or screening improperly;
- Failing to maintain VFC records and comply with other requirements of the VFC program;
- Failing to fully account for VFC vaccine;
- Failing to properly store and handle VFC vaccine;
- Ordering VFC vaccine in quantities or patterns that do not match provider profile or otherwise involve over-ordering of VFC doses;
- Excessive or unnecessary wastage of VFC vaccine.

Fraud and abuse situations that should be referred to an external agency include any of the above activities which, upon assessment, are found to have been conducted purposefully and with the intent to misrepresent or defraud the VFC program, and/or negligence of VFC responsibilities has occurred. Situations involving Medicaid will be referred to the North Dakota Medicaid program. All non-Medicaid situations will be referred to the Office of the Attorney General. [See Fraud and Abuse Referral Procedure]

If the suspected case is identified by Immunization Program staff, the program manager and VFC manager will be notified immediately. Within 5 working days, the appropriate Immunization Program staff member will contact the provider in question to perform an in-depth interview. This interview will be recorded using the Fraud and Abuse Report Form. Data to be collected includes dates, names of staff involved, method by which the suspect activity was identified, a narrative of the activity in question, any corrective actions taken by the Immunization Program staff, and any referrals made. If deemed appropriate, a referral to an external agency will be made. [See Fraud and Abuse Referral Procedure]

If the suspected case is identified by an outside individual, within 5 working days the appropriate Immunization Program staff member will first interview the individual and then the provider, again recording this information on the Fraud and Abuse Report Form. If deemed appropriate, a referral to an external agency will be made. [See Fraud and Abuse Referral Procedure]

A file will be started for the provider in question and a copy of all verbal and written correspondence retained. The Immunization Program will follow-up with the external agency within 7 working days, or sooner if further information needs to be shared.

The NDDoH will investigate all allegations of suspected fraud and abuse and will determine if the situation is intentional fraud and abuse or unintentional abuse or error due to excusable lack of knowledge of the VFC program with no purposeful intent to misrepresent or defraud the VFC Program. If the situation is found to be unintentional, an educational intervention will be made.

Immunization Program staff will provide in-depth education to the provider's key staff about the VFC program and North Dakota enrollment and accountability requirements. The provider will be required to complete and return a corrective action plan detailing the steps that will be taken to prevent further incidents. This signed plan must be returned to the Immunization Program within one month. The provider will also be required to sign an acknowledgment that it received additional education, and that any recurrence of suspected fraud and abuse may result in termination from the VFC program and referral to an external agency for investigation.

If the investigation determines the situation is intentional the situation will be reported to an external agency for investigation.

FRAUD & ABUSE REFERRAL PROCEDURE

If the VFC program determines from the assessment of information available that the situation requires referral for further investigation by an outside agency, the VFC program must make these referrals within 10 working days from assessment. **All suspected cases of fraud and abuse that require further investigation must be referred to the Medicaid Integrity Group (MIG).** All referrals will be sent to:

CMS Medicaid Integrity Group
(F) 410-786-0711
MIG_Fraud_Referrals@cms.hhs.gov

The following information should be included to assist the MIG and the state Medicaid agency in evaluating the case:

- Name, Medicaid provider ID (if known), address, provider type (e.g., private provider).
- Source of complaint (e.g., provider officer, VFC staff, anonymous caller).
- Date on which awardee received information that provider might be engaged in behavior putting the VFC program at risk of loss due to fraud or abuse.
- Description of suspected misconduct with specific details including:
    - Complete description of alleged behavior, persons involved and contact information if available; include actions taken by program to confirm behavior.
    - Specific Medicaid statutes, rules, regulations violated, and how conduct of provider violated the rules or regulations.
    - Value of vaccine involved, when available.
- Contact information for VFC Fraud and Abuse Coordinator.
- Have available all communication between the VFC program and the provider concerning the suspected misconduct. This includes signed provider enrollment forms, any education given to provider as a result of previous compliance problems, and any general communication given to all enrolled providers.

