2025 Vaccine Management Policy

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Health & Human Services

Immunizations, Disease Control, and Forensic Pathology, North Dakota Department of Health and Human Services

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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 fragile and require extra time and diligence.

As always, contact the North Dakota Department of Health and Human Services (ND HHS) Immunization Unit 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 August 10, 1993, and the VFC program became operational October 1, 1994.

The VFC program offers free vaccines 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 private physicians' offices and public health clinics that are registered as VFC providers.

VFC PROGRAM REQUIREMENTS

The following requirements are included on the Prevention Partnership Program enrollment agreement. It is important that all providers are familiar with the federal program requirements. The official VFC-registered health care provider signing the agreement must be a practitioner authorized to administer pediatric vaccines under state law who will also be held accountable for compliance by the entire organization and its VFC providers with the responsible conditions outlined in the provider enrollment agreement. The individual listed must sign the provider agreement.

*Note: For the purposes of the VFC program, the term 'vaccine' is defined as any FDA-authorized or licensed ACIP-recommended product for which ACIP approves a VFC resolution for inclusion in the VFC program.

Providers must 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 North Dakota Immunization Information System (NDIIS) doses administered data based on the previous calendar year.
   - It is the provider's responsibility to notify the ND HHS Immunization Unit 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 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 who 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 eligible for public vaccine can be found on the https://www.hhs.nd.gov/immunizations/immunization-resources
- The options for administering VFC or private vaccine for children who have Medicaid as secondary insurance.
- The VFC program does not have any authority over administration fees charged to privately insured children.
- ND HHS 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 of age.
- 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 of age.
- How to document changes to VFC eligibility status.
- How to appropriately document VFC eligibility in NDIIS and/or electronic medical record.

3. **For the vaccines identified and agreed upon in the provider profile, I will comply with immunization schedules, dosages and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFC program unless:**
    a. **In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate 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.
    - That it is expected that all ACIP recommended vaccines will be stocked at the enrolled facility unless previous arrangements have been made with the ND HHS Immunization Unit. Starting in September of 2024 all enrolled providers were required to carry VFC supply of COVID-19 and Nirsevimab if appropriate for the population they vaccinate. In September of 2025 this requirement will be expanded to ensure that all enrolled facilities also carry private stock of COVID-19 and Nirsevimab, if appropriate.
    - The process ND HHS 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 ND HHS VFC Vaccine Borrow/Return Form and follow ND HHS requirements related to the borrowing and returning of all state-supplied vaccine.
   - ND HHS will monitor the borrowing activities of VFC-enrolled providers during VFC compliance site visits and monthly error reports.
   - Borrowing VFC vaccine to administer to a non-VFC-eligible patient may occur only in rare, unplanned situations (e.g., a delayed vaccine shipment, vaccine spoiled in-transit or delayed vaccine or swapping for a short outdate).
   - 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 children on Medicaid, 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:
   - That patients must never be billed more than once and must never be turned over to collections for a VFC vaccine administration fee.

- The maximum amount that can be charged to VFC-eligible children or their families.
- 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 current Vaccine Information Statement (VIS) [or Immunization Information Statement (IIS) for nirsevimab] 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).**

   Note: If a COVID-19 Vaccine Information Statement (VIS) is not available, providers should provide information prior to vaccination as follows: EUA Fact Sheet for Recipients, Emergency Use Instructions (EUI) or BLA package insert, as applicable.

   For nirsevimab when not co-administered with other vaccines, report all suspected adverse reactions to MedWatch. Report suspected adverse reactions following co-administration of nirsevimab with any vaccine to the Vaccine Adverse Event Reporting System (VAERS).

   Providers and staff must understand:
   - How to obtain the most current VIS, IIS and/or EUA 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 and MedWatch.

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 ND HHS 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 ND HHS Vaccine Management Policy.
- ND HHS Vaccine Loss Policy.
- ND HHS Fraud and Abuse Policy.
- How to order vaccine using the 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: intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to him/herself 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 ND HHS Immunization Unit, 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 explain 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 ND HHS to serve underinsured VFC-eligible children, I agree to:**
    a. **Include "underinsured" as a VFC eligibility category during the screening for VFC eligibility at every visit.**

b. **Vaccinate "walk-in" VFC-eligible underinsured children.**
c. **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, then the policy would apply to underinsured patients as well. "Walk-in" may also include VFC-eligible newborn infants at a birthing facility.

Providers and staff must understand:

- The 28 LPHUs in North Dakota are the only VFC-enrolled providers that are deputized to administer VFC vaccine to underinsured children.
- The ND HHS supplies 317 vaccine to private providers to vaccinate underinsured children.

13. **For pharmacies, urgent care, or school-located vaccine clinics, I agree to:**
    a. **Vaccinate all "walk-in" VFC-eligible children.**
    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, then 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 dose-for-dose basis.**

Providers and staff must understand:

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

15. **I will document demographic, VFC and state eligibility and immunization information in the 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 ND HHS, North Dakota State Auditor or the Auditor's designee in accordance with N.D.C.C. 54-10-19.**

17. **I understand that this facility or the ND HHS 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 ND HHS.**

    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.

VFA PROGRAM REQUIREMENTS

The following requirements are included on the VFA enrollment form. It is important that all providers are familiar with the program requirements. Providers must sign the enrollment form annually and agree to the following.

1. **I will screen patients and document eligibility status at each immunization encounter and administer publicly purchased vaccine only to adults who are at least 19 years of age and meet one of the following categories:**
    a. **Uninsured: A person who does not have health insurance.**
    b. **Underinsured: A person who has health insurance, but the insurance does not include any vaccines; a person whose insurance covers only selected vaccines.**

    Providers and staff must understand:
    - The eligibility requirements for the VFA program.
    - The additional eligibility requirements required for some VFA vaccines. The coverage table detailing these requirements can be found here.
    - How eligibility requirements differ between the VFC and VFA program.
    - The VFA program does not have any authority over administration fees charged to privately insured adults.
    - How to appropriately document VFA eligibility in NDIIS and/or electronic medical record.

2. **I will comply with immunization schedules, dosages and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP) and included in the VFA vaccine 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 person.**
    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.
    - The process HHS uses to notify VFA-enrolled providers about changes to the VFA program.
    - The true contraindications for each vaccine.

3. **I will maintain all records related to the VFA program for a minimum of three years and upon request make these records available for review. Adult records include, but are not limited to, 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 VFA program must be maintained for the required time period.

4. **I will administer vaccine to eligible persons with publicly purchased vaccine at no charge to the patient for the cost of the vaccine.**

    Providers and staff must understand:
    - Patients, Medicaid, Medicare or private insurance cannot be billed for the cost of publicly funded vaccine.
    - Providers must use the ND HHS vaccine coverage table. and follow ND HHS requirements related to the borrowing and returning of all state-supplied vaccine.
    - ND HHS will monitor the borrowing activities of VFA-enrolled providers during compliance site visits and monthly error reports.
    - Borrowing state supplied vaccine to administer to a non-VFA-eligible patients may occur only in rare, unplanned situations (e.g., a delayed vaccine shipment, vaccine spoiled in-transit or delayed vaccine or swapping for a short outdate).
    - VFA vaccine cannot be used as a replacement system for a provider's privately purchased vaccine inventory.
    - Providers must document all borrow/return occurrences in the NDIIS and on the borrow/return form.

5. **I will not charge a vaccine administration fee to eligible adults that exceeds the $20.99 administration fee cap per vaccine dose.**

Providers and staff must understand:

- That patients must never be billed more than once and must never be turned over to collections for a VFA vaccine administration fee.
- The maximum amount that can be charged to VFA-eligible adults.
- The administration fee is per vaccine and not per antigen in the vaccine.

6. **I will not deny administration of a publicly purchased vaccine to an established patient because the 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.

7. **I will distribute the current Vaccine Information Statement (VIS) or Emergency Use Authorization (EUA) fact sheet (if applicable) 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).**

   Note: If a COVID-19 Vaccine Information Statement (VIS) is not available, providers should provide information prior to vaccination as follows: EUA Fact Sheet for Recipients, Emergency Use Instructions (EUI) or BLA package insert, as applicable.

   Providers and staff must understand:

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

8. **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 and Human Services storage and handling recommendations and requirements and follow the CDC Vaccine Storage and Handling toolkit.**
   d. **Returning all spoiled/expired public vaccines in a manner designated by CDC and/or ND HHS with six months of spoilage/expiration.**

   Providers and staff must understand:

   - The need to comply with all requirements outlined in the ND HHS Vaccine Management Policy.

