Vaccines for Children and Adult Immunization Program Clinic Provider Manual

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Overview of Programs

Vaccines for Children Program
The Vaccines for Children Program (VFC) is a federally funded program that provides vaccine at no cost to children who might not otherwise be vaccinated because of an inability to pay. CDC buys vaccine at a discount and distributes them to grantees, such as NDHHS, which in turn distributes them at no charge to private physicians' offices and public health clinics enrolled as VFC providers. Children who are eligible for VFC vaccines are entitled to receive them as recommended by the Advisory Committee on Immunization Practices (ACIP). These vaccines protect babies, young children, and adolescents from sixteen diseases. A child is eligible for the VFC Program if he or she is younger than nineteen years of age and is one of the following: Medicaid eligible, Uninsured, Underinsured, American Indian or Alaska Native.

Adult Immunization Program
The Adult Immunization Program (AIP) provides some adult vaccines at no cost to uninsured or underinsured adults nineteen years of age and older. Public immunization clinics that are also adult providers include Federally Qualified Health Centers (FQHC), health departments, and other local public clinics.

Immunization Quality Improvement for Providers
Immunization Quality Improvement for Providers (IQIP) supports and promotes providers to engage in vaccine quality improvement strategies. IQIP consultants work with VFC providers to increase vaccine uptake among children and adolescent patients. IQIP assists and supports health care providers by identifying opportunities to improve vaccine uptake and immunization delivery practices.

NDHHS Immunization Program
Vaccine funding for the VFC and AIP programs is distributed by CDC to the NDHHS Immunization Program. NDHHS supplies vaccine at no cost to enrolled public and private providers, and is responsible for ensuring enrolled providers adhere to program requirements, are good stewards of resources given, and are ensuring vaccine viability at all times.

Nebraska State Immunization Information System
The Nebraska State Immunization Information System (NESIIS) is a confidential, population-based, computerized database that records all immunization doses administered by participating providers to persons residing within Nebraska. NESIIS offers providers consolidated immunization histories to help determine point of clinical care for patients, and assists with public health efforts to improve vaccination rates and reduce vaccine preventable disease.

Centers for Disease Control and Prevention
The Centers for Disease Control and Prevention (CDC) is a federal agency that conducts and supports health promotion, prevention, and preparedness activities in the United States, with the goal of improving overall public health. The CDC works with partners at the local, state, and

national levels to monitor and prevent disease outbreaks (including bioterrorism), implement disease prevention strategies, and maintain national health statistics. The agency also leads public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. The CDC focuses on the following five strategic areas: increasing support to local and state health departments, improving global health, decreasing leading causes of death, strengthening surveillance and epidemiology, and reforming health policies.

Advisory Committee on Immunization Practices
The Advisory Committee on Immunization Practices (ACIP) is comprised of medical and public health experts who develop recommendations on the use of vaccine in the civilian population of the United States. The recommendations stand as public health guidance for the safe use of vaccine and related biological products. All VFC providers must comply with immunization schedules, dosages, and contraindications established by ACIP.

Public Clinics in Nebraska
The NDHHS Immunization Program defines a public clinic as a clinic operated by a public or non-profit agency, such as a county or district health department, tribal health facility, or community action agency that meets the needs of a community not already met by another provider. A public clinic serves as a "safety net" for those populations.

Public clinics…
- Have a sponsoring physician who is located off-site.
- Serve healthy clients without contraindications.
- Offer all ACIP recommended vaccines, with the exception of those intended for use with high risk patients.
- Have the capacity to serve all eligible patients.
- Must accommodate walk-in patients

Sponsoring agencies are responsible for…
- Securing a sponsoring physician.
- Implementing appropriate policies and procedures to govern clinic operations.
- Providing appropriate staff and adequate training.
- Ensuring that immunization records are entered manually into NESIIS, or are provided via data exchange.

Sponsoring physicians are responsible for…
- Annually providing written vaccine administration standing orders and emergency protocol to staff.
- Acknowledging and signing the annual recertification form.
- Being on call, or providing a back-up physician during vaccination clinic hours to provide consultation.

Eligibility for Vaccine and Screening

Screening for Eligibility
It is a requirement to screen and document VFC eligibility for each vaccination given.

VFC vaccine eligibility…
- Children birth through eighteen years of age and one of the following:
    - Medicaid eligible: Under legislation that created the VFC program, "Medicaid eligible" is defined as a child entitled to medical assistance under a Medicaid state plan.
    - Uninsured: A child who has no health insurance. Health Care Sharing Ministries are not considered health insurance in accordance with Nebraska law. If the patient has no other insurance, this program would consider the patient uninsured, and VFC eligible.
    - 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).
    - American Indian or Alaska Native

** Note: As an enrolled provider, the provider agrees to never deny vaccination or refer eligible patients elsewhere due to an inability to pay the administration fee. In addition, if the patient is eligible for more than one category, the provider must select the category requiring the least amount of out of pocket expense for the patient. Any patient whose insurance has a very high deductible or copay is not considered underinsured.