The Medicaid Integrity Group will then refer the case to the appropriate state Medicaid agency. The state Medicaid agency will conduct preliminary investigations and, as warranted, refer appropriate cases

to the state's Medicaid Fraud Control Unit following the Federal Regulatory scheme found in 42 CFR section 455.15.

Upon receiving a suspected fraud and abuse case, an auditor/investigator will conduct a thorough investigation and compile a criminal report or audit report (depending on the type of case). The report is discussed with Utilization Review Management to determine course of action. Cases may then either be handled internally or referred to the Office of Inspector General or Attorney General's office. The entity taking action will be responsible for reporting any sanctions to the Office of Integrity for the national register. The contacts for Medicaid are:

Cliff Rhodes, Administrator, Fraud and Abuse
Medical Services Division Department of Human Services
600 E Boulevard. Ave, Department 325, Bismarck, ND 58505
701-328-4024
cprhodes@nd.gov

Jodi Hulm, Administrator, Health Tracks/Healthy Steps Programs
Medical Services Division Department of Human Services
600 E Boulevard. Ave, Department 325, Bismarck, ND 58505
701-328-2323
jhulm@nd.gov

Allegations not involving Medicaid will be reported by the State Health Officer to the Office of the Attorney General within 5 working days requesting the assistance from the Office of the Attorney General. The contact for the Office of the Attorney General is:

Wayne Stenehjem, Attorney General
State Capitol
600 E. Boulevard Ave.
Dept. 125
Bismarck, ND 58505
701-328-2210
wstenehjem@nd.gov

If deemed necessary after review by the state Medicaid agency, fraud may be referred to the Department of Health and Human Services (DHS) Office of the Inspector General using the following link:

https://oig.hhs.gov/fraud/report-fraud/index.asp

Initial contact for referrals will be made by the Immunization Program to the appropriate agency via a phone call to the designated contact person. The Immunization Program will then provide the agency with written documentation, including a completed Fraud and Abuse Report Form, North Dakota

Provider enrollment agreements and profiles, North Dakota Immunization Information System (NDIIS) data, and any other pertinent information that has been obtained. Follow-up contact may be made via phone or email but must be documented.

REPORTING OF VFC FRAUD AND ABUSE CASES TO THE CDC

All suspected cases of VFC fraud and abuse that are referred to the Medicaid Integrity Group for further follow-up must be reported to the grantee's Program Operations Branch (POB) project officer within two working days of the referral to the Medicaid Integrity Group. It is acceptable to copy the project officer on the referral to the Medicaid Integrity Group as the official report to the CDC.

North Dakota POB Project Officer:

Sapana Parikh
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd, MS A-19, Atlanta, GA 30333
(P) 404-639-7523
euh8@cdc.gov

PERSONNEL TRAINING

All VFC program staff will be trained on how to prevent, identify and follow up on situations that involve suspected VFC fraud and abuse or non-compliance with VFC program requirements. All VFC program staff will be trained on the proper use of the Centers for Disease Control and Prevention's (CDC) *Non-compliance with VFC Provider Requirements Protocol*. The Fraud and Abuse policy will be disseminated to new employees as part of employee orientation and will be reviewed as part of new employee training. The North Dakota VFC Program Staff Manual outlines procedures to ensure the identification of fraud and abuse.

ENROLLMENT & EXCLUSION CHECKING PROCEDURE

The North Dakota Immunization Program will exclude providers from participating in the VFC program and the Prevention Partnership Program if the provider is found to be in non-payment status under Medicare, Medicaid, and other Federal health care programs. Exclusion of providers may also occur due to Office of Inspector General (OIG) sanction, failure to renew license or certification registration, revocation of professional license or certification, or termination by the North Dakota Medicaid Agency. The North Dakota Immunization Program will monitor OIG exclusions by checking the List of Excluded Individuals and Entities on the OIG website upon provider enrollment at exclusions.oig.hhs.gov/. This list will be checked quarterly thereafter and compared to currently enrolled providers. Claims are not processed by Medicaid for providers on the OIG list. **Providers are strongly encouraged to check the OIG list of excluded individuals/entities on the OIG website prior to hiring or contracting with any individuals or entities. Enrolled providers who employ a person (including, but not limited to, physicians, mid-level practitioners, nurses or nursing aides) from the excluded provider list will be terminated from the program and the state Medicaid and MIG agencies will be notified.**