- ND HHS Vaccine Loss Policy
- ND HHS Fraud and Abuse Policy
- How to order vaccine using the NDIIS and how to submit monthly temperature logs.
- The procedure to return vaccines to the centralized distributor.

9. **I agree to operate within the VFA 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 VFA 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 explain fraud and abuse and how it is detected, reported and followed up.
   - Activities that are deemed as fraudulent or abusive.

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

11. **I agree to replace vaccine purchased with state and federal funds that are deemed non-viable due to provider negligence on a dose for dose basis.**

    Providers and staff must understand:

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

12. **I agree to submit vaccine administration data for all publicly purchased vaccines using Section 317 and state/local funds to the jurisdiction's Immunization Information System (IIS) in accordance with VFA regulations and reporting timelines.**

Providers and staff must understand:

- All demographic, 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).

13. **I understand this facility or the North Dakota Department of Health and Human Services 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 and Human Services.**

Providers and staff must understand:

- Situations that would terminate their participation in the VFC program.
- How to return unused VFA vaccine.
- How to discontinue enrollment from the VFA program.
- If a provider terminates their VFA enrollment they must return all unused VFA vaccine within 30 days of the termination date.

VFC ELIGIBILITY

All patients must be screened for VFC eligibility at every immunization encounter. All demographic, VFC and state eligibility, and immunization information must also be documented in the NDIIS **and** on a VAR, Patient Eligibility Screening Form, or in the facility's EMR system. **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.

Persons who meet one or more of the following categories are considered eligible for public vaccine 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 (only until June 30, 2025). After July 1st, 2025, insured infants need to receive private supply vaccine.
c. uninsured and underinsured adults for COVID-19, HPV, MCV4, MMR, Hepatitis A, Hepatitis B, mpox, Polio (IPV), PCV15, PCV20, PCV21, PPSV23, Td and Tdap. Additional eligibility requirements apply to mpox, PCV15, PCV20, PCV21 and PPSV23.
d. uninsured and underinsured adults may receive influenza vaccine at facilities who prebooked adult influenza vaccine through the VFC/317 influenza vaccine prebooking process.

An updated vaccine coverage table can be found at www.hhs.nd.gov/immunizations/immunization-resources.

Underinsured children may only be vaccinated with VFC vaccine at a rural health center (RHC), FQHC or deputized LPHU. 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.

NDIIS VFC ELIGIBILITY OPTIONS

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 where insurance is being billed should be entered as "not eligible" at private provider offices.

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 VFA program.

Other State Eligible: Privately insured infants receiving the birth dose of hepatitis B vaccine at enrolled birthing hospitals. After July 1, 2025, insured infants will receive privately supplied vaccine and should be entered as "Not Eligible".

For further questions about VFC eligibility, please consult the VFC Questions and Answers section or www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations

VFA ELIGIBILITY

All patients should be screened for VFA eligibility at every immunization encounter. All demographic, VFA and state eligibility, and immunization information must also be documented in the NDIIS and on a VAR, Patient Eligibility screening form, or in the facility's EMR system. VFA vaccine should only be given to adults who are 19 years of age or older who meet one of the following categories.

A. Have no health insurance.
B. Are underinsured.

For the purposes of the VFA program underinsured is defined as a person who has health insurance, but the insurance does not include any vaccines: a person whose insurance covers only selected vaccines; and in the case of COVID-19 vaccine a person whose insurance does not provide first-dollar coverage for vaccines. Patients who go to an out-of-network provider and experience additional charges do not qualify as underinsured.

For some vaccines available as part of the VFA program additional eligibility requirements apply. For additional information on what vaccines are available as part of our VFA program and what eligibility requirements apply please see the vaccine coverage table at https://www.hhs.nd.gov/immunizations/immunization-resources

NDIIS VFA ELIGIBILITY OPTIONS

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

Other State Eligible: Uninsured or underinsured adults receiving vaccines through the VFA Program. Other options, such as No Insurance, should only be utilized for children receiving VFC vaccine.

Not Eligible: Insured adults or for use in any adults receiving vaccines not offered through the VFA program.

For further questions about VFA eligibility, please consult the VFA Questions and Answers section.

BILLING FOR VFC VACCINE

Enrolled facilities must not bill for the cost of a VFC or state-supplied vaccine when administered to an eligible individual. Vaccine is provided to the facilities at no charge. VFC eligible patients, if not billed at the time of service, must be billed within 90 days of receiving the vaccine and can only be billed one time. If the administration fee is not recouped after that billing cycle, the fee must be waived. VFC eligible patients must never be turned over to collections for the administration fee. A patient must never be turned away or referred due to their inability to pay the vaccine administration fee.

Administration fees associated with VFC or state supplied vaccines are capped at $20.99 per vaccine, not per antigen. Providers may receive a lower reimbursement from Medicaid, but they are required to accept this reimbursement.

All other charges associated with the facility (e.g., labs, clinic fees, procedures) are outside of the scope of the VFC program and the facility can bill as they see fit.

BILLING FOR VFA VACCINE

Enrolled facilities must not bill for the cost of a VFA vaccine when administered to eligible individuals. Vaccine is provided to the facilities at no charge.

Administration fees associated with VFA vaccine are capped at $20.99 per vaccine.

VFC PROVIDER ENROLLMENT AND RECRUITMENT

Any provider who has the potential to vaccinate a VFC or VFA patient is eligible to participate in the VFC or VFA program.

To participate in the VFC or VFA 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: https://exclusions.oig.hhs.gov/
- Enroll annually.
- Serve a VFC and/or VFA eligible population.
- Have a valid medical license.
- Can adequately store vaccine and vaccine products.
- Safely administer vaccine.
- Follow the ACIP recommended immunization schedule.
- Follow all VFC/VFA program requirements for reporting.

The ND HHS Immunization Unit 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/VFA PROVIDERS

The ND HHS Immunization Unit will recruit any provider who expresses interest in participating in the VFC program and has the potential to vaccinate VFC, VFA, or other state-eligible patients. Through professional memberships, collaboration with other state agencies and active outreach the ND HHS Immunization Unit 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 large 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/VFA PROGRAM

Once a new provider is identified and is deemed eligible (see VFC eligibility) for providing VFC or VFA vaccine, an enrollment visit is scheduled with the corresponding regional VFC coordinator. At the same time, the link for the electronic enrollment survey is sent to the primary contact at the clinic. The electronic form must be completed, and the last page of the survey printed and signed by the medical director. The new provider is also informed that they should begin monitoring temperatures as soon as possible. Before vaccine orders will be processed, the new provider must show records of one week of stable, in-range temperatures and submit them to the ND HHS Immunization Unit. The primary and secondary immunization contact should also view an educational module focusing on the VFC program and proper storage and handling. Once the module has been viewed, a short post-test must be taken on the ND HHS Immunization Unit's website. Once the post-test is taken, the ND HHS Immunization Unit will receive notification of the completed test.

New NDIIS providers pins will not always be assigned. A few examples of when a new NDIIS provider pin would be issues are for brand new facilities, those not previously enrolled with the NDIIS, if a healthcare facility decides to split clinics for better accountability (family practice and pediatrics for example), if a significant change is made to the practice type or services offered or for facilities who closed permanently and were purchased by another facility. The ND HHS Immunization Unit reserves the right to determine if creating a new NDIIS pin is warranted. Facilities who are purchased by another health care entity, but do not physically close the practice and maintain staff and/or vaccine inventory will not be issued a new NDIIS provider pin. All previous corrective actions, vaccine orders and balances owed according to the NDIIS will transfer with the purchase of the clinic.

VFC/VFA RE-ENROLLMENT

Enrollment is done annually, generally in late winter/early spring. Every enrolled provider from the previous year will receive a memo by email with instructions on how to complete the enrollment process. The online enrollment survey will obtain all contact information and designate a primary and secondary contact. The final page of the survey requires a medical director signature agreeing to all VFC program requirements. This page is necessary because it must be signed by the medical director and must be returned to ND HHS.

The VFA enrollment will be a separate online enrollment survey. Providers wishing to provide any vaccines to eligible adults must complete the survey. The online enrollment survey will obtain all contact information and designate a primary and secondary contact. The final page of the survey requires a medical director signature agreeing to all VFA program requirements. This page is necessary because it must be signed by the medical director and must be returned to ND HHS.