AIP vaccine eligibility…
- Nineteen years of age or older and one of the following:
    - Uninsured
    - Underinsured

Federal Law Requirements

National Childhood Vaccine Injury Act Documentation
The National Childhood Vaccine Injury Act (NCVIA) has recordkeeping requirements for all health care providers administering vaccines.

NCVIA requires the following:
- Provide a Vaccine Information Statement (VIS) in an understandable format. Allow the parent/guardian time to review the VIS and ask questions prior to vaccine administration.
- Vaccine documentation must include the following:
    - Vaccine name
    - Date vaccine was administered
    - Vaccine manufacturer
    - Lot number

- Clinic or facility address
- Name and title of individual administering vaccination
- VIS publication date
- Date VIS was provided to patient, parent, or legal guardian

Vaccine Adverse Event Reporting System
The Vaccine Adverse Event Reporting System (VAERS) is a surveillance program which collects information about adverse events following administration of a licensed vaccine. This information is used to monitor side effects and identify any important safety concerns regarding a vaccine. Anyone has the ability to file a VAERS report, including health care providers, manufacturers, vaccine recipients, and families. Submit a report as soon as possible after an adverse event following vaccination. Information about VAERS can be found on the back of every VIS.

Providers are required to…
- Report any event(s) listed in the "Reportable Events" table occurring within a specified time period after vaccination.
- Report any event(s) listed by the vaccine manufacturer as a contraindication to subsequent doses of that vaccine.

Providers are asked to…
- Report any clinically significant adverse event(s), even if unsure the vaccine caused the event.
- Report vaccine administration errors.

Records Retention
Maintain all records related to the NDHHS Immunization Program for a minimum of three years, as required. Records must be made available to NDHHS upon request.

This includes…
- VFC screening and eligibility documentation
- Billing records
- Vaccine administration verification
- Vaccine packing slips, borrowing reports, monthly transaction summaries, and waste reports
- Temperature logs

Fees, Donations, and Medicaid Billing

Fees
- Clinics cannot charge for the cost of VFC vaccine.
- For Medicaid enrolled children, accept reimbursement for the vaccine administration fee as final payment.
- For non-Medicaid VFC eligible children, a clinic may charge an administration fee not to exceed $19.82 per vaccination.
  - Clinics must not deny the administration of federally purchased vaccine to an established patient because of an inability to pay the administration fee.
- Providers choosing to bill for the vaccine administration fee of a non-Medicaid, VFC eligible child after the date of service may issue only a single bill to the patient within ninety days of vaccine administration. Unpaid administration fees must not be sent to collections.

Donations
- Clinics may request a modest donation from a patient not to exceed $19.82 per vaccination, instead of an administration fee. However, no provider can deny vaccination due to an inability to make a donation.
- Funds received from donations or administration fees are to be used to support the public immunization clinic.

Medicaid Billing
- Bill Medicaid appropriately. Questions regarding coverage or billing should be directed to the Medicaid office at 402-471-9227, 1-855-632-7633, or email dhhs.medicaidpharmacyunit@nebraska.gov

Storage Units and Vaccine Storage

Storage units…
- Are required to have stand-alone freezer units. Pharmaceutical grade may be combined.
- Refrigerators must be either stand-alone, or use only the refrigerated section of a combination unit. Best practice is to use pharmaceutical grade units.
- Cannot be dormitory style refrigerators, per CDC requirements.
- Must be large enough to accommodate the largest volume of inventory, and allow for air circulation within the unit.
- Must be able to maintain required vaccine storage temperatures.
- Must be in good working order. Frost build-up should be addressed according to the storage and handling toolkit.
- May hold both biologicals and vaccine, but must be stored below vaccine.
- Must be free of food and drink.
- Must have water bottles or cold packs labeled "DO NOT DRINK" in refrigerators and freezers to keep temperatures stable.
- Must have a digital data logger or a continuous temperature monitoring system with a current and valid certificate of calibration meeting CDC requirements.

**Note: If a clinic obtains a new unit or an existing unit is repaired before use, NDHHS must be contacted.

Safeguarding the Electrical Supply
- Plug storage units directly into outlets; extension cords are not acceptable.
- Make sure units cannot be accidentally unplugged. Use a safety lock plug, if possible.
- Label the refrigerator, freezer, electrical outlets, fuse boxes, and circuit breakers with "DO NOT UNPLUG" or "WARNING" stickers.
- Use an outlet connected to a generator, if possible.

**Note: In hospitals or large health care systems with comprehensive written policies and standard operating procedures; detailed measures taken to prevent vaccine storage units from being accidentally disconnected from the power supply may replace the "WARNING" sticker on the circuit breaker.