The North Dakota Immunization Program also has the right to exclude providers that are not following any other Prevention Partnership Program requirements. Vaccine will be removed from the provider's possession and the provider will be prohibited from receiving future shipments until the exclusion is lifted. The excluded provider or entity will be required to re-apply for the Prevention Partnership Program after the exclusion is lifted. The North Dakota Immunization Program, State Attorney's Office, and the Medicaid Fraud and Abuse Unit will work closely together to share any information regarding allegations and exclusions due to fraud and abuse.

The North Dakota VFC Program Manual: Module 10 Fraud and Abuse outlines procedures regarding exclusion of providers from the VFC program.

VFC PROVIDER TERMINATIONS

The NDDoH will determine whether or not a provider should be terminated from the VFC program. Providers will be notified in writing (certified letter) and through email of termination from the VFC program.

Providers that are terminated from the VFC program (both voluntarily and involuntarily) will be reported to the state Medicaid agency via email. [See Fraud and Abuse Referral Procedure, North Dakota Medicaid contacts]

ANNUAL REVIEW OF FRAUD AND ABUSE POLICY

This policy will be reviewed, at a minimum, annually. The NDDoH VFC Manager is responsible for maintaining and updating this policy. When updated, this policy must be reviewed and approved by the Immunization Program Manager and the Attorney General's Office. A copy of the updated policy will be sent to the Medicaid contacts.

FRAUD AND ABUSE AND PROVIDER ACCOUNTABILITY

North Dakota providers will sign an annual agreement, on behalf of all practitioners associated with their clinic, to adhere to the rules of the VFC and North Dakota Immunization Program.

The North Dakota Immunization Program recognizes that staff turnover is a frequent occurrence within clinics. North Dakota providers are required to train new staff regarding the Fraud and Abuse Policy and VFC requirements.

Providers may request education on the requirements of the Vaccines For Children (VFC) and Prevention Partnership programs for their staff at any time. This education may be accomplished through the use of compliance site visits or informative presentations. Providers interested in further education on program requirements should contact the North Dakota Immunization Program at 701.328.2378 or toll-free 800.472.2180.

FRAUD AND ABUSE PREVENTION

The North Dakota Immunization Program takes many steps to prevent fraud and abuse. VFC Coordinators conduct site visits at a minimum of 50% of enrolled providers per year. The NDIIS tracks VFC eligibility at the dose level. A random sample of ten records from the provider's medical records is compared to the NDIIS VFC eligibility. If a discrepancy is found, the VFC provider issues a corrective action. Site visit data and corrective actions are tracked in CDC's online database. The North Dakota Immunization Program reviews NDIIS data monthly for VFC accountability issues, including VFC doses being administered to "not eligible" children. VFC Coordinators then follow-up with providers as needed. The NDIIS is also used by providers for vaccine ordering. Providers are limited to a three month vaccine supply based on current inventory and past doses administered. Providers who wish to order more than a three month supply must provide a justification. The NDDoH provides ongoing education to providers regarding VFC accountability. Educational opportunities include "Lunch and Learn" presentations, a statewide immunization conference, site visit presentations, and the requirement for two staff at each provider office to review an online VFC Accountability and Storage and Handling presentation each year.

VACCINES FOR CHILDREN (VFC) QUESTIONS AND ANSWERS

Vaccines for Children Program Eligibility

1. What is the VFC Program?

The VFC program is a federally-funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. VFC 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 program was officially implemented in October 1994 as part of the 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.