The provider profile contains pre-populated estimates of clients with NDIIS data from the previous calendar year. Providers will receive a profile specific to their facility along with the

annual enrollment email. Providers are then asked to review the numbers noted on the pre-populated profile. If for some reason the numbers are deemed inaccurate, the provider should make changes to the profile form and include it with the signature page of the enrollment form. The ND HHS will then contact providers who feel their numbers were incorrect and work to resolve the issue. The number of patients per provider will be determined on their last provider visited, excluding influenza.

If ND HHS does not receive copies of the signature page by the due date providers will be unable to order VFC and VFA vaccine until the necessary paperwork is received.

All providers must also complete an educational component each year. There is an educational module focusing on storage and handling and the VFC program. For each facility the primary and secondary vaccine contact must complete this training along with a post-test provided by the ND HHS Immunization Unit. If this is not done prior to the enrollment due date the provider will not be able to receive VFC vaccine until these steps are 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 choose to continue in the VFC program.

If a facility leaves the VFC or VFA program and then chooses to reenroll they will need to complete the entire enrollment process, including a VFC or VFA enrollment visit. All previous VFC compliance site visit corrective actions and any outstanding balances owed to the state according to the NDIIS will need to be addressed and paid back prior to receiving their first VFC or VFA vaccine order.

VACCINE ORDERING AND DISTRIBUTION

VFC AND VFA VACCINE ORDERING

Providers must submit all vaccine orders using the NDIIS. No paper or online orders are accepted. Providers may still place material orders online at: www.hhs.nd.gov/immunizations/providers.

Vaccine orders will not be processed until the ND HHS has received monthly data logger temperature logs from the provider. The only temperature log that should be sent to the ND HHS is the log that is downloaded from the provider's data loggers. Data logger temperature logs should be emailed to dohtemplogs@nd.gov monthly. Paper temperature logs are reviewed at VFC or VFA site visits but are not required to be sent in monthly. As a reminder, all storage units that contain VFC, VFA, or other state-supplied vaccines must use a continuous recording data logger for monitoring temperatures (see Thermometers for more information). The NDIIS vaccine ordering module populates doses administered and current inventory on hand. Providers must complete a vaccine reconciliation within seven days of placing a vaccine order. Completing a vaccine reconciliation in the NDIIS updates a provider's inventory based on current doses on hand.

Before proceeding to the vaccine ordering section of the ordering module, providers must verify that contact information and business hours for your facility are correct. This will determine who should be contacted when the vaccine arrives as well appropriate hours for it to 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 suggested maximum. Providers are not guaranteed to receive anything over a three-month inventory. Orders may be adjusted by the ND HHS if a provider has ordered too much vaccine based on VFC-eligible population, provider inventory, balances based on borrowing activity, vaccine availability and doses administered reports.

All providers are strongly recommended to carry both PPSV23 and Men B vaccines for use in high-risk pediatric patients. At compliance site visits, providers will be asked if they are providing these vaccines and, if not, how they would ensure that high-risk VFC patients received them. Providers will not be required to keep either PPSV23 or Men B vaccines on hand but will be educated at the time of the visit that they must be ordered if a VFC patient requests PPSV23 and Men B vaccine, or is recommended to receive them, based on a high-risk condition. As a reminder PPSV23 is available for order from ND HHS in single dose increments.

Providers should not place more than one vaccine order per month except in the case of an emergency. Please call the ND HHS Immunization Unit for approval prior to placing a second order or email vaccine@nd.gov.

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.

RESPIRATORY SEASON VACCINE PRE-BOOKING

There is a different process for ordering influenza and COVID-19 vaccine than from ordering other vaccines. The ND HHS Immunization Unit will request providers to pre-book influenza and COVID-19 vaccine for VFC and VFA eligible adults in late winter to early spring prior to the following respiratory season. Example: pre-book in January for distribution of influenza and COVID-19 vaccine in late summer, fall and winter. Providers will be able to prebook influenza and COVID-19 vaccine for un/underinsured adultsInfluenza and COVID-19 vaccine that is prebooked by providers for VFC eligible pediatric patients should not be used for the adult population. Once influenza and COVID-19 vaccine is available for distribution, ND HHS will allocate doses to providers based on their pre-book and vaccine availability. For example, if 20 percent of the total state's pediatric injectable vaccine pre-book is available then each provider will be allocated approximately 20 percent of their pre-book (some variability may exist due to rounding). After all the pre-booked vaccine has been allocated the ND HHS will allow for additional orders of influenza vaccine.

VACCINE DISTRIBUTION

ND HHS Immunization Unit will act as the central contact for VFC and VFA vaccine distribution and ordering. McKesson Specialty, Ltd., Merck and Pfizerwill act as the distributors for VFC and VFA vaccine.

Non-frozen vaccine is shipped Mondays, Tuesdays and Wednesdays only. This ensures the vaccine will arrive before the weekend. The method of shipping vaccine is a commercial shipping company. Frozen vaccines (Varicella and MMRV) can be shipped Monday – Friday and delivered Monday – Friday, so providers should keep this in mind when placing orders for frozen vaccines.

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

For facilities who have shorter business hours on a certain day they may consider marking their business hours as closed on that particular day in the NDIIS ordering module. If a facility is marked as open a commercial carrier may try to deliver at any point in that business day regardless of what hours are posted for that day (i.e., closes at noon on Fridays). Vaccine depots may not replace non-viable vaccine if the attempted delivery was on a day the facility was marked as open.

Occasionally weather delays such as extreme cold, blizzards or flooding will occur either nationally or locally which may delay VFC and VFA vaccine shipments. The ND HHS Immunization Unit will do their best to communicate these delays using the message boards in the NDIIS or via email. If a vaccine order is taking longer than expected providers can always login to the NDIIS to look for vaccine tracking information or email questions to vaccine@nd.gov.

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 will be responsible for the following:

- Monitor and record the min/max temperatures once daily, preferably in the morning, from the data logger on the paper temperature logs for each storage unit containing state-supplied vaccine. Paper temperature log recording is still required if the data logger is not able to capture date, time and initials of person checking temperatures. If a provider's data logger is able to capture those data points, electronic recording is sufficient. Paper temperature logs do not need to be submitted to the ND HHS but should be kept on hand for three years and will be reviewed at VFC or VFA site visits. Providers are strongly encouraged to check the temperature of the storage unit each time obtaining vaccine to ensure appropriate temperatures are being maintained.
- If necessary, adjust the temperature of a vaccine storage unit.
- The primary vaccine coordinator should review temperature logs weekly if daily monitoring is conducted by a backup person to ensure proper temperature recording. Backup staff should monitor the temperature logs if the primary coordinator is recording the daily temperatures.
- Check expiration dates of vaccine and ensuring the earliest outdates are placed in the front of the freezer/refrigerator weekly.
- Track beyond-use-dates and ensure vaccines are returned to McKesson for disposal.
- Receive all state-supplied vaccine shipments or ensure that others who may receive the order are aware of the procedure for receiving vaccine.
- Train 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.
- Contact the ND HHS Immunization Unit as soon as there is a change in vaccine coordinators.
- Utilize and maintain proper vaccine storage equipment and temperature monitoring devices.
- Perform vaccine management practices through proper ordering and inventory management.
- Develop and maintain an organizational system to distinguish between public and private stock.
- Post appropriate signage in order to protect vaccine supply from loss of power.
- Ensure the Vaccine Management Template and emergency vaccine relocation plan are updated at least annually or more frequently if staffing has changed. The plan must be signed and dated by the person completing it.

It is recommended that all birthing hospitals have a contact designated from the pharmacy and one from the delivery floor. VFC vaccine is often stored and ordered by the pharmacy, but eligibility screening and administration is done on the delivery floor, so it is important to make sure that both areas are actively involved in the VFC program.

Each year the primary and secondary VFC contact from each enrolled facility are required to complete an online module about the VFC program. All staff who work with vaccines should

complete the training, but at least two contacts from each facility are required. The online training will be posted on the ND HHS Immunization Unit webpage and will need to be completed by each facility prior to the enrollment deadline or other specified date by the ND HHS Immunization Unit. After viewing the module, providers will need to fill out a post-test found on the Immunization Unit website. The information from the post-test will be sent to the Immunization Unit 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 to prevent the wastage of increasingly expensive vaccines.