Storing Vaccine
- Vaccine from VFC, AIP, and private stock may be stored together, but must be labeled clearly. Mark boxes, use color coded baskets, or keep vaccine on separate shelves.
- Shorter expiration dates must be kept in front to be utilized first.
- Short dated vaccine must be reported to NDHHS at least three to six months in advance.
- Smaller clinics must contact NDHHS regarding vaccine that won't be used prior to expiration.
- Immediately remove expired or wasted vaccine from storage units.
- Store vaccine away from cold air vents, drawers, floors, and walls.
- Allow enough space for proper air circulation around vaccines.
- If using containers to organize vaccines, use open and ventilated types.
- Keep vaccines in their original boxes with lids intact until administration to protect from light.
- Store diluents according to manufacturer's instructions, and do not store in freezers.

Temperature Monitoring and Devices

Vaccine Storage
- Vaccine must be stored at appropriate temperatures from the time of manufacture to the time of administration.
    - Refrigerators 2°C to 8°C (36°F to 46°F)
    - Freezers -15°C to -50°C (5°F to -58°F)
- At the beginning of each workday, review and record temperature readings of vaccine storage units utilizing NDHHS approved continuous temperature monitoring devices. Utilize temperature logs provided in the appendix to record the following:
    - Date
    - Time
    - Initials of staff member assessing temperatures
    - Min/max temperatures of the refrigerator and freezer

- Weekly, download digital data loggers (DDLs).

Temperature Excursions
A temperature excursion is defined as any time temperatures go out of acceptable ranges, even by one tenth of a degree. The protocol below must be initiated for each temperature excursion:
- Mark the vaccine "DO NOT USE", and store at appropriate temperatures.
- Move to another refrigerator, freezer, or cooler per the emergency vaccine protocol.
- Call the assigned community health nurse or NDHHS. If after hours, proceed to the next step.
- Call the vaccine manufacturer to determine vaccine viability. Clinic staff must request manufacturer documentation be sent regarding vaccine viability.
- Document excursion details, action steps taken, and outcome. Email or fax documentation, along with manufacturer information, to the assigned community health nurse and retain a copy at the clinic.

**Note: If vaccine has been deemed unviable due to a temperature excursion and patients have been vaccinated with compromised vaccine, consult with the primary provider regarding revaccination.

Continuous Temperature monitoring devices are required to…
- Be certified as calibrated.
- Be recalibrated according to the certificate of calibration.
- Have a digital display easily readable outside of units.
- Display current min/max temperatures.

**Note: Place probes in the central section of storage units where vaccine is located. Units pre-approved by NDHHS may have a built-in thermometer. These units must have valid certificates of calibration, and clinics must have a back-up logger in current calibration.

Temperature monitoring devices are recommended to…
- Have a temperature probe in buffered material to mimic vaccine temperatures.
- Buffered material may be:
  - Liquid
  - Loose media
  - Solid block of material
- Have an alarm for out of range temperatures.
- Have a low battery indicator.
- Have an accuracy of plus/minus .5°C or 1°F
- Have memory storage of at least 4,000 readings.

Ordering and Receiving Vaccine

Ordering Vaccine

- All vaccine orders are placed via NESIIS.
- All age appropriate ACIP recommended vaccines must be ordered and offered to patients.
- Best practice is to maintain enough vaccine for two months.
- Clinics should ensure that quantities ordered are reflective of populations served.
- Prior to placing an order, inventory must be adjusted, and monthly transaction summaries completed and submitted to NDHHS.
- The CDC requires NDHHS to monitor ordering patterns to ensure appropriate vaccine quantities are being ordered. If unusual ordering activity is noted, orders will be placed on hold until the clinic has been contacted for clarification.
- Vaccine ordering privileges may be suspended for non-compliance with NDHHS requirements.

Special Ordering Circumstances

- Influenza vaccine may be ordered independently of other vaccine.
- Td vaccine may be ordered by a single dose.
- PPSV23 may be ordered by a single dose for the VFC program. Contact the NDHHS Immunization Program.

Receiving Vaccine

- Vaccine shipments will arrive according to days and times as indicated on the clinic's NESIIS profile.
- Shipping or profile changes must be updated immediately in NESIIS, and NDHHS notified.
    - o Clinics will be held liable for non-viable vaccine not effectively delivered due to changes in clinic operating days, hours, or address.
- Allow up to two weeks for receipt of vaccine.
- If vaccine has not arrived within two weeks, contact NDHHS.
- Always accept vaccine shipments. If an order is damaged or incorrect, place in the appropriate storage unit and mark "DO NOT USE". Contact NDHHS immediately.
- Check the condition of vaccine and temperature monitor card(s), if enclosed.
- Check the order in NESIIS against the packing slip and package contents.
- Store vaccine in appropriate storage units, with the earliest expiration dates in front.
- In NESIIS, click on "Inventory", then "Manage Transfers", and "Accept Transfer". This action auto populates the shipment information into inventory.

**Note: Varicella and ProQuad will arrive frozen separately from Merck. MMR vaccine arrives refrigerated, and best practice is to store it in a freezer, as it doesn't tolerate warmth.

