2025 Required VFC Education

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Acronyms/Terminology

- VFC – Vaccines for Children
- VFA – Vaccines for Adults
- 317 – Vaccine budget that allows for special vaccination programs
- CDC – Centers for Disease Control and Prevention
- NDIIS – North Dakota Immunization Information System
- ND HHS – North Dakota Department of Health and Human Services

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Enrollment process

- First Step: 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
- Second Step: Provider Profiles
  - Provider profiles will be emailed to all primary and back up VFC contacts. The enrollment survey will ask whether you agree with these estimates or not. If your facility feels that these population estimates are not accurate please email vaccine@nd.gov with your provider number and updated estimates along with the data source.

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Enrollment Process, cont.

- Third Step: VFC and VFA online survey (two separate surveys)
  - Will be sent out next week (2/17/25)
  - www.hhs.nd.gov/immunizations/providers
  - Update contact information
  - Storage and handling information
  - Medical Director signature (should be sent electronically to vaccine@nd.gov)
- Final Step: Signatures
  - Have Medical Director sign VFC and/or VFA enrollment surveys and email signatures to vaccine@nd.gov.

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Enrollment Cont.

- Good time to review and update materials:
  - Vaccine Management Template, Borrow/Return forms and Vaccine Coverage Tables are always available on our website.
- 2025 Vaccine Management Policy will be printed and will be mailed to each VFC enrolled facility.
  - After initial mailing additional copies will be available for order.

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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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VFA Program Eligibility

- Un/underinsured adults:
  - Td/Tdap
  - MCV4
  - MMR
  - PPSV23
    - 19 – 64 year old with a high-risk condition
  - Pneumococcal Conjugate (PCV15, PCV20 and PCV21)
    - 19 – 64 year old with a high-risk condition

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VFA Program Eligibility, cont.

- Un/underinsured adults:
  - HPV
    - 19 – 45 years of age
  - Influenza
    - Available for all providers to prebook and order
  - COVID-19 vaccine
    - Administration fees can be charged to un/underinsured patients

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VFA 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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2025 Updates, Cont.

- Changes to VFA vaccines included for un/underinsured adults.
  - IPV
    - When ordering please leave a comment as to whether the vaccine will be administered to children or for un/underinsured adults.
  - Mpox
    - Mpox is also available in limited quantities for use in insured individuals. Available to facilities who otherwise could not/would not order for insured individuals.
    - Please leave a comment when ordering whether this vaccine will be used for insured or un/underinsured adults.

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317 Program Eligibility, cont.

- 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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2025 Updates, Cont.

- 317 Vaccine Policy Change
  - Birthing facilities have been considered universal, meaning all hepatitis B inventory has been publicly sourced. Immunization unit used 317 vaccines for insured newborns.
  - Starting July 1, 2025 317 vaccine can no longer be used for insured newborns so birthing facilities will need to purchase private inventory for insured newborns.
    - Facilities already have two separate stocks for Nirsevimab.
    - Education on the importance of screening and data entry will be imperative.
  - Memo sent to birthing facilities on January 24th communicating this change.

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Frequently Asked Questions

- Which vaccines have to be separated based on whether they are used for VFC eligible children or VFA eligible adults?
  - **Influenza and COVID-19** are the only two immunizations that need to be separated based on how they are ordered/prebooked. This is because they are prebooked or reserved by funding source in advance.

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Common Eligibility Misconceptions

- Out of network
  - Not VFC eligible
- High deductible
  - Not VFC eligible
- Christian based cost sharing plan (example: Medi-share)
  - 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.
  - All demographic fields should also be verified at every immunization encounter
- 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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NDIIS Reporting Requirements

- ND State Century code requires all pediatric doses be entered into the NDIIS within four weeks of administration.
  - The majority of doses come in through the interoperability between the NDIIS and your facility's EMR but if you are manually entering doses please take note of this timeframe.
- VFA signed agreement requires adult doses also be entered into the NDIIS within four weeks of administration.

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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 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

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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.

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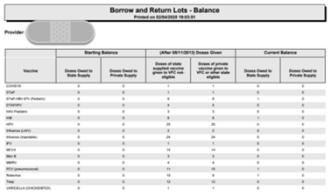
Borrow/Return Reports in NDIIS


Borrow and Return Lots - Balance

- 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.

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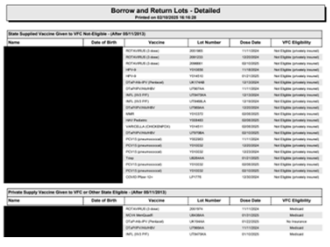
Borrow/Return Reports in NDIIS

- 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.


Borrow and Return Lots - Detailed

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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 offering 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/IIS/EUA with each and every immunization, regardless of age of patient or participation in the VFC program.
- Anytime there is an update to these documents, all clinic contacts will receive the update via the immunization unit listserv.
- When in doubt consult the CDC website.
- Immunize.org also provides translated versions.
- Providers are not required to keep large printed inventories 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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Additional Information

- Immunization Information Statement
  - When administering Nirsevimab, which is an antibody not a vaccine an immunization information statement (IIS) should be given to the patient's family in place of a VIS
  - RSV Preventive Antibody Immunization Information Statement
- Emergency Use Authorization
  - An EUA should be given to all patients under 12 who are receiving COVID-19 vaccine.