2. Who is eligible for the VFC Program?

Children through 18 years of age who meet at least one of the following criteria are considered federally vaccine-eligible and therefore eligible to participate in the VFC program:

- **Medicaid eligible:** a child who is eligible for the Medicaid program. (For the purposes of the VFC program, the terms Medicaid-eligible and Medicaid-enrolled are equivalent and refer to children who have health insurance covered by a state Medicaid program.)

- **Uninsured:** a child who has no health insurance coverage.

- **Indian (American Indian or Alaska Native):** as defined by the Indian Health Care Improvement Act (25 U.S.C. 1603).

- **Underinsured:** Children who have commercial (private) health insurance but the coverage does not include vaccines, children whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only), or children whose insurance caps vaccine coverage at a certain amount – once that coverage amount is reached, these children are categorized as underinsured. **Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC), unless the child's clinic has signed an agreement with a FQHC to administer vaccines to underinsured children on their behalf. Local public health units in North Dakota are delegated authority to vaccinate underinsured children with VFC vaccine. The North Dakota Department of Health supplies federal 317 vaccine to private providers to vaccinated underinsured children.**

3. Are children who are on Healthy Steps (SCHIP) VFC-eligible?

No. Children who are on Healthy Steps are considered insured. Providers should administer privately-purchased vaccine and bill the Healthy Steps program.

4. If a child has health insurance that covers vaccinations but has a high deductible, is that child VFC-eligible?

No. Children who have health insurance but have high deductibles are considered insured. Once the deductible is met, insurance covers vaccinations. They should be given privately-purchased vaccine and insurance or the parent should be billed.

5. Are all children who have Medicaid as a secondary insurance covered by VFC?

Situations can occur where children have private health insurance that includes full immunization benefits and Medicaid as a secondary insurance. These children are VFC-eligible as long as they are enrolled in Medicaid. VFC is an entitlement program, and participation is not mandatory for an eligible child. **For children that have full immunization benefits through a primary private insurance, the decision to participate in the VFC program should be made based on what is financially most cost effective to child and his/her family.** The options for private providers are described below:

Option 1
Providers can administer VFC vaccine and bill insurance only for the administration fee. If this option is used, providers must not bill insurance for the cost of vaccine. Providers may choose to

bill insurance at the private rate for the vaccine administration fee. If the insurance company refuses payment, Medicaid can then be charged for the administration fee. As a precaution, Medicaid may not be billed more than the VFC vaccine administration fee cap. The parent or child should never be charged more than the VFC vaccine administration fee cap.

This option is easiest for providers and best for patients, as there is no risk that the patient will be billed for any amount for which the primary insurance or Medicaid refuses payment.

Option 2
A provider can administer private stock vaccine and bill the primary insurance carrier for both the cost of the vaccine and the administration fee. If the primary insurance pays less than the Medicaid amount for the vaccine administration fee, the provider can bill Medicaid for the balance of the vaccine administration fee up to the amount Medicaid pays for the administration fee. If the primary insurance denies payment of vaccine and the administration fee, the provider may replace the privately purchased vaccine with VFC vaccine and bill Medicaid for the administration fee. The provider must document this replacement in the NDIIS using the borrow/return functionality.

The parent/guardian of a child with Medicaid as secondary insurance must never be billed for a vaccine or an administration fee. Providers may be reimbursed a higher amount if privately purchased vaccine is administered and both the vaccine and administration fee are billed to the primary insurance. **The deciding factor on which vaccine inventory to use should be based on what will be most cost effective for the family.**

Note: Local public health units (LPHUs) participating in the universal supply program must use option 1.

6. If a child is American Indian and has health insurance, is the child eligible for VFC vaccine?

American Indian/Alaskan Native children are always VFC-eligible. VFC is an entitlement program and participation is not mandatory for an eligible child. For AI/AN children that have full immunization benefits through a primary private insurance, the decision to participate in the VFC program should be made based on what is financially most cost advantageous to the child and family.