Clinic Roles and Responsibilities

It is a requirement that all clinics have a designated primary and back-up VFC coordinator. Both roles must be able to assume oversight of all responsibilities.

VFC and back-up vaccine coordinators must…
- Ensure min/max temperatures are manually recorded each day the clinic is open.
- Download data loggers, preferably weekly, and review for temperature trends.
- Perform accurate physical counts of VFC vaccine the last day of each month.
- Adjust inventory in NESIIS.
- Submit transaction summaries to NDHHS by the 15th of each month for the previous month.
- View the CDC developed training module, "You Call the Shots: Vaccine Storage and Handling", and submit the certificate of completion to NDHHS within sixty days. This is required for new coordinators.
- Immediately report personnel or clinic changes to NDHHS, such as coordinator, address, phone number, shipping hours, and/or medical director.

Vaccine Accountability

Vaccine Accountability
- Ensure all staff administering vaccine know which vaccine stock to use according to eligibility.
- Track administered, returned, and/or wasted doses.
- Borrowing vaccine should be a rare occurrence, and only performed when there are unforeseen circumstances or delays in vaccine supply. Ensure this will not impact a VFC eligible child's ability to receive vaccine.
- Reasons for borrowing:
  - Vaccine manufacturer or the CDC centralized distributor experiences shipment delays.
  - Vaccine is not usable upon arrival.
  - Ran out of stock between orders.
  - Short dated dose exchanged with longer dated dose.
  - Accidental borrowing (human error).
  - Replacement of private dose with VFC dose when an insurance plan did not cover vaccine.

Required Reports
- Transaction Summary
  - Actual inventory and vaccine accountability must be tracked in NESIIS.
  - Submit by the 15th of the following month.
- Doses Wasted Summary
  - Submit with Transaction Summary, if applicable.
- Vaccine Borrowing Report
  - Submit immediately once stock has been replenished or returned.
  - The medical director (or equivalent) must sign and date the report.

- Provider Agreement and Profile Forms
  - Completed annually and signed by the medical director (or equivalent) with prescribing authority agreeing to comply with program requirements.
  - Per the federal requirement, if patient populations significantly change during a calendar year, an updated profile must be completed and submitted to NDHHS.
  - VFC and private patient numbers must be included with the provider profile.
- Temperature Excursion Documentation
  - Submit documentation from the vaccine manufacturer after the event.

**Note: If reports are not submitted on time, ordering privileges may be suspended until required documentation has been received by NDHHS. Submit reports to dhhs.immunization@nebraska.gov or fax to 402-471-6426.

Wasted Vaccine
- Is vaccine that cannot be returned due to:
  - Broken syringes or vials.
  - Syringes or vials that were uncapped, or drawn-up and not administered.
  - Lost or unaccounted for vaccine.
  - Doses left in an open multi-dose vial after expiration, beyond use date, or involved in a temperature excursion.
  - Being disposed of in a sharps container.

**Note: Vaccine waste must be rare.

Returned Vaccine
Is defined as vaccine being returned to NDHHS due to it being exposed to a temperature excursion and deemed unviable, or being expired.
- Vaccine is viable on the expiration date, but not the day after.
- Expired and unviable vaccine must be immediately removed from storage units.
- All unopened expired or unviable vaccine must returned to NDHHS at room temperature, and be packaged to prevent breakage.
- Return vials with plastic lids intact, and syringes with rubber stoppers.

**Note: Contact NDHHS at least ninety days prior to vaccine expiration dates, or if quantities on hand exceed populations served.

Borrowed Vaccine
Is defined as vaccine borrowed from VFC and private stock, and vice versa, within a clinic.
- Cannot occur between VFC and AIP vaccine.
- Cannot occur for influenza vaccine.
- Is appropriate only when unexpected circumstances occur, such as:
  - Delayed vaccine shipments.
  - Vaccine spoiled during transit to a clinic.
- May occur for short dated vaccine between VFC and private stock.
- Must be replaced on a dose for dose basis.

**Note: Vaccine borrowing is never to be used as a continuous replacement system of a provider's privately purchased vaccine inventory, and must be rare. Strategies to maintain adequate inventories are to be discussed with NDHHS, prior to borrowing.

Restitution Policy
Is defined as the replacement of VFC and/or AIP vaccine lost due to provider negligence. NDHHS will request replacement vaccine on a dose for dose basis.

Situations requiring vaccine replacement…
- Failure to rotate, causing vaccine to expire
- Failure to provide a list of vaccine set to expire within ninety days or greater to NDHHS
- Preventable storage and handling incidents, resulting in non-viable vaccine:
  - Vaccine left out of storage units.
  - Freezing vaccine that should have been refrigerated.
  - Refrigerating vaccine that should have been frozen.
  - Leaving storage units unplugged.
  - Leaving storage unit doors ajar.
  - Failure to adhere to temperature monitoring and devices protocol.
- Discarding vaccine before the manufacturer's expiration date.
- Provider negligence resulting in vaccine loss.