Proper vaccine storage and handling is necessary to prevent having to repeat vaccinations in children who received doses of improperly stored vaccine. Repeat vaccinations can lead to an increase in adverse reactions, distrust from patients 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 the *Vaccine Storage and Handling Toolkit* published by the CDC. The toolkit can be found at https://www.cdc.gov/vaccines/hcp/downloads/storage-handling-toolkit.pdf.

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 now requires 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. 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 a given timeframe.

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

VACCINE STORAGE

STORAGE REQUIREMENTS

All VFC providers are required to have appropriate equipment that can store and maintain proper conditions for 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 Immunization Unit for guidance prior to purchasing new refrigerators or freezers.. After purchasing a new refrigerator or freezer, providers should monitor and document the min/max temperatures in the unit one daily for one week prior to storing any vaccine in the unit.

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

- Can maintain required, stable vaccine storage temperatures year-round.
- Be large enough to hold the year's largest inventory.
- Have a working, certified and calibrated continuous recording data logger inside each storage compartment.
- Be dedicated only to the storage of vaccines. Non-medical food or 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 does not allow 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. If vaccine has been stored in a dorm-style unit at any point, it should be considered non-viable.

GUIDELINES FOR PROPER STORAGE

The information in this section is vital to the proper storage of vaccines.

INSIDE THE STORAGE UNIT

Do not store non-medical food or beverages in a refrigerator that contains vaccines. If other biologicals (e.g., medications, blood products, etc.) must be stored in the same storage unit, vaccine should always be stored above the other biologicals to prevent spills.

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 air vent in the top of the refrigerator might be colder than the rest of the refrigerator and could freeze vaccines. Vaccines 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 and replace with cold water jugs or bottles. **DO NOT STORE VACCINE IN THE SPACE FORMERLY OCCUPIED BY VEGETABLE BINS.**

Place frozen water bottles 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 label 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. The CDC has template vaccine labels for vaccine storage bins to help differentiate between like sounding vaccines and contain brief vaccine recommendations and indications. Providers should keep in mind that labels may need to be updated, as vaccine recommendations or indications change. Template labels can be found here: www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf

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. Most state VFC and VFA vaccines do not have to be separated. Influenza and COVID-19 vaccine ordered with adult intent must be separated from the VFC stock of influenza and COVID-19 vaccine. ND HHS has protocol in place that has been approved by the CDC allowing providers to store most state-supplied vaccines together. Bright orange VFC stickers are available from the ND HHS at no charge for providers to help in differentiating between different stocks of vaccine. Bright green VFA stickers are also available from HHS at no charge. The labels can be stuck to vaccine packaging to make it clear that this is VFC or VFA vaccine. Providers may order these online: www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/providers

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

Remove expired vaccine or vaccine that has reached it's beyond-use-date from the storage unit as soon as possible after its expiration or beyond-use date to prevent administration errors. Check vaccine inventory weekly for expiring vaccine, and rotate stock so the shortest outdated vaccines are in the front. All VFC and VFA vaccines must be reported and returned within six months of expiration.

Store vaccine in its original packaging. This protects vaccine from light which can affect viability. It also makes checking expiration dates and documenting correct lot numbers much easier.

STORING DILUENTS

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

Must be refrigerated: ActHib®, Menveo®, Pentacel® (DTaP-IPV/Hib) and Shingrix® (RZV).

Room temperature: COVID-19 vaccine (6 months – 4 years)

Refrigerate or room temperature: Hiberix® (Hib), MMR®II, Priorix®, ProQuad® (MMRV), Rotarix® (RV1) and Varivax® (Var).

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 vaccines 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 by a data logger 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 AND FROZEN VACCINE

The following vaccines **MUST** be stored at temperatures of 2°C – 8°C or 36°F – 46°F:

DT	RSV (Nirsevimab)	RSV (Abrysvo)
DTaP	**Hepatitis A/B**	**Men B**
DTaP/HBV/IPV	**Hepatitis A**	**MMR***
DTaP/HBV/Hib/IPV	**Hepatitis B**	**PCV**
DTaP/Hib/IPV	**HPV**	**PPSV23**
DTaP/IPV	**HIB**	**Rotavirus**
Moderna COVID-19 Vaccine[1]	**Influenza**	**Td**
Novavax COVID-19 Vaccine	**IPV**	**Tdap**
Pfizer COVID-19 Vaccine[2]	**MCV-4**	**Zoster (RZV)**

[1] Moderna COVID-19 vaccine may be stored between -50°C and -15°C (-58°F and 5°F) until the expiration date or between 2°C and 8°C (36°F and 46°F) for up to 60 days.

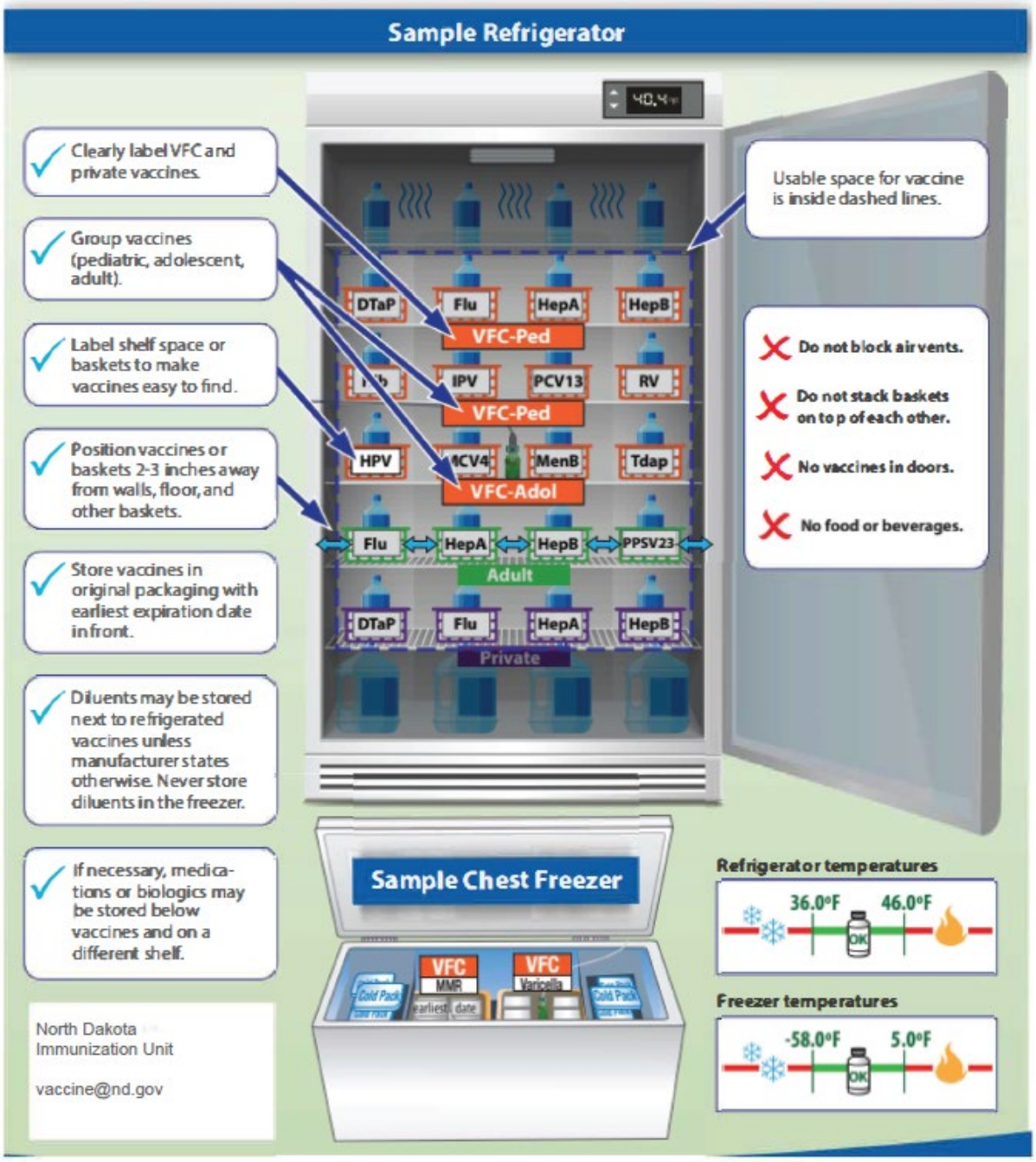
[2] Pfizer COVID-19 vaccine in single and multi-dose vials may be stored between -90°C and -60°C (-130°F and -76°F) until the expiration date or between 2°C and 8°C (36°F and 46°F) for up to 10 weeks. Pfizer COVID-19 vaccine in Manufacturer-filled syringes MUST be stored between 2°C and 8°C (36F and 46F) until the expiration date.

