


2023 Required VFC Education
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Be Legendary.

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VFC Program Only

- The program requirements discussed today only impact the VFC program. COVID-19 vaccine recommendations and program requirements may differ. For specific programmatic questions on COVID-19 vaccine please consult the Adult Vaccine Program at covidvaccine@nd.gov.

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Overview



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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
- HHS – North Dakota Department of Health and Human Services

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Enrollment Process

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Enrollment process

- Vaccine Management Template, Borrow/Return forms and Vaccine Coverage Tables are always available on our website
- 2023 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 later this week.

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Enrollment process

- Education
 - Surprise – you are part of the way through the education requirement!
 - Lunch and Learn posttest satisfies education requirement
 - Posttest must be completed and passed by AT LEAST two people from each VFC enrolled facility
- Online survey: www.hhs.nd.gov/immunizations/providers
 - Update contact information
 - Storage and handling information
 - Medical Director signature (can be sent electronically to vaccine@nd.gov)
- **Due on or before Friday, March 3rd**

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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

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317 Program Eligibility

• Un/underinsured adults:

- Td/Tdap
- MCV4
- MMR
- PPSV23
 - 19 – 64 year old with a high-risk condition
- Pneumococcal Conjugate (PCV15 and PCV20)
 - 19 – 64 year old with a high-risk condition

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317 Program Eligibility, cont.

• Un/underinsured adults:

- HPV
 - Medicaid adults should receive private vaccine (no longer an age gap in Medicaid coverage for adults)
 - 19 – 45 years of age (2022 change)
- Influenza
 - Available for all providers to prebook and order

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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.hhs.nd.gov/immunizations/providers

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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.

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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

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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.

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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

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Billing

- 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.

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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 the 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.hhs.nd.gov/health/diseases-conditions-and-immunization/immunizations/immunization-resources



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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.
 - Example: A provider office that is not administering hepatitis A vaccine to any of their patients would be in violation of the VFC program requirements.

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VFC Record Retention

- 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.

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Vaccine Information Statements

- 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 unit listserv.
- When in doubt consult the CDC [website](#).
- 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.

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Vaccine Adverse Event Reporting System

- 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 all VAERS to their website: <https://vaers.hhs.gov/>
- Icon in NDIIS



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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 HHS Immunization Unit.
- 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.
 - 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.
- Td and PPSV23 are available for order in 1-dose increments.
- DT being discontinued.

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ND – Vaccine Brand Choices

- ND has a brand choice law, meaning the Immunization Unit is required to offer all vaccines that are offered by the [Federal Contract](#).
- As new vaccines are made available, they are added to the NDIIS to allow for facility ordering.
- The HHS Immunization Unit will never express a brand preference and facilities are able to choose which vaccine brands and presentations they carry.

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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.
- HHS 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.

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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

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Virtual Visits to Discontinue

- The federal VFC program has made the determination that virtual VFC visits will be discontinued effective July 1, 2023.
 - After this date only in-person VFC visits will be offered.
 - Virtual VFC visits may continue until June 30th.
 - IQIP will remain having both an in-person or virtual option.

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Vaccine Loss Policy

- 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

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Vaccine Storage and Handling



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Importance of Storage and Handling

- 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.

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Vaccine Storage and Handling

- All vaccines, except varicella, MMR®II, and MMRV must be stored in the refrigerator at **36°F - 46°F (2 - 8°C)**.
 - Optimal refrigerator temperatures are **39°F - 42°F (4 - 6°C)**.
- MMRV 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 ($\leq -17^{\circ}\text{C}$)**
- MMR®II can be stored in the refrigerator or freezer
 - Priorix® MMR vaccine **MUST** be stored in the refrigerator only.



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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.

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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 $\pm 0.5^{\circ}\text{C}$ ($\pm 1^{\circ}\text{F}$)
 - 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

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Temperature Charts

- 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.

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Min/Max Temperature Requirement


- 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.

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Storage and temperature monitoring equipment

- 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.
- Dormitory units must NEVER be used to store state-supplied or VFC vaccine.
 - Regardless of reason or duration.

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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!

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Do not disconnect signs

- 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.



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Vaccine transport

- 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 **HOUR** (2023 change to align with CDC recommendations).
- 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.
- All non-COVID 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.

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Vaccine ordering

- We ask that providers only order once per calendar month.
 - Please contact the Immunization Unit (vaccine@nd.gov) prior to placing additional orders.
- Vaccine orders are submitted to the HHS Immunization Unit via NDIIS by providers for review and approval.
 - Order minimum – 1 month
 - Order maximum – 3 months

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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.
- It is incredibly important to keep the NDIIS up-to-date with accurate address, contact and business hour information each time a vaccine order is placed.

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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!

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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.

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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.

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Recent NDIIS Changes

- Lot numbers are no longer a drop down
 - No more dummy doses!
 - Accurate data entry and inventory control are ESSENTIAL
- Borrow/Return reports removed COVID-19 vaccine from reports.
 - Once COVID-19 vaccine is available on the private market the vaccine will reappear on this report.
 - Also alphabetized again!
- Patient based doses administered report
 - Allows providers to pull patient information for a certain vaccine or time period

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Commercialization of COVID-19 Vaccine

- Later in 2023 COVID-19 vaccine will go from being fully supplied by the Federal Government to the private market.
 - Will need to maintain private and VFC inventory for COVID-19 vaccine
 - May require EMR changes

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Post-Test

- Required VFC Education Survey: https://ndhealth.co1.qualtrics.com/jfe/form/SV_ekPTnDZKA9pmvFc
- 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@qemaiserver.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 mlbaumgartner@nd.gov
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations/providers

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