Situations not requiring vaccine replacement…
- Natural disasters, including power failures.
- Storage unit failures.
- Shipments received containing non-viable vaccine.
- Vials that are accidentally dropped or broken.
- Vaccine drawn at the time of a visit, but not administered due to parental refusal.

**Note: Extenuating circumstances will need to be discussed by the provider and NDHHS.

Restitution Process
- Contact the assigned community health nurse.
- Reconcile inventory in NESIIS indicating vaccine replacement within ninety days.
- Send a follow-up email to the assigned community health nurse communicating doses have been replaced.

**Note: If vaccine is deemed non-viable by NDHHS, the prescribing authority will be notified by NDHHS, leaving the responsibility to revaccinate patients to the discretion of the clinic's medical director.

Emergency Vaccine Management Plan and Transportation

Providers must have an Emergency Vaccine Management Plan (EVMP)
- The plan must be written.
- Review, date and initial annually.

Transporting Vaccine
- Only occurs when an enrolled public clinic transports vaccine from their main clinic to provide outreach to an off-site location.
    - Pack only enough vaccine needed for the day.
    - Must be stored in containers with the functionality to maintain appropriate temperatures.
    - Monitor and record temperatures hourly while in transport. A certified/calibrated thermometer must be used.

**Note: Please contact NDHHS if a public clinic decides to provide a new outreach opportunity.

Nebraska State Immunization Information System – NESIIS

NDHHS requires all VFC/AIP enrolled providers to use NESIIS for:
- Entering administered vaccines into patient records.
- Generating required reports.
- Managing inventory.
- Ordering VFC/AIP vaccine.

**Note: Any patient presenting for immunizations under the VFC/AIP programs must have their immunization entered into NESIIS, unless the patient and/or the parent or guardian "opts-out." The NESIIS Opt-out Form must be completed, signed, and submitted to NDHHS.

NESIIS provides…
- Data exchange of information through electronic medical records. Supported through State statutes 71-539 to 71-544.
- Vaccine transfers from one enrolled clinic to another enrolled clinic to reduce waste, and encourage use before expiration.
- Patient privacy and confidentiality.
- Support for clinical decision making.
- Reminders for families when immunizations are due, or have been missed.

**Note: All enrolled VFC/AIP providers will receive NESIIS training and ongoing technical support by the NDHHS NESIIS staff. Questions should be directed to the assigned community nurse, or refer to NESIIS webpages.

Visits

Compliance Site Visits
- Occur on an annual basis.
- Ensures compliance with VFC and AIP requirements.
- Clinics must have VFC personnel present, and billing staff may be called upon.
- Will include assessing compliance of the following:
  - Verification of demographics and contact information
  - Eligibility screening
  - Billing practices
  - NCVIA requirements
  - Vaccine accountability
  - Storage and handling
- Technical assistance will be provided, as needed
- Five percent of VFC clinics will receive an unannounced storage and handling visit each year.

Follow-up occurs…
- When issues are identified. The assigned community health nurse will develop a corrective action plan.
  - Clinics must address any issues of non-compliance.
  - Timeframes may vary.

Follow-up types…
- Additional training
- Call/email
- Follow-up visit
- Submission of requested materials

**Note: Unsuccessful attempts to resolve issues of non-compliance will result in suspension of ordering privileges, or termination of program participation.

Immunization Quality Improvement for Providers (IQIP)
- Promotes and supports implementation of provider level strategies to increase on time vaccination.
- Assigned community health nurses will work with providers to create appropriate strategies.
- Improvements are individualized for each provider.
- Twenty five percent of clinics will receive an IQIP visit each year.
- IQIP meetings:
  - One face to face meeting will be conducted.
  - Follow-up calls at two months, six months, and one year.

Fraud and Abuse

Fraud
- Is the 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 laws.
  - *Example: A provider administers federally purchased vaccine to all patients regardless of eligibility, or a provider administers federally purchased vaccine to a child who is insured, and bills the insurance company for the cost of the vaccine.*

Abuse
- Includes provider practices that are inconsistent with sound fiscal, business, or medical practices, and results 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 patient), or in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care. Abuse also includes recipient practices that result in unnecessary cost to the Medicaid program.
  - *Example: Vaccine not maintained according to CDC standards and is deemed non-viable; resulting in patients needing revaccination.*
  - *Example: A provider does not accurately account for federally purchased vaccine, and does not know how many doses were used for their eligible patients.*

NDHHS must…
- Conduct preliminary investigations and refer all suspected cases of VFC fraud and abuse directly to the Medicaid Fraud Control Unit.
- Follow the federal regulatory scheme at 42 CFR §455.15 and 42 CFR §455.23
- Direct unanswered questions and concerns to: Medicaid_Integrity_Program@cms.hhs.gov
- Make referrals within ten working days from the initial assessment.

**Note: If fraud or abuse is identified, NDHHS must be notified. Ordering privileges will be suspended upon an investigation is opened. Future participation in this program will be dependent upon outcome.