*MMR®II vaccine may be stored in the refrigerator or the freezer. Storing MMR®II 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. Priorix® brand MMR vaccine MUST be stored in the refrigerator only.

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

Protect varicella and MMRV vaccine from light before and after reconstitution.

Best Practices for Vaccine Storage and Handling



TEMPERATURE RECORDING DEVICES

Providers must monitor the temperature of their refrigerator/freezer with certified thermometers. All providers are required to use an electronic data logger to monitor the temperatures of all units that store VFA or VFC-supplied vaccine. 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. Providers are encouraged to contact the ND HHS Immunization Unit for guidance prior to purchasing new thermometers. Follow the 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. Purchasing thermometers and maintaining a current calibration certificate is the responsibility of the health care provider, not ND HHS. If a current certificate of calibration is not retained, the calibration company should be contacted by the provider to request a replacement certificate. If replacing the certificate is not possible, a new data logger will need to be purchased by the provider.

Certificates of calibration must meet certain criteria to be considered acceptable. They must meet all criteria listed below in order to meet the requirement:

- Model/Device Name or Number
- Serial Number
- Date of Calibration (Report or Issue Date)
- Instrument Passed Testing (Instrument in Tolerance)

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 data logger in a refrigerator or freezer that contains VFC or state-supplied vaccine. Providers must have a back-up certified, calibrated data logger to use when the primary thermometer is sent to be recalibrated or if the primary data logger malfunctions. Having a back-up data logger is a VFC program requirement and will be assessed at compliance site visits.

All providers are required to use an electronic data logger to monitor the temperatures of any units that storage state or VFC-supplied vaccine. Thermometers should be placed in the center of the refrigerator, next to the vaccine. The CDC requires the use of a digital data logger with a detachable 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:

- Detachable probe that best reflects vaccine temperatures, such as a probe buffered with glycol, glass beads, sand or Teflon®
- Alarm for out-of-range temperatures.

- Current temperature as well as minimum and maximum temperatures.
- 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).

All providers are required to have a certified and calibrated back-up data logger on hand. The thermometers should not be stored in storage units with vaccines. The back-up data logger must be available for use in case the primary data logger fails or needs to be recalibrated or replaced. The VFC coordinator will ask to see the back-up data loggers at all VFC compliance site visits. Back-up data loggers should be stored in a place where staff have access and know where they are stored. It is the responsibility of the provider to keep a certified and calibrated data logger available for use as a back-up recording device.

TEMPERATURE MONITORING

Providers are required to record the minimum and maximum temperatures, preferably at the beginning of each clinic day. Reviewing and recording minimum and maximum temperature readings at the beginning of the workday ensures that refrigerator and freezer temperatures have been in the appropriate range. Even though the min/max temperature requirement has taken the place of the twice daily temperature checks however, it is still a good preventative step for clinic staff to check and document temperatures twice daily even though it is no longer required. Staff should be educated to visually check the temperature of the unit, each time it is entered. 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.hhs.nd.gov/storage-and-handling. **Copies of data logger temperature recording charts must be submitted to the ND HHS monthly for each unit containing state-supplied vaccine**. Data logger temperature logs should be emailed to dohtemplogs@nd.gov.

Temperature logs must be kept on hand for a minimum of three years. This applies to both electronic data logger temperature charts and paper temperature logs.

Actions must be taken and RECORDED on every out-of-range temperature. If refrigerator or freezer temperatures are out-of-range, record the temperature on a temperature log and immediately isolate the affected vaccine. Mark “do not use” until the vaccine manufacturers and ND HHS has been contacted. Do not assume that the vaccine is not viable, and do not discard any state-supplied vaccine. Recorded actions should be sent to ND HHS monthly 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. Providers may find it help to complete the Vaccine Storage Troubleshooting Guide during a temperature excursion which can be found on the Immunization Unit’s website:www.hhs.nd.gov/storage-and-handling. This form contains the steps to take when dealing with a temperate excursion. It also includes

vaccine manufacturer contact information, and a section to document all steps that have been taken. Temperature excursions can now be reported online here: https://www.hhs.nd.gov/storage-and-handling.

In 2024, the Immunization Unit changed the definition of a temperature excursion to be 30 minutes outside of the recommended temperature range, whether that be a warm or cold excursion. This change was based on updated guidance from the CDC. If facilities are able to reset their data logger, alarm triggers should be set at 30 minutes outside of the acceptable temperature range, whether it be warm or cold. If facilities need assistance in resetting data loggers, or to find out if your data logger can be reset, please email vaccine@nd.gov.

For those who are not able to reset their data loggers due to manufacturer constraints, the updated excursion time frame will need to be in place by January 1, 2026. This should give providers enough time to replace data loggers as they expire. In the meantime, previous excursion time frame will still be honored. Most brands of data loggers should be able to be reset.

Electronic data logger temperature charts should be emailed to dohtemplogs@nd.gov **monthly.** Vaccine orders will not be approved without data logger temperature charts. Data logger temperature log monthly submissions will be tracked in NDIIS. Providers may still place vaccine orders if there is a message stating missing temperature logs. The vaccine order will either be returned if the temperature logs are truly missing or approved if temperature logs have been sent in. Please keep in mind it is staff who are documenting when temperature logs are being submitted so the NDIIS may not be updated real-time.

The thermometer probe must be located in the center of the storage unit. If the probe is located near a fan or wall, the thermometer may have distorted temperatures as these locations in the storage unit may actually be colder or warmer than where the vaccine is stored. It is also important to be sure that the probe is located with or near the vaccine in order to give the actual temperature of the vaccine.

INAPPROPRIATE OR UNKNOWN STORAGE ENVIRONMENTS

The Immunization Unit reviews temperature logs submitted by enrolled providers. The following situations may prompt action by the ND HHS:

- Minimum and maximum temperatures are not being documented daily when the clinic 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 Immunization Unit 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 Immunization Unit reserves the right to invalidate any doses of vaccine that were administered after being exposed to unknown or inappropriate temperatures. ND HHS 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, ND HHS 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 their listed expiration date or beyond use date whichever comes first. If the expiration date is listed as a month and year only, vaccine is valid until the end of that month (e.g., July 2026 – valid until July 31, 2026). **Vaccines must be utilized until the expiration or beyond-use date**.

This guidance does not replace information provided on a vaccine package insert. Package inserts should be consulted by providers any time a new vaccine is licensed, there is a large change in recommendations or licensure has been made or for each influenza vaccine season.

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

The most current version of the Vaccine Information Statement (VIS), immunization information statement (IIS) or EUA/fact sheet should be given at each immunization encounter and for every immunization given. The Immunization Unit does not provide copies of these documents for provider offices. However, the Immunization Unit does notify providers when versions of these documents have been updated. This notification occurs through the immunization email list-serve. On each compliance site visit, all dates are checked to ensure provider offices have the most recent copy. If a provider is using an old version or not supplying these documents, they will receive follow-up and must demonstrate that they have corrected the issue.

According to North Dakota Century Code 23-01-05.3, all immunizations administered to those 18 and younger must be entered into the NDIIS within four weeks of administration. The VFA enrollment agreement requires participating facilities to also enter all doses of publicly supplied

vaccines to eligible adults in the NDIIS. . Eligibility is a required field in NDIIS and is entered at the dose level. All required fields must be completed in the NDIIS; 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, IIS or EUA
- 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 email and can also be found at https://www.hhs.nd.gov/immunizations/immunization-resourcess. This template should be reviewed and updated as needed, and at least annually. ND HHS staff making compliance site visits will be reviewing provider vaccine management plans. At a minimum, the 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.
- Date the plan was last updated and signature of staff person who completed the plan.
- 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. 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

Providers that care for VFC-eligible and privately insured children in North Dakota must maintain two separate inventories of vaccines: privately purchased vaccine for 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 (nonviable vaccine shipment, vaccine delivery delay etc.). Accidentally administering a dose of vaccine from the wrong inventory (e.g., giving a dose of VFC MMR vaccine to a not-eligible child) is considered borrowing. In the event of a vaccine-preventable disease outbreak, the use of VFC vaccine for non-VFC eligible patients must first be approved by ND HHS and may constitute borrowing if this approval is not given beforehand. **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: https://www.hhs.nd.gov/immunizations/immunization-resources.