7. If a parent is unsure if their child is underinsured, should I give VFC vaccine to that child?

No. You should request that the parent check their child's insurance coverage. If unknown, administer private vaccine and bill insurance. After insurance is billed, if it is found that the child is underinsured, VFC vaccine may be swapped for the private dose of vaccine administered. All borrow/return transactions of state-supplied vaccine must be documented in the NDIIS.

8. **How often do I have to check a child's VFC status?**

A child's VFC status must be checked every time the child comes to a clinic for vaccination. The VFC status must be entered into the NDIIS for every dose of vaccine administered.

9. **If a child is a member of a Participating Provider Organization (PPO) or Exclusive Provider Organization (EPO) and travels "out of network" for immunizations and the immunizations are not covered "out of network," but would have been covered within the PPO or EPO, is the child VFC-eligible?**

No. The child is not considered VFC-eligible, because the child's immunizations would have been covered within the PPO or EPO.

10. **If a child's insurance coverage for immunizations is capped at a certain amount, is the child considered VFC-eligible once the cap is met?**

Yes. Once the insurance cap is met, the insurance will no longer cover immunizations, so the child is considered underinsured and therefore VFC-eligible. For example, if an insurance company will only cover up to $500 for immunizations and that amount has been met, then the child is considered VFC-eligible.

11. **Are children who have health insurance but whose insurance covers only a percent of the cost of one or more vaccines eligible for the VFC program? For example, the insurance covers 80% of the cost of MCV4.**

No, these children are considered to be insured for the purposes of the VFC program and are not eligible to receive VFC vaccine.

12. **Can a child who has insurance that limits the coverage to a specific number of provider visits annually be considered underinsured for the purposes of the VFC program once the number of covered visits is reached?**

If the child's insurance will not cover the cost of the vaccine after the child has exceeded the number of covered provider visits, the child can be considered underinsured for the purposes of the VFC program.

13. **Is it acceptable for a VFC-enrolled provider to turn away a VFC-eligible child because his/her parent didn't want all the vaccines that a child was eligible to receive administered at one clinical encounter?**

This question is outside the scope of the VFC program.

14. **Is it acceptable for a VFC-enrolled provider to ask that parents who do not wish to have their child vaccinated to find a new medical home?**

This question is outside the scope of the VFC program.

Administration Fees

1. **What is the maximum vaccine administration fee I can charge for the VFC Program?**

Starting January 1, 2013, the Centers for Medicare and Medicaid Services (CMS) set the vaccine administration fee cap at **$20.99** for North Dakota. This means that once providers sign the 2013 VFC Enrollment form, they can charge an administration fee, no higher than $20.99, for vaccines given to VFC-eligible children.

2. **How much does ND Medicaid reimburse for the vaccine administration fee?**

Starting with the 2013 Prevention Partnership Agreement providers are able to bill up to $20.99 per dose of vaccine administered. Medicaid will reimburse providers up-front at a lower rate. Providers are required to accept ND Medicaid's reimbursement. Physician's offices that specialize in internal medicine, family medicine or pediatrics and self-attest to their eligibility are able to receive a quarterly lump sum payment to bring reimbursement up to $20.99 per dose. The self-attestation form is located at http://www.ndhealth.gov/Immunize/Providers/Forms.htm. At this time pharmacies and local public health units are not eligible for the quarterly payment.

3. **If a child is American Indian and has insurance, what is the maximum vaccine administration fee I can charge for the VFC Program?**

If using VFC vaccine for an American Indian child who has insurance, the provider may bill insurance $0 for the cost of vaccine and the private rate for the vaccine administration fee. However, if insurance does not fully cover the private vaccine administration fee, the provider cannot charge the patient or their parent more than the VFC vaccine administration fee cap.

4. **If a parent of a VFC-eligible child is unable to pay the vaccine administration fee, can I refuse to vaccinate that child?**

No. A provider cannot refuse to vaccinate a VFC-eligible child if the parent is unable to pay the vaccine administration fee.