Leaving the Program

NDHHS will do it's best to work with providers to reach a resolution that still affords providers continued participation. The agreement may be terminated at any time due to non-compliance of program requirements.

Termination will commence…
- If providers are determined to be abusive or fraudulent.
- If a vaccine order has not been placed within the past twelve months.

Prior to termination...
- A notice will be sent via USPS certified mail.
- Providers will have the opportunity to discuss issues of non-compliance.

Voluntary Disenrollment
- Providers must submit written notice.
- Submit a final monthly transaction summary.
- All current vaccine stock being returned that was exposed to a temperature excursion must have manufacturer(s) documentation.
- All vaccine must be returned to the NDHHS.
- Any NDHHS equipment must be returned.

Appendix

Quick Reminders

Vaccine Manufacturer Contact Information

Web Links

Once/Twice Daily Refrigerator Temperature Log

Once/Twice Daily Freezer Temperature Log

Vaccine Borrowing Report

Vaccine Restitution Form

Vaccine Transport Log

Vaccine Storage Troubleshooting Record

Clinic Line Listing

Blank Clinic Line Listing

Packing Vaccines for Transport during Emergencies

Emergency Vaccine Management Plan

Acknowledgement of Policies and Signature Page

Quick Reminders

Daily
- Read and record storage unit minimum and max temperatures, time, date and initial at least once per day when the clinic opens.
- Temperature excursions must be handled immediately to protect vaccine.

Weekly
- Download data loggers
- Review and assess reports for temperature trends on storage units.

Monthly
- Perform an accurate physical count of VFC vaccine the last day of each month using the NESIIS, "Manage Inventory Report" as a tool.
- Check vaccine expiration dates and rotate stock, placing vaccine expiring soonest up front.
- Contact NDHHS at least ninety days prior to vaccine expiration date, or if quantities on hand exceed populations served.
- Send in monthly transaction.

Annually
- Primary vaccine coordinator and their back-up(s) read this manual and sign the Acknowledgement of Policies and Signature Page
- Review and update the Emergency Vaccine Management Plan, then initial and sign.
- Complete provider re-enrollment in NESIIS.

Every Two Years
- Calibrate any non-NDHHS supplied data loggers in order to remain in compliance.

New Coordinators
- View the CDC developed training module, "You Call the Shots: Vaccine Storage and Handling", and submit the certificate of completion to NDHHS within sixty days.

Vaccine Manufacturer Contact Information

- GlaxoSmithKline (GSK)
  - 866-475-8222, Option 4
  - https://gskpro.com/en-us/therapy-areas/vaccines/?cc=v_ERR39X6K11445816&mcm=140000
  - VFC/AIP Vaccine: BEXSERO®, BOOSTRIX®, ENGERIX-B®, FLUARIX®, FLULAVAL®, HAVRIX®, HIBERIX®, INFANRIX®, KINRIX®, MENVEO®, PEDIARIX®, ROTARIX®, TWINRIX®

- Merck & Co., Inc.
  - 877-829-6372, Option 2
  - https://www.merckvaccines.com/
  - VFC/AIP Vaccine: GARDASIL®9, M-M-R®II, PedvaxHIB®, PNEUMOVAX®23, ProQuad®, RECOMBIVAX HB®, RotaTeq®, VARIVAX®, VAQTA®, ZOSTAVAX®

- Pfizer, Inc.
  - 800-438-1985, Option 3
  - https://www.pfizerpro.com/
  - VFC/AIP Vaccine: PREVNAR 13®, Trumenba®

- Sanofi Pasteur, Inc.
  - 800-822-2463
  - https://www.vaccineshoppe.com/
  - VFC/AIP Vaccine: ActHIB®, Adacel®, DAPTACEL®, Fluzone®, IPOL®, Menactra®, Pentacel®, Quadracel®, TENIVAC®

- Seqirus A CSL Company
  - 855-358-8966
  - https://www.seqirus.com/
  - VFC/AIP Vaccine: Flucelvax®

- AstraZeneca
  - 800-236-9933, Option 1, Option 4
  - https://www.astrazeneca.com/
  - VFC/AIP Vaccine: FluMist®

Web Links

- CDC Vaccines Landing Page:
  https://www.cdc.gov/vaccines/hcp/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fhcp.htm

- CDC Immunization Schedules: http://www.cdc.gov/vaccines/schedules/hcp/index.html

- CDC Storage and Handling Toolkit:
  https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

- CDC You Call The Shots: https://www.cdc.gov/vaccines/ed/youcalltheshots.html

- DHHS Immunization Program: http://dhhs.ne.gov/Pages/Immunization.aspx

- DHHS Reporting Concerns or Complaints: http://dhhs.ne.gov/Pages/complaints.aspx

- Immunization Action Coalition: https://www.immunize.org/

- Immunization Action Coalition Standing Orders Templates for Administering Vaccines:
  https://www.immunize.org/standing-orders/

- Nebraska Legislature Revised Statute 44-311:
  https://nebraskalegislature.gov/laws/statutes.php?statute=44-311

