2022 REQUIRED VFC EDUCATION
Abbi Berg, MPH
VFC QI Manager

OVERVIEW
- Enrollment Process
- Eligibility and Vaccine Consent
- Billing
- Borrow/Return
- VFC Agreement
- Storage and Handling
- NDIIS Update

ACRONYMS/TERMINOLOGY
- VFC – Vaccines for Children
- 317 – Vaccine budget that allows for special vaccination programs
- CDC – Centers for Disease Control and Prevention
- NDIIS – North Dakota Immunization Information System
- NDDoH – North Dakota Department of Health
Enrollment Process

Vaccine Management Template, Borrow/Return forms and Vaccine Coverage Tables are always available on our website.

2022 Vaccine Management Policy is in the process of being printed and will be mailed to each VFC enrolled facility by the end of the month.

After initial mailing additional copies will be available for order.

Email with enrollment survey and VFC provider profile will be sent out next week (week of February 14th).

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ENROLLMENT PROCESS

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ENROLLMENT PROCESS

- **Education**
  - Surprise – you are part of the way through the education requirement!
  - Lunch and Learn posttest satisfies attestation survey requirement
  - Survey must be completed by at least two people from each VFC enrolled facility.
    - www.health.nd.gov/immunize/providers
- **Online Survey**
  - Update contact information
  - Medical Director signature (can be sent electronically)
  - Storage and handling information
  - Due on or before Friday, March 4th.
Program Eligibility and Vaccines Covered

VFC PROGRAM ELIGIBILITY

- Individuals who are 18 years and younger who are:
  - Uninsured
  - Underinsured – has private health insurance but it does not cover vaccines.
  - American Indian
  - Medicaid enrolled/eligible
  - Through 19th birthday
  - Do not need to prove tribal membership

317 PROGRAM ELIGIBILITY

- Un/underinsured adults:
  - Td/Tdap
  - MCV4
  - MMR
  - PPSV23*
    - 19 – 64 year old with a high risk condition
  - PCV13*
    - 19 – 64 year old with a high risk condition

*Given recent changes to adult pneumococcal vaccine recommendations 317 coverage will likely be updated soon.
317 PROGRAM ELIGIBILITY, CONT.

- **Un/underinsured adults:**
  - **HPV**
    - Medicaid adults should receive private vaccine (no longer an age gap in Medicaid coverage for adults)
    - HPV vaccine is licensed for individuals 9 – 45 years of age however until insurance coverage is more universal for the upper age group, the 317 vaccine program coverage will remain the same and be offered for un/underinsured adults who are 19 – 26 years of age.
  - **Influenza**
    - Available for all provider to prebook and order

317 PROGRAM ELIGIBILITY, CONT.

- **Un/underinsured adults:**
  - **Adult Hepatitis A and B**
    - Not available to adults whose sole purpose of vaccination is for travel or employment.
    - Should be prioritized for those at risk of infection such as drug users and people experiencing homelessness.
    - For a complete list of risk factors please consult the vaccine coverage table at: [www.health.nd.gov/immunize/providers/resources](http://www.health.nd.gov/immunize/providers/resources)

317 PROGRAM ELIGIBILITY, CONT.

- All infants born in a North Dakota birthing facility receive state-supplied hepatitis B vaccine, regardless of insurance status.
- Underinsured patients seen at private healthcare facilities
  - Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs) and deputized local public health units use VFC vaccine for underinsured patients.
COMMON ELIGIBILITY MISCONCEPTIONS

- Out of network
- Not VFC eligible
- High deductible
- Not VFC eligible
- Christian based cost sharing plan
- VFC eligible – not considered insurance
- Questionable insurance? – Insurance commissioner’s office
- Out of state Medicaid
- VFC Eligible but patient will have to pay out of pocket for VFC administration fee

PATIENT ELIGIBILITY SCREENING

- Every patient must be screened at every immunization encounter.
- Patient insurance changes constantly and it is important for several reasons to make sure the clinic has the most up-to-date insurance information.
- Proof of screening will be reviewed at every VFC compliance site visit.
  - Example: If the patient’s eligibility is “Medicaid” the clinic will need to show proof of Medicaid number or card and that the screening information was checked on the date of the immunization encounter.