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.hhs.nd.gov/public-health-information/diseases-conditions-and-immunization/immunizations/trainings

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 (e.g., 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. Certain providers have found that due to billing issues in their electronic medical record, they are unable to enter doses involved in a borrow or return exactly as they were given. If this is the case, the provider should enter the dose the way it is necessary for correct billing and then go into NDIIS and correct the dose to show it as it was given.
- ND HHS requires that providers return any borrowed vaccine (whether private or state supply) within four weeks of the occurrence.
- No more than five doses of COVID-19 or Nirsevimab should be borrowed from either inventory at a time.
- 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.

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, they are considered a VFC-

eligible child 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.

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 vaccine considered to be non-viable because it has expired, spoiled because of a temperature excursion or due to a vaccine recall must be returned to McKesson. 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.

All vaccine returns and wastages must be entered into the NDIIS. For training on how to use the NDIIS vaccine return and wastage module, go to www.hhs.nd.gov/public-health-information/diseases-conditions-and-immunization/immunizations/trainings.

Notify the ND HHS Immunization Unit if any vaccine must be wasted as a result of exposure to temperatures outside of the acceptable range. Failure to report wasted vaccine may result in your facility no longer being able to receive state-supplied vaccine. Reporting of all temperature excursions, regardless of wasted vaccine, can now be reported online on the Immunization Unit's website: https://www.hhs.nd.gov/storage-and-handling..

Return all unopened vials and manufacturer's pre-filled syringes of non-viable vaccine to McKesson. Vaccine provided by ND HHS 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 cannot be sent back to McKesson. The vaccine should be reported as wastage in the NDIIS vaccine return and wastage module. The open vials and syringes should then be discarded per your facility's policy.

All spoiled/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

NDIIS vaccine return and wastage module. 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. All vaccine returns should be entered into the NDIIS vaccine return and wastage module.
2. Within one to two business days, the primary contact should receive an automated email from NDIIS saying that their packing slip is ready to be printed. The provider should then go back into the previous vaccine return and print the packing slip. McKesson will send a return label in the mail, or email the label to the primary contact, depending on what method of delivery was chosen when the vaccine return was submitted in NDIIS. If a pickup needs to be scheduled, please contact the ND HHS Immunization Unit. 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 pickup.
3. If the provider chose to have the return label emailed, the primary contact should receive the emailed label within 1-2 business days of submitting the vaccine return in NDIIS.
4. Prior to shipping unopened, non-viable vaccine, you must have a packing slip from NDIIS **AND** a shipping label from McKesson.
5. Ship unopened non-viable vaccine and a copy of the packing slip in a shipping container received from previous vaccine shipments.
6. **DO NOT** ship viable vaccine to McKesson.
7. **DO NOT** ship viable or non-viable vaccine to the ND HHS.

VACCINE TRANSFER

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

Providers are required to use electronic data loggers when transporting any VFC or state-supplied vaccines. All vaccine transport data logger temperature charts must be submitted to ND HHS within the same month that the vaccine was transported in.

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*

https://www.cdc.gov/vaccines/hcp/downloads/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. Never place vaccine in the trunk of a car or leave it unattended for long periods of time. Whenever transferring or transporting vaccine an electronic data logger should be placed in the package. When the vaccine arrives at its destination the data logger should be checked to ensure that the vaccine has stayed within the appropriate temperature range.

Frozen vaccine must 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 ND HHS Immunization Unit has developed a short tip guide on transporting vaccine which can be found on our website at www.hhs.nd.gov/storage-and-handling.

PROVIDER-TO-PROVIDER TRANSFER OF VACCINES

Providers who have excess vaccine on hand that will not be used before expiration are encouraged to transfer the 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. The provider must also properly pack and transport the vaccine to the receiving provider following standard cold-chain procedures.** While ND HHS is willing to assist, when possible, it is very difficult to match an odd number of vaccines with other provider orders and try to arrange for transferring between providers. Providers can find contact information for other VFC providers in their area in the NDIIS under the Provider "Management" section. Providers must also transfer the doses in NDIIS. Providers may only transfer state or VFC vaccine to other providers who are currently enrolled in the Prevention Partnership Program. If you need help determining which providers are enrolled in the program, please contact the ND HHS Immunization Unit.

VACCINE PACKAGING/SHIPPING

There are a variety of materials available to ensure vaccines are protected and kept at the appropriate temperature during transport. Vaccines other than varicella and MMRV vaccine need to be kept cool but not frozen during the shipping process. Varicella and MMRV vaccines need to be kept frozen while being shipped. Because the use of dry ice is no longer allowed for transporting frozen vaccines from provider offices, the Immunization Unit 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 hourly 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, view CDC's Storage and Handling Toolkit at https://www.cdc.gov/vaccines/hcp/downloads/storage-handling-toolkit.pdf. The Immunization Unit has also developed a short tip guide on transporting vaccine and can be found on our website at www.hhs.nd.gov/storage-and-handling.

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: deq.nd.gov/Publications/WM/NorthDakotaPharmaceuticalWasteGuidance.pdf. For information about vaccines that contain thimerosal, visit: www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228#thi.
- Hazardous waste should be kept separate and be disposed of properly. A list of hazardous waste disposal companies can be found at: deq.nd.gov/WM/HazardousWasteProgram/PermittedFacilities/. 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, and a back-up employee should also be trained. Providers must be on site with appropriate staff to receive vaccine at least one day a week, other than Monday, and for at least four consecutive hours on that day. If this is not possible, vaccine cannot and will not be delivered to the facility.

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.

Steps for Receiving Vaccine:

- Examine the shipping container and its contents for any signs of physical damage.
- Determine if the shipping time was less than 48 hours for McKesson shipments. Varicella vaccine from Merck may be shipped in either a two day or four-day shipper. MMRV is always shipped overnight and is only guaranteed for 24 hours. 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 and MMRV vaccines, must be refrigerated immediately at 36°F – 46°F (2°C – 8°C).
- Varicella and MMRV vaccines must be immediately stored in the freezer at a temperature between -58°F and +5°F (-50°C and -15°C). MMR®II can be refrigerated or frozen upon receipt. Priorix® brand MMR must be refrigerated, never frozen.

If there are any discrepancies with the packing slip or concerns about the shipment, immediately notify the primary vaccine coordinator (or back-up coordinator). Label the vaccines “DO NOT USE,” and store the vaccines under appropriate conditions separate from other vaccine supplies. Then contact the ND HHS Immunization Unit and either Merck or McKesson, based on who the shipment is from.

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 Unit's budget.

Prevention Partnership Providers are required to report all wasted, expired, spoiled or lost vaccine to the Immunization Unit, and it 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 Immunization Unit'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 Unit 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 VACCINE REPLACEMENT

The ND HHS Immunization Unit, with cooperation from the provider, may determine that replacement is not necessary, even if criteria from this section have been met based on reasons that were outside of the provider's control.

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 Immunization Unit 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 Unit 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 min/max temperatures once 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 purchasing 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 ND HHS Vaccine Coverage Table which can be found here: https://www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/immunization-resources.
- Discarding vaccine before the manufacturer's expiration date (includes multi-dose vials).

SITUATIONS THAT DO NOT REQUIRE VACCINE REPLACEMENT

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 for vaccine loss. 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 vaccine manufacturer later deems the vaccine not viable.
- Power was interrupted or discontinued due to a storm and, after consultation with the vaccine manufacturer, 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.
- Refrigerator/freezer equipment problems where proof of repair or equipment replacement is provided to the Immunization Unit within 30 days from the date the situation was discovered.
- Extraordinary situations not listed above which are deemed by the North Dakota Immunization Unit to be beyond the provider's control.

PROCEDURES FOR VACCINE REPLACEMENT

The vaccine replacement policy applies to any vaccine reported as wasted or returned. All vaccine must be replaced on a dose-for-dose basis if deemed necessary by the Immunization Unit.

- The provider will receive notification from the ND HHS for vaccine reported as wasted to the North Dakota Immunization Unit.
- The notification 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, unless otherwise determined appropriate by the Immunization Unit.
- Replacement of the vaccine is **due within 60 days** of receiving the invoice.
- If replacement is not completed within 60 days, Immunization Unit will not supply vaccine to the negligent provider until proof of replacement is received.

- The ND HHS 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 ND HHS 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:

https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-455.