- Nebraska Public Clinics:
  https://mapsengine.google.com/map/viewer?mid=zUmqOvOqNtwA.k6KVBMFyOBSs

- Nebraska State Immunization Information System: http://dhhs.ne.gov/Pages/Nebraska-Immunization-Information-System.aspx

- Nebraska State Immunization Information System Opt-Out Form:
  http://dhhs.ne.gov/epi%20docs/Opt_Out_Form.pdf

- Vaccine Adverse Event Reporting System: https://vaers.hhs.gov/index.html

- Vaccine Information Statements: http://www.immunize.org/vis/

Once/Twice Daily Refrigerator Temperature Log
2°C to 8°C (36°F to 46°F)

Clinic Name: _____   NESIIS PIN: _____   Month/Year: _____

Day	Int.	Time		Current	Min	Max	In Range Yes or No	Day	Int.	Time		Current	Min	Max	In Range Yes or No
1			am					17			am				
			pm								pm				
2			am					18			am				
			pm								pm				
3			am					19			am				
			pm								pm				
4			am					20			am				
			pm								pm				
5			am					21			am				
			pm								pm				
6			am					22			am				
			pm								pm				
7			am					23			am				
			pm								pm				
8			am					24			am				
			pm								pm				
9			am					25			am				
			pm								pm				
10			am					26			am				
			pm								pm				
11			am					27			am				
			pm								pm				
12			am					28			am				
			pm								pm				
13			am					29			am				
			pm								pm				
14			am					30			am				
			pm								pm				
15			am					31			am				
			pm								pm				
16			am												
			pm												

Once/Twice Daily Freezer Temperature Log
-15°C to -50°C (5°F to -58°F)

Clinic Name: _____ NESIIS PIN: _____ Month/Year: _____

Day	Int.	Time		Current	Min	Max	In Range Yes or No	Day	Int.	Time		Current	Min	Max	In Range Yes or No
1			am					17			am				
			pm								pm				
2			am					18			am				
			pm								pm				
3			am					19			am				
			pm								pm				
4			am					20			am				
			pm								pm				
5			am					21			am				
			pm								pm				
6			am					22			am				
			pm								pm				
7			am					23			am				
			pm								pm				
8			am					24			am				
			pm								pm				
9			am					25			am				
			pm								pm				
10			am					26			am				
			pm								pm				
11			am					27			am				
			pm								pm				
12			am					28			am				
			pm								pm				
13			am					29			am				
			pm								pm				
14			am					30			am				
			pm								pm				
15			am					31			am				
			pm								pm				
16			am												
			pm												

Facility Name:
Pin #:

VACCINE BORROWING REPORT

VFC-enrolled providers are expected to manage and maintain an adequate inventory of vaccine for both their VFC and non–VFC-eligible patients. **Planned borrowing of VFC vaccine including the use of VFC vaccine as a replacement system for a provider's privately purchased vaccine inventory is not permissible.**

VFC-enrolled providers must ensure borrowing VFC vaccine will not prevent a VFC-eligible child from receiving a needed vaccination. Infrequent exchanging between VFC and private stock of a short-dated vaccine dose may be performed if the provider serves a small number of private pay patients, the dose is one month from expiration, or the dose of vaccine cannot be used for the population it is intended for prior to the expiration date.

COMPLETE THIS FORM WHEN:

- A dose of VFC vaccine is administered to a non VFC-eligible child
- A dose of privately-purchased vaccine is administered to a VFC-eligible child

HOW TO COMPLETE THIS FORM:

- Enter information on each dose of vaccine borrowed in a separate row in the Vaccine Borrowing Report Table.
- All columns must be completed for each dose borrowed
- The provider must sign and date at the bottom of this report
- Enter the corresponding reason code in column F of the Borrowing Report Table on page 2.
- Enter details of reason in Column F if an Other code (7Other or 13Other) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

Reason for Borrowing VFC Dose	Code	Reason for Borrowing Private Dose	Code
Private vaccine shipment delay (vaccine order placed on time/delay in shipping)	1	VFC vaccine shipment delay (order placed on time/delay in shipping)	8
Private vaccine not useable on arrival (vials broken, temperature monitor out of range)	2	VFC vaccine not useable on arrival (vials broken, temperature monitor out of range)	9
Ran out of private vaccine between orders (not due to shipping delays)	3	Ran out of VFC vaccine between orders (not due to shipping delays)	10
Short-dated private dose was exchanged with VFC dose	4	Short-dated VFC dose was exchanged with private dose	11
Accidental use of VFC dose for a private patient	5	Accidental use of a Private dose for a VFC eligible patient	12
Replacement of Private dose with VFC when insurance plan did not cover vaccine	6	Other – Describe:	13Other
Other – Describe:	7Other		

WHAT TO DO WITH THIS FORM:

- Completed forms must be retained as a VFC program record and made available to the State/Local or Territorial Immunization Program upon request.