BILLING FOR VFC VACCINE

- Never bill for the cost of the vaccine
- Vaccine provided to clinics at no charge
- Cannot bill more than $20.99
- Per dose
- Cannot turn over to collections or turn patient away due to the inability to pay for the administration fee
- Must accept Medicaid reimbursement rate
BILLING

- In 2020 some billing practices have changed.
- Clinics must bill at the time of service or:
  - Bill within 90 days of service AND
  - Bill patient only once
- Patient cannot be sent to collections for the administration fee (this is not new and has always been a part of the VFC program).
- Unpaid administration fees must be waived by the clinic/health system.
- Patients cannot be turned away or referred if they are unable to pay the administration fee.
- These billing requirements are only applicable for the vaccine administration fee, all other clinic/lab/hospital fees are outside of the scope of the VFC program.

BORROW AND RETURN

- Any time a vaccine funding source (VFC/State vs. Private) is given to someone that doesn’t match their eligibility a borrow is created in NDIIS. If a balance already exists for that vaccine a return is created in NDIIS.
  - Example: Private vaccine given to uninsured child
  - Example: VFC vaccine given to an insured child
- All borrow and returns should be documented on a borrow and return form AND in NDIIS.
- Borrow/Return form available here: www.health.nd.gov/immunize/providers/re

BORROW/RETURN DOCUMENTATION

- If you are part of a health system work with IT, billing and administration to determine the most appropriate way to document borrow/returns in your EMR.
- Some health systems must document according to how the patient should be billed and not how the dose was administered.
- In this situation the data entry must be corrected in NDIIS so a borrow or return occurs.
BORROW/RETURN REPORTS IN NDIIS

- **NDIIS Borrow/Return Balance Report**
  - Shows doses owed to state and doses owed to private.
  - All doses ever borrowed or returned, no date range option.
  - Currently COVID-19 vaccines are included in borrow/return reports but will be removed.

- **NDIIS Borrow/Return Detailed Report**
  - Shows patient information for doses involved in a borrow or return.
  - Providers can run for a specific date range or look at all borrows/returns.
  - A good tool for catching unreported borrowing or data entry mistakes.
  - All doses on this report must be documented on a borrow/return form.

FOLLOW ALL ACIP RECOMMENDATIONS

- Providers are required to follow immunization schedules, dosage and contraindications established by the ACIP unless:
  - In the provider's medical judgement, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the child;
  - The particular requirements contradict state law, including laws pertaining to religious and other exemptions;
  - Examples: A provider office that is not administering hepatitis A vaccine to any of their patients would be in violation of the VFC program requirements.
All records that pertain to the VFC program must be kept on hand for at least three years. These records include, but are not limited to:

- Paper temperature logs
- Electronic data logger temperature logs
- Vaccine Packing Slips
- VFC screening and eligibility documentation
- Immunization information in a patient’s medical chart should be held at least as long as the VFC requirement (3 years) but may need to be kept longer according to the clinic’s medical record retention rule.

Federal law to give a VIS with each and every vaccination, regardless of age of patient or participation in the VFC program.
- Anytime there is an update to a VIS, all clinic contacts will receive the update via the immunization program listserv.
- Periodically a list of the updated dates will also be included in the Immunization Program Newsletter.
- When in doubt consult the CDC website: https://www.cdc.gov/vaccines/hcp/vis/current-vis.html
- Providers are not required to keep large printed inventories of VISs on hand.
- A paper free option: providers can have a binder of VISs in their office for parents to review prior to vaccination.
- Parents and patients must be given the option to take home printed copies of the VISs.
- Print directly from CDC website or EMR each time VIS is needed.
- Both options save on printing and reduce wastage when updates to VISs are made.

VAERS is a database that is used to analyze vaccine adverse events.
- Anyone can report to VAERS. This includes health departments, healthcare providers, patients and vaccine manufacturers.
- This also means that the same adverse event could be reported more than once or events that most would not deem related to a vaccine (car accident following immunization) can be reported as such.
- Report to VAERS to their website: https://vaers.hhs.gov
- Icon in NDIIS
OFFERING ALL ROUTINE AND NON-ROUTINE VACCINES

- All enrolled VFC facilities are required to carry ALL routinely recommended vaccines.
- Certain exceptions can apply but must be approved by the NDDoH Immunization Program.
- Non-routinely recommended (PPSV23 and Men B) vaccines must be made available to all VFC eligible patients who either request them or are recommended to receive them based on a high-risk condition.
- VFC is an entitlement program, so therefore anyone who is eligible is entitled to that vaccine.
- DT, Td and PPSV23 are available for order in 1-dose increments.
- Providers are encouraged to keep both PPSV23 and Men B on hand at all times, however it would be acceptable to order at the time the dose is needed.

VFC SITE VISITS

- All providers are required to have a VFC compliance site visit at least every other year.
- Many large providers or those with more severe corrective actions will receive visits each year.
- NDDoH is required to conduct unannounced storage and handling visits.
- Some clinics are chosen at random or may be based on previous storage and handling issues along with provider or patient report of issues.