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 Unit, a health insurance company, or a patient]; or in reimbursement for services that are not medically necessary or 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 Berg, VFC Manager, is designated as the primary contact.
600 E Boulevard Ave, Dept 325
Bismarck, ND 58505
(P) 701-328-3324 (F) 701-328-0355
alberg@nd.gov

Molly Howell, Immunization Unit Director, is designated as first back-up.
600 E Boulevard Ave, Dept 325
Bismarck, ND 58505
(P) 701-328-4556 (F) 701-328-0355
mahowell@nd.gov

Miranda Baumgartner, VFC/QI Coordinator, is designated as second back-up.
600 E Boulevard Ave, Dept 325
Bismarck, ND 58505
(P) 701-328-2035 (F) 701-328-0355
mlbaumgartner@nd.gov

FRAUD AND ABUSE HOTLINE

Suspected cases of fraud and abuse should be reported immediately to the ND HHS Immunization Unit 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 ND HHS Immunization Unit
- Description of suspected misconduct
- Specific VFC requirements violated
- Specific dates and actions taken with provider (specific follow-up activities: education, site visit, suspension, removal of vaccine or other actions taken prior to disposition)
- 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 to prevent or detect than others, depending on how the VFC program is implemented. The Immunization Unit 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 Unit 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 ND HHS Immunization Unit staff, the program manager and VFC manager will be notified immediately. Within five working days, the appropriate Immunization Unit 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 Unit 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 five working days the appropriate ND HHS Immunization Unit staff member will first interview the individual and then the provider, 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 Unit will follow-up with the external agency within seven working days or sooner if further information needs to be shared.

The ND HHS 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.

ND HHS Immunization Unit 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 Unit 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 Office of the Inspector General, U.S. Department of Health and Human Services.** All referrals will be sent to:

Office of the Inspector General,
U.S. Department of Health and Human Services
1-800-447-8477 (1-800-HHS-TIPS)

The following information should be included to assist the ND HHS OIG 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 information is that a provider might be engaging in behavior that puts 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 or 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 ND HHS OIG 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 Attorney General's Office 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 Program Integrity Management to determine course of action. Cases may then either be handled internally or referred to the Medicaid Fraud Control Unit. The entity taking action will be responsible for reporting any sanctions to the Office ND HHS OIG for the national register. The contacts for Medicaid are:

Denise Martino, Medicaid Program Integrity Unit
Medical Services Division Department of Human Services
600 E Boulevard. Ave, Department 325, Bismarck, ND 58505
701-328-4024
medicaidfraud@nd.gov

Stacy Chadwick, Administrator, Quality Performance & Health Tracks
Medical Services Division Department of Human Services
600 E Boulevard. Ave, Department 325, Bismarck, ND 58505
701-328-2230
schadwick@nd.gov

Allegations involving a facility who bills Medicaid or involving an individual with Medicaid coverage will also be reported to:

Office of the ND Attorney General, Medicaid Fraud Control Unit (MFCU)
PO Box 2495
Bismarck ND 58502-2495

Phone # 701-328-5446
agomedicaidfraud@nd.gov
attorneygeneral.nd.gov/sites/ag/files/documents/MFCU/MFCU-Complaint-SFN61788.pdf

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 and the North Dakota Insurance Department (if appropriate). The contact for the Office of the Attorney General is:

Drew Wrigley, Attorney General
State Capitol
600 E. Boulevard Ave.
Dept. 125
Bismarck, ND 58505
701-328-2210
dwrigley@nd.gov

The website to report fraud to the North Dakota Insurance Department:
www.insurance.nd.gov/consumers/fraud

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 ND HHS Immunization Unit to the appropriate agency via a phone call to the designated contact person. The Immunization Unit will then provide the agency with written documentation, including a completed Fraud and Abuse Report Form, North Dakota Provider enrollment agreements and profiles, 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 ND HHS OIG as the official report to the CDC.

North Dakota POB Project Officer:

Jason Rothbard
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd, MS A-19, Atlanta, GA 30333
cwp0@cdc.gov

North Dakota POB Back-up Project Officer:

Mimi Eckert
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd, MS A-19, Atlanta, GA 30333
mml9@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 CDC's *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 ND HHS Immunization Unit 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 Immunization Unit 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 ND HHS OIG agencies will be notified.**

The ND HHS Immunization Unit 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 ND HHS Immunization Unit, 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/VFA PROVIDER TERMINATIONS

ND HHS will determine whether or not a provider should be terminated from the VFC/VFA program. Providers will be notified in a written, certified letter via email of termination from the VFC/VFA program. Providers who have been terminated from the VFC/VFA program due to allegations of fraud and abuse will immediately be suspended from ordering vaccines and all other VFC/VFA programmatic activities.

Providers that are terminated from the VFC/VFA 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 ND HHS VFC Manager is responsible for maintaining and updating this policy. When updated, this policy must be reviewed and approved by the ND HHS Immunization Unit 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 ND HHS Immunization Unit.

The ND HHS 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 Unit at 701.328.2378 or toll-free 800.472.2180.

FRAUD AND ABUSE PREVENTION

The ND HHS Immunization Unit takes many steps to prevent fraud and abuse. VFC Coordinators conduct site visits at a minimum of 50 percent 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 Immunization Unit 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 Immunization Unit 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.

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

- **<u>Underinsured</u>:** 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. LPHUs in North Dakota are delegated authority to vaccinate underinsured children with VFC vaccine. The ND HHS supplies federal 317 vaccine to private providers to vaccinated underinsured children.**

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

Children who had health insurance through Healthy Steps are now enrolled in North Dakota Medicaid. These families should have Medicaid cards and eligibility should be updated. VFC vaccine should be given to these children and Medicaid billed for the VFC administration fee.

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.**

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 and on a VFC vaccine borrow/return form.

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, therefore the child is underinsured and considered 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 only covers 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.

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. Providers are required to accept ND Medicaid's reimbursement.

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)?**

Providers must bill patients/families within 90 days of the date of service and can only bill once. Additional bills for the VFC administration fee cannot be sent to the family and if not paid must be written off. Providers may continue to bill for office visits as allowed under VFC policy, and unpaid bills related to office visit fees or other fees (e.g., labs) may be sent to collections. Unpaid administration fees, however, may not be sent to collections, and the provider may not refuse to vaccinate an eligible child whose parents have unpaid vaccine administration fees.

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 those doses 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 (e.g., 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 the 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 ND HHS, 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.

6. **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?**

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 a VFC-eligible child 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.

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. Providers may also visit the ND HHS Immunization Unit website at www.hhs.nd.gov/storage-and-handling.

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?**

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:

- The refrigerator and freezer compartments each have a separate external door, or
- 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 data logger 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 recommends 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. Storing in the original packaging also makes it easier to check expiration dates and ensure that staff are using the correct lot number for documenting immunizations.

VACCINES FOR ADULTS (VFA) QUESTIONS AND ANSWERS

Vaccines for Adult Program Eligibility

1. What is the Vaccines for Adult program?

The Vaccines for Adult (VFA) program is a small program in North Dakota that allows uninsured and underinsured adults to be vaccinated with some immunizations mostly free of cost. This program, unlike the VFC program, is not an entitlement program created by federal legislation. This program is funded using funds known as 317-funds. These funds are awarded to states to help immunize underserved populations. North Dakota has chosen to use a portion of these funds to provide immunizations to VFA-eligible adults.

2. Who is eligible for the VFA program?

VFA vaccine should only be given to adults who are 19 years of age or older who meet one of the following categories.

a. Have no health insurance.
b. Are underinsured.

For the purposes of the VFA program underinsured is defined as a person who has health insurance but the insurance does not include any vaccines; a person whose insurance covers only selected vaccines; and, in the case of COVID-19 vaccine, a person whose insurance does not provide first-dollar coverage for vaccines.

For some vaccines available as part of the VFA program additional eligibility requirements apply.

3.Are Medicaid/Medicare eligible adults eligible to receive VFA vaccine?

No. Medicaid and Medicare are considered private insurance in adults. Adults who are Medicaid/Medicare eligible should receive private vaccine.

4. If an adult has health insurance that covers vaccinations but has a high deductible is that adult VFA-eligible?

Yes, for COVID-19 vaccine only. Adults whose insurance doesn't cover COVID-19 vaccine costs in network are eligible to receive a VFA COVID-19 vaccine. These adults must receive private vaccine for all other vaccines and insurance , or the patient should be billed.