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Vaccine Adverse Event Reporting System

- VAERS is a database that is used to monitor the safety of all vaccines licensed in the United States.
- An "adverse event" is any health problem or "side effect" that happens after a vaccination.
- VAERS cannot determine if a vaccine caused an adverse event, but can determine if further investigation is needed.
- Anyone can report to VAERS. This includes health departments, healthcare providers, patients and vaccine manufacturers.
- Report all VAERS to their website: https://vaers.hhs.gov/
- Icon in NDIIS help menu

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Vaccine Adverse Event Reporting System

- Healthcare providers are **required by law** to report to VAERS:
  - Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations
  - An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine
- Healthcare providers are strongly **encouraged** to report to VAERS:
  - Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event
  - Vaccine administration errors
- 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.

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Reporting to MedWatch

- If an adverse event occurs following administration of Nirsevimab (a protective RSV antibody) the event should be reported to MedWatch
  - MedWatch
- If an adverse event occurs following administration of other vaccines AND Nirsevimab the reaction can be reported to VAERS

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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 NDHHS 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.
- Abrysvo and PPSV23 are available for order in 1-dose increments.

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2025 Updates

- Private inventory requirements for COVID-19 and Nirsevimab
  - Beginning September 1, 2025 VFC enrolled facilities will be required to have both private and VFC inventories of COVID-19 and Nirsevimab if appropriate for the population they vaccinate.
    - Current requirement for all other ACIP recommended vaccines
  - Ongoing discussions with CDC about potential burdens with carrying private inventories.
  - Meant to make immunizations available for all children and avoid potential inventory issues such as B/R and potential for fraud by having only one inventory.

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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 NDHHS 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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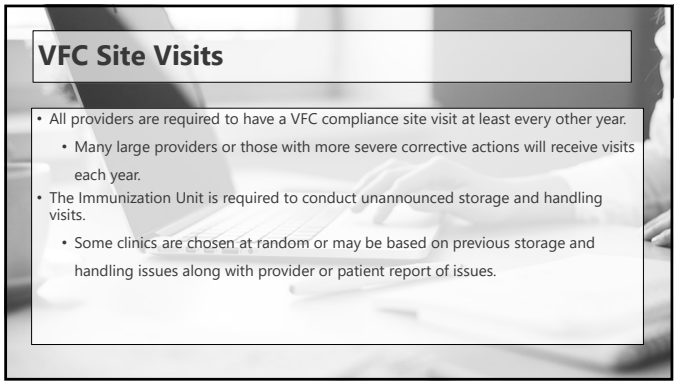

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VFC Site Visit Overview

- 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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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 $3,000 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 $1,00,000 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 (≤ -17˚C)**
- MMR®II can be stored in the refrigerator or freezer
  - Priorix® 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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Frequently Asked Questions

- Can you explain the new temperature log review process in the NDIIS?
  - Data logger temperature logs must still be sent to the immunization unit via dohtemplogs@nd.gov inbox on a monthly basis.
  - Those temperature logs are now documented in the NDIIS by immunization unit staff.
  - 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.

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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 +/-0.5º C (+/-1ºF)
  - 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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Updated Temperature Excursion Guidance

- If providers are able to reset their data logger, alarms triggers should be set at 30 minutes outside of the acceptable temperature range, whether it be warm or cold.
  - Email vaccine@nd.gov for assistance in resetting data loggers or to find out if your data logger can be reset.
- For those who are not able to reset their data loggers the updated excursion time frame will need to be in place by January 1, 2026 which 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.

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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.
  - 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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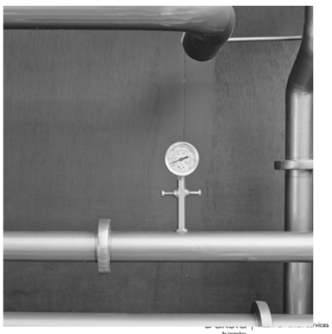
Frequently Asked Questions

- **What duration is used to determine a temperature excursion?**



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Frequently Asked Questions

- **30 minutes either warm or cold.**
- **Changed January 2024.**
- **Did you know you could report temperature excursions online?**
- **https://www.hhs.nd.gov/storage-and-handling**

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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 NDHHS 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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McKesson Update

- Our McKesson depot location will be changing.
- After March McKesson shipments will come from Kentucky instead of Colorado.
- No changes to process aside from location change.

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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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Post-Test

- Required VFC Education Survey: https://ndhealth.co1.qualtrics.com/jfe/form/SV_0VRHtLVjASSDvFA
- 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 mlbaumgartner@nd.gov
- This presentation will be posted to our website: www.hhs.nd.gov/immunizations/providers

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Questions?
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