VFC SITE VISIT OVERVIEW

- There are many areas that are covered during a VFC compliance site visit but some of the important and often incorrect areas include:
  - Borrow/return documentation
  - Doses owed to the state that have not yet been repaid
  - Correct storage and handling procedures
  - Review of temperature logs
  - Chart Audit
  - VIS publication dates
  - Current calibrated data loggers
  - Current calibrated back-up data loggers
  - Vaccine Management Template complete and up-to-date
There are certain thresholds in which providers will be required to pay back VFC or state-supplied vaccines on a dose for dose basis.

Exact situations found in the vaccine loss policy which is part of each year’s Vaccine Management Policy.

Common reasons for repayment:
- More than 20 doses of a particular vaccine expire in a 30-day time period
- Storage and handling mishaps that are deemed to be the provider’s fault
- Not taking appropriate actions when a temperature excursion happens

Storage and handling can be a time consuming and costly endeavor!

However, if you think that one box of HPV9 vaccine purchased privately is over $2,000 and most providers store on average between $30,000 – $40,000 worth of vaccine in their refrigerators at any given time.

VFC providers in North Dakota receive anywhere up to $800,000 per facility worth of VFC vaccine in any given year!

Without good storage and handling, facilities can lose thousands of dollars, patients can receive sub optimal vaccines and may not be protected against very serious, even fatal disease.
VACCINE STORAGE AND HANDLING

- All vaccines, except varicella, MMR, and MMRV must be stored in the refrigerator at 36°F - 46°F (2°C - 8°C).
- Optimal refrigerator temperatures are 39°F - 42°F (4°C - 6°C).
- MMR and varicella vaccine must be stored in the freezer at -58°F to 5°F (-50°C to -15°C).
- Optimal freezer temperatures are 3°F or colder (≤ -17°C).
- MMR can be stored in the refrigerator or freezer.

DATA LOGGERS

- All storage units that contain VFC or state-supplied vaccine must use a continuous recording data logger.
- Back-up data loggers are also required in the event that the data logger would malfunction or quit working.
- Required even if facility has a built-in temperature monitoring system.
- Vaccine orders will not be approved without a data logger temperature chart.
- Any provider that does not submit monthly data logger temperature charts will be contacted by the Immunization Program and will not be able to order until they have been submitted.

DATA LOGGER REQUIREMENTS

- The following are additional recommended characteristics for these devices that are required of all data loggers:
  - Detachable probe that best reflects vaccine temperatures (e.g., a probe buffered with glycol)
  - Alarm for out-of-range temperatures
  - Current, minimum, and maximum temperature indicator
  - Low-battery indicator
  - Accuracy of ±0.5°F (±1°C)
  - Memory storage for at least 4,000 readings
  - Recommended maximum logging interval (or reading rate) of every 30 minutes that can be programmed by the user
Paper temperature logs may still be required to be used at clinics. If a clinic's data logger can track date, time and staff initials of temperature checks, paper logs may be discontinued. Paper logs should be kept at clinic and will be reviewed at VFC compliance site visits. Must be saved for three years. Can be discarded after that. Electronic data logger temperature charts should be emailed monthly (or sooner with temperature excursions) to dohtemplogs@nd.gov.

All providers are required to document minimum/maximum temperatures once daily. Preferably at the start of the clinic day. This requirement replaces the previous twice daily temperature checks. Providers can continue to check temperatures twice daily and record if that is their preference. Clinic staff should visually check temperatures each time a vaccine storage unit is entered to ensure that correct temperatures are being maintained throughout the day.

To fully ensure the safety of vaccines, the following equipment is recommended:
- Stand-alone refrigerator(s) with enough space to accommodate your maximum inventory without crowding.
- Stand-alone freezers with enough space to accommodate your maximum inventory without crowding.
- Combination units may still be used, but only the refrigerator section should be used for vaccine storage. A separate stand-alone freezer should store all frozen vaccines.
- Dormitory units must NEVER be used to store state-supplied or VFC vaccine. Regardless of reason or duration.
VACCINE STORAGE AND HANDLING

- Out-of-range temperature: what do I do?
  - Vaccine manufacturers should be contacted first to determine vaccine viability.
  - Do NOT assume that vaccine is not viable.
  - Do NOT discard any vaccine until the NDDoH has been notified.
  - Label the vaccine as "DO NOT USE".
  - All actions must be recorded and submitted monthly with temperature logs.
  - Even one out-of-range temperature, especially on the cold side, may result in the need for revaccination!