5. If an adult has health insurance that only covers vaccinations at certain providers is that adult VFA-eligible?

No. Adults who have health insurance that covers vaccines only at certain medical providers are considered insured. They should be given privately purchased vaccine and insurance should be billed.

6. Are adults in correctional facilities VFA-eligible?

If an adult in a local or state correctional facility is uninsured or underinsured, then they are eligible to receive VFA vaccine. Facilities that receive federal or state funds for the purchase of immunizations are asked to first utilize this funding to provide immunizations to their residents. Due to the limited nature of the funds for the VFA program HHS is unable to provide all vaccines needed to immunize all residents in correctional facilities.

7. What vaccines are available as part of the VFA program?

Not all vaccines for all adults are covered under the VFA program. Additionally, for some vaccines available as part of the VFA program additional eligibility requirements apply. For additional information on what vaccines are available as part of our VFA program and what eligibility requirements apply please see the vaccine coverage table at https://www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/providers.

8. Why aren't all vaccines available to all adults on the VFA program?

Due to the limited funding that is available for the VFA program not all vaccines are able to be offered to all adults. For additional information on what vaccines are available as part of our VFA program and what eligibility requirements apply please see the vaccine coverage table at https://www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/providers.

9. Are all VFC providers required to participate in the VFA program?

No, VFC providers are not required to participate in the VFA program. Providers such as birthing hospitals or pediatric offices may choose not to enroll in the VFA program if they are not vaccinating those populations.

Administration Fees

1. What is the maximum vaccine administration fee I can charge for the VFA 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 administration fee cap applies to all available VFA vaccines except COVID-19.**

3. If a VFA eligible adult is unable to pay the vaccine administration fee, can I refuse to vaccinate that adult?

No. A provider cannot refuse to vaccinate a VFA-eligible adult if they are unable to pay the vaccine administration fee.

4. Can my clinic offset any of the cost of administering COVID-19 vaccine to VFA-eligible adults?

Yes. Some providers who have administered COVID-19 vaccine to VFA-eligible adults may be eligible to receive a $40 offset per dose administered. For additional information please email vaccine@nd.gov.

Private and VFA stocks

1. Do I need to maintain a separate stock of VFA vaccine from my VFC vaccine?

No – not for all vaccines. Generally speaking, VFC and VFA vaccines do not need to be separated. The only exception to this would be Influenza and COVID-19 vaccines. VFA Influenza and COVID-19 vaccines should be marked as VFA and kept separate from other VFC stock. Bright green VFA stickers are available from HHS at no charge for providers to help in differentiating between different stocks of vaccine. Providers may order these online: https://www.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/providers.

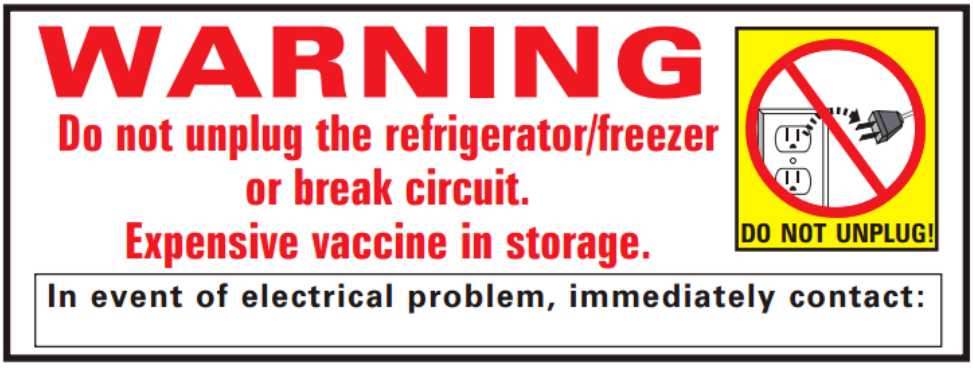
2. If my clinic does not have any private vaccine for insured adults, can I borrow VFA vaccine and then pay those doses back later when I receive additional private vaccine?

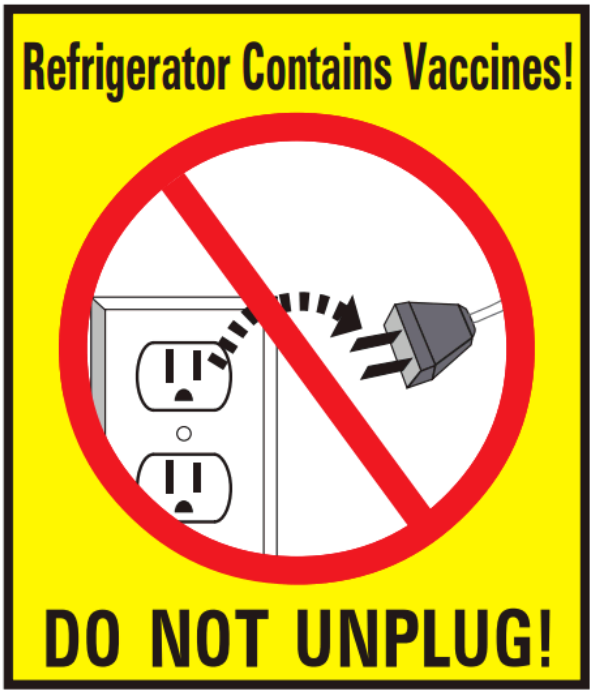
Providers that care for VFA-eligible and privately insured adults in North Dakota must maintain two separate inventories of vaccines -- privately purchased vaccine for the privately insured adults, and state-supplied vaccine for those who are eligible. Borrowing between the two inventories of vaccines may occur but must be a rare occurrence (e.g., delayed vaccine shipment, outbreak). VFA 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 VFA eligible adults if VFA seasonal influenza stock is not yet available. Those private stock doses used on VFA eligible adults can later be replaced when VFA stock becomes available. As a caution, due to the nature of influenza vaccine supply, providers may borrow private vaccine to VFA stock at their own risk, as replacement VFA doses are not guaranteed. Providers must never borrow VFC influenza vaccine to vaccinate privately insured adults.**

APPENDICES

1. **“Do Not Disconnect” Warning Signs**
2. **Vaccine Manufacturers’ Quality Control Phone Numbers**

DO NOT DISCONNECT WARNING SIGNS





NORTH Dakota Be Legendary.
Health & Human Services

Vaccine Manufacturers' Quality Control Phone Numbers

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. For questions please contact the North Dakota Immunization Program at 800.472.2180.

Vaccine Manufacturer	Contact Information	Vaccines
AstraZeneca	800.236.9933	• FluMist®
Bavarian Nordic	844.422.8274 Email: medical.information_us@bavarian-nordic.com	• Jynneos®
Dynavax	844.375.4728	• Heplisav-B®
GlaxoSmithKline	888.825.5249 https://gskusmedicalaffairs.com/stability-calculator/	• Bexsero® • Boostrix® • Engerix-B® • Fluarix® • FluLaval® • Havrix® • Hiberix® • Infanrix® • Kinrix® • Menveo® • Pediarix® • Priorix™ • Shingrix® • Twintix® • Rotarix®
Grifols	800.520.2807	• Td
Merck	800.672.6372 https://www.merckmedicalportal.com/s/temperature-stability-calculator	• Gardasil9® • MMR-II® • PedvaxHib® • Pneumovax® • Proquad® • Recombivax HB® • RotaTeq® • Vaqta® • Varivax® • Vaxelis® • Vengeance™

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Moderna	866.663.3762 Email: excursions@modernatx.com https://tools.modernamedinfo.com/excursion/	• COVID-19 Moderna
Novavax	855.239.9174	• COVID-19 Novavax
Pfizer	800.438.1985 https://www.pfizermedicalinformation.com/en-us/stability-calculator	• Prevnar 13® • PCV 20™ • Trumenba®
Pfizer COVID-19	800.666.7248 Option 2 https://www.pfizermedicalinformation.com/en-us/stability-calculator	• COVID-19 Pfizer
Protein Science	800.488.7099	• Flublok®
Sanofi Pasteur	800.822.2463 https://www.sanofimedicalinformation.com/s/stability-calculator/?language=en_US&CN=US	• ActHib® • Adacel® • Daptacel® • Fluzone® • I-POL® • Pentacel® • Quadracel™ • Tenivac®
Seqirus	855.358.8966	• Aluria® • Fluad® • Flucelvax® • Fluvirin® • Rapivab®
CDC/VFC Merck Shipments	https://cdcshipping.merck.com/	• Varivax® • Proquad®