5. **What are the administration fee requirements for insured children who have private health insurance benefits that include immunization coverage (non-VFC-eligible children)?**

The VFC administration fee caps only apply to VFC-eligible children and do not apply to privately-insured children.

6. **Can providers send a bill in order to collect the vaccine administration fee after the date of service (for vaccines provided to non-Medicaid VFC-eligible children)?**

There are no restrictions against sending a bill for the vaccine administration fee after the point of service. However, the provider cannot send the bill for the vaccine administration fee to collections if the parent cannot afford to pay (i.e., if the parent does not pay the bill). The provider can send the office visit fee or any other visit fee (i.e., labs) to collections if unpaid, but not the vaccine

administration fee. The federal requirement restricts the provider from seeking payment if the parent cannot afford it.

Private and VFC Inventories

1. **If my clinic does not have any private vaccine for insured children, can I borrow VFC vaccine and then pay that back later when I receive additional private 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 state-supplied vaccine for those who are eligible. Borrowing between the two inventories of vaccines may occur, but must be a rare occurrence (i.e., delayed vaccine shipment, outbreak). VFC vaccine cannot be used as a replacement program for a provider's privately purchased vaccine inventory. All borrow/return activity must be documented in the NDIIS and on the VFC Vaccine Borrow/Return Report. The VFC Vaccine Borrow/Return Report must be kept on hand for three years. **Please note: for seasonal influenza vaccine, providers may use private stock seasonal influenza vaccine to vaccinate VFC eligible children if VFC seasonal influenza stock is not yet available. Those private stock doses used on VFC eligible children can later be replaced when VFC stock becomes available. As a caution, due to the nature of influenza vaccine supply, providers may borrow private vaccine to VFC stock at their own risk, as replacement VFC doses are not guaranteed. Providers must never borrow VFC influenza vaccine to vaccinate privately insured children.**

2. **If a VFC-eligible child starts a series at age 18, can the series be completed using VFC vaccine after the child turns 19?**

No. Once a child turns 19, the child is no longer VFC-eligible. Adults 19 and older must receive privately-purchased vaccine.

3. **As a VFC provider, do I have to order or offer all VFC vaccines available from the state health department?**

Yes. A provider may make a medical judgment that a specific VFC-eligible child should not receive a certain vaccination, but the vaccine must be stocked so it is available to all other VFC-eligible children.

4. **Must specialty providers offer all age-appropriate VFC vaccines to their VFC-eligible patients in order to enroll in the VFC program?**

Specialty providers, at the discretion of the NDDoH, may limit their VFC practice to particular relevant vaccines. Specialty providers may include inpatient settings such as birthing hospitals, pharmacies, juvenile detention centers and family planning clinics.

5. **Does a Medicaid-enrolled provider have to offer VFC vaccines?**

A Medicaid-enrolled provider has to offer all services to Medicaid children that they offer to insured children. Therefore, if a provider is offering vaccines to insured children, then they have to offer vaccines to Medicaid children. Medicaid will not cover the costs of privately-purchased vaccines, which is why providers are highly encouraged to enroll in the VFC program.

Vaccine storage and handling

1. Where can I get more information on vaccine storage and handling?

CDC's Vaccine Storage and Handling Toolkit is available online and was sent out with the 2013 annual enrollment. Providers may also visit the ND Immunization Program website at www.ndhealth.gov/immunize.

2. What is the impact of a power outage on vaccine and what should be done with vaccine?

General procedures for power outages are described in the Vaccine Storage and Handling Toolkit.

All providers should have an Emergency Vaccine Retrieval and Storage Plan Worksheet prepared in advance to guide them in the event of a power outage or other emergency. This should include plans for alternative storage and transport of vaccines.

Note: The following key messages for immunization providers:

In any type of power outage:

- Do not open freezers and refrigerators until power is restored, except to transport vaccine to an alternative storage location.
- Monitor temperatures and duration of power outage; don't discard vaccine; don't administer affected vaccines until you have discussed with public health authorities.