- Do not disconnect and circuit breaker signs are required for all outlets and circuit breakers connected to storage units with VFC or state-supplied vaccines.
- May seem obvious to clinical staff but in a healthcare facility many other staff involved with storage units, i.e., weekend maintenance or cleaning staff.

DO NOT DISCONNECT SIGNS

- Vaccine transport is discouraged whenever possible.
  - If providers must transport vaccine, data loggers must be used at all times.
  - Transport temperature charts must be submitted to the immunization program anytime VFC vaccine is transported.
  - Temperatures should be checked and documented every 30 minutes.
  - VFC or state-supplied vaccine must be transported in qualified coolers or packouts.
  - Never leave vaccine unattended in a car for long periods of time, and never store in a trunk.
  - All vaccines transfers (between providers) must be approved by the immunization program.
  - Vaccine should never be stored in a transport cooler for more than 8 hours.
  - Frozen vaccine must be transported in a frozen transport cooler, cannot use dry ice or transport refrigerator.
VACCINE ORDERING

- We ask that providers only order once per calendar month.
- Please contact the immunization program prior to placing additional orders.
- Vaccine orders are submitted to the NDDoH in NDIIS by providers for review and approval.
  - Order minimum – 1 month
  - Order maximum – 3 months

DISTRIBUTION SYSTEM

- Non-frozen vaccine is shipped directly to your clinic from centralized distributor (McKesson).
- Vaccines are generally shipped on Monday, Tuesday and Wednesdays.
- Flu will be shipped separately and is generally overnighted.
- Varicella and MMRV vaccines are shipped directly from Merck.
- Varicella and MMRV can ship any day Monday through Friday.
- All private lot numbers must be entered into NDIIS by clinic staff.
- This must be done by all clinics, even if connected electronically to NDIIS.

DISTRIBUTION SYSTEM (CONT.)

- **DO NOT** ship viable vaccine to McKesson.
- **DO NOT** ship viable or non-viable vaccine to the NDDoH.
- **DO NOT** contact UPS for vaccine returns or your facility may be charged!
RETURNS VS. WASTAGES

- Vaccine Return: nonviable vaccine that needs to be returned to McKesson because it was expired, was spoiled because of a temperature excursion or because of a vaccine recall.
- Multi-dose vials (MDV) can only be returned if no doses have been drawn from the vial. Partially used MDVs must be documented as wasted vaccine.
- Example: Expired vaccine, delivered non-viable etc.
- Vaccine Wastage: nonviable 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 multi-dose vials.
- Example: Open multi-dose vials, broken vials etc.

VACCINE RETURNS AND WASTAGES

- All vaccine returns and wastages must be entered into NDIIS and returned to McKesson within six months of becoming nonviable.
- Once the return has been submitted in the NDIIS, the primary contact will receive an email 1-2 business days later letting them know that their packing slip is ready to be printed.
- The provider should go back into the submitted return and print the packing slip.
- By submitting the return in NDIIS your pre-paid shipping label has been requested from McKesson and should be received in the mail 1-3 weeks later or via email within a few business days.
- If you do not receive your packing slip or shipping label, please contact a member of the immunization program.
- Allow 2-3 business days before contacting.

UPCOMING CHANGES TO NDIIS

- The lot number field will move from a prepopulated drop down to an open text field.
- Alleviate dummy doses in the NDIIS.
- Set to go into production Feb 12th.
**HOW DOES THIS AFFECT ME?**
- Can no longer use dummy dose report for borrow/return.
- Will not receive dummy dose reports to fix.
- If lots are entered incorrectly in EMR they will not decrement inventory in the NDIIS.
- Potential loss of data integrity.

**NDIIS NEW REPORT/ TRAINING**
- An NDIIS report is in the works that will allow providers to pull a patient-level doses administered report that will run a list of patients that received doses from their facility within a specific time period.
- NDIIS training website: www.health.nd.gov/immunize/ndiis/trainings

**POST-TEST**
- Required VFC Education Survey:
  https://ndhealth.co1.qualtrics.com/jfe/form/SV_1QiI5pe2DdyfXVw
- Successfully complete the five-question post-test to receive your certificate for nursing credit and to complete the VFC enrollment requirement
  - Certificates will be an email from noreply@qemailserver.com. If you don't receive your certificate within a few minutes of passing the posttest, please check your junk mail and check with IT.
    - If you still cannot retrieve the certificate, please email Miranda at mbaumgartner@nd.gov
  - This presentation will be posted to our website: www.health.nd.gov/immunize