3. Are "Dorm Style" refrigerators acceptable storage units for VFC vaccines?

Starting January 1, 2013, dorm style refrigerators may never be used to store VFC vaccines. These types of refrigerators may not be used for even temporary storage.

4. Some of our providers have small compact storage units that were designed to hold medical biologicals. Are these storage units acceptable for permanent storage of VFC vaccine?

Yes, these types of vaccine storage units are acceptable if they meet the following conditions:

a) The refrigerator and freezer compartments each have a separate external door, or
b) Units are stand-alone refrigerators and freezers

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

- Be able to maintain required vaccine storage temperatures year-round;
- Be large enough to hold the year's largest inventory;
- At a 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.)

5. Some of our providers have been removing VFC vaccine that comes in manufacturer prefilled syringes from the original packaging to store in plastic containers if storage space is a concern. What is CDC's position on this?

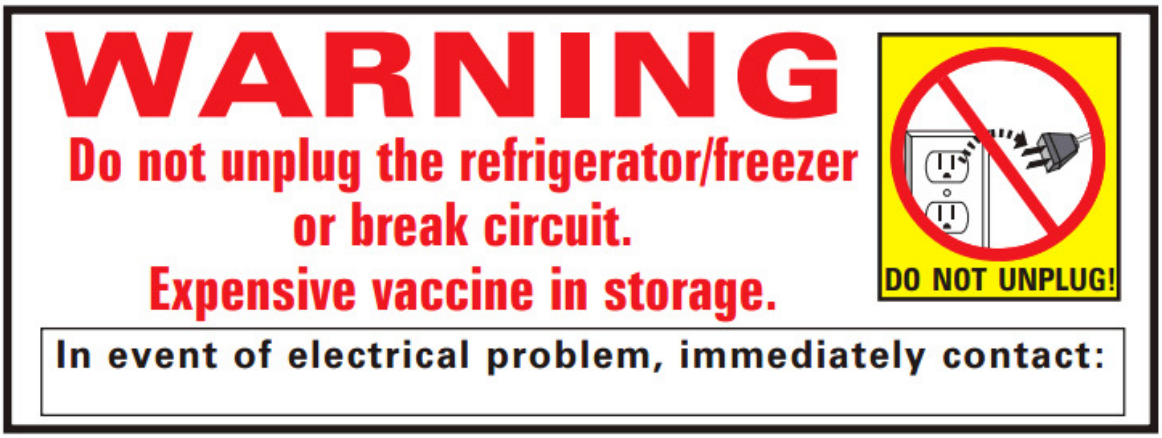
CDC's position is to have providers store vaccine in their original containers to help protect the vaccine from damage due to storage errors, as well as, to decrease the possibility of administration errors from inadvertently confusing similarly packaged vaccines.

APPENDICES

1. **“Do Not Disconnect” Warning Signs**

2. **Vaccine Manufacturers’ Quality Control Phone Numbers**

DO NOT DISCONNECT WARNING SIGNS



Vaccine Manufacturers' Quality Control Phone Numbers

GlaxoSmithKline 877-356-8368	Merck 877.829.6372	sanofi pasteur 800.822.2463
• Infanrix® • Kinrix® • Pediarix® • Cervarix • Boostrix® • Havrix® • Engerix-B® • Twinrix® • Rotarix®	• PedvaxHIB® • VAQTA® • GARDASIL® • MMR-II® • PNEUMOVAX 23® • RECOMBIVAX® • RotaTeq® • VARIVAX® • ZOSTAVAX® • ProQuad®	• DAPTACEL® • DECAVAC® • Pentacel® • ADACEL® • ActHIB® • I-POL® • Menactra®

Massachusetts Biological Labs 617.474.3000	Novartis 800.244.7668	Pfizer 800.999.9384 (opt 1)	MedImmune 877.633.4411
• Td	• Menveo®	• Prevnar 13®	• FluMist®

NORTH DAKOTA DEPARTMENT of HEALTH

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 at 800.472.2180.