1

Date Range of Vaccine Reporting (date of first dose borrowed to date of last dose borrowed): _____ / _____ / _____ to _____ / _____ / _____

VACCINE BORROWING REPORT TABLE

A Vaccine Type Borrowed	B Stock Used (VFC or Private)	C Patient Name	D Patient DOB (XX/XX/XXXX)	E Date Dose Administered (XX/XX/XXXX)	F Reason Appropriate Vaccine Stock was not Used (Use legend code on page 1 to mark one reason for each dose borrowed)	G Date Dose Returned to Appropriate Stock (XX/XX/XXXX)

I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3730) and other applicable Federal and state law, that VFC vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC provisions for such borrowing and further certify that all VFC doses borrowed during the noted time period have been fully reported on this form.

Provider Name:

Provider Signature: Date:

2

NEBRASKA
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DEPT. OF HEALTH AND HUMAN SERVICES

Nebraska Immunization Program Vaccine Restitution Form

State and local immunization programs with vaccine restitution or replacement policies must follow CDC policy on vaccine replacement of federally funded vaccines. All vaccines which have been lost and are eligible for replacement (according to state/local restitution policy) must be replaced dose for dose within 90 days of loss. Providers must submit a receipt of vaccine purchase reflecting dose for dose replacement to the Nebraska Immunization Program within 90 days of the vaccine loss, and submit this report once replacement doses have been administered. Replaced doses must only be used to support eligible VFC children and AIP adults.

Clinic Name: _____   NESIIS PIN: _____

Vaccine Type	Loss Date	Lot #	NDC #	VFC or AIP	# Doses Lost	Date Replaced

"I hereby certify, subject to penalty under the False Claims Act (31 U.S.C. § 3729) and other applicable federal and state laws, that VFC and/or AIP vaccines reported on this form are accurate and replaced in conformance with state provisions for restitution, and that all doses lost during the noted time period have been fully reported and replaced according to this form."

Provider Name: _____   Provider Signature: _____   Date: _____

Vaccine Transport Log

To be utilized during off-site clinic activities. Temperatures must be documented each hour while vaccine remains out of dedicated storage units.

Acceptable Temperatures: 2°C to 8°C (36°F to 46°F) or -15°C to -50°C (5°F to -58°F)

Clinic Name: _____ NESIIS PIN: _____ Date: _____

Unit Type	Time		Refrigerator Cooler Temp	Freezer Cooler Temp	Initials
	6	am pm			
	7	am pm			
	8	am pm			
	9	am pm			
	10	am pm			
	11	am pm			
	12	am pm			
	1	am pm			
	2	am pm			
	3	am pm			
	4	am pm			
	5	am pm			

**Notes:

_____
_____
_____

Vaccine Storage Troubleshooting Record (check one) ◯Refrigerator ◯Freezer ◯Ultra-Cold Freezer

Use this form to document any unacceptable vaccine storage event, such as exposure of refrigerated vaccines to temperatures that are outside the manufacturers' recommended storage ranges.

Date & Time of Event If multiple, related events occurred, see Description of Event below.	Storage Unit Temperature at the time the problem was discovered		Room Temperature at the time the problem was discovered	Person Completing Report
Date:	Temp when discovered:		Temp when discovered:	Name:
Time:	Minimum temp:	Maximum temp:	Comment (optional):	Title: Date:

Description of Event *(If multiple, related events occurred, list each date, time, and length of time out of storage.)*

- General description (i.e., what happened?)
- Estimated length of time between event and last documented reading of storage temperature in acceptable range (2° to 8°C [36° to 46°F] for refrigerator; -50° to -15°C [-58° to 5°F] for freezer; -80° to -60°C [-112° to -76°F] for ultra-cold freezer (may be used for Pfizer COVID-19 vaccine).
- Inventory of affected vaccines, including (1) lot #'s and (2) whether purchased with public (for example, VFC) or private funds (Use separate sheet if needed, but maintain the inventory with this troubleshooting record.)
- At the time of the event, what else was in the storage unit? For example, were there water bottles in the refrigerator and/or frozen coolant packs in the freezer?
- Prior to this event, have there been any storage problems with this unit and/or with the affected vaccine?
- Include any other information you feel might be relevant to understanding the event.

Action Taken *(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)*

- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)
- Who was contacted regarding the incident? (For example, supervisor, state/local health department, manufacturer—list all.)
- IMPORTANT: What did you do to prevent a similar problem from occurring in the future?

Results

- What happened to the vaccine? Was it able to be used? If not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)

DISTRIBUTED BY THE
IMMUNIZATION ACTION COALITION   Saint Paul, Minnesota · 651-647-9009 · www.immunize.org · www.vaccineinformation.org

www.immunize.org/catg.d/p3041.pdf · Item #P3041 (8/21)

Date	Name	Age	Private	Medicaid	Uninsured	NA / AM	DTap	Pediarix	Kinrix	Pentacel	Hep A	Hep B	Hib	HPV	Mening	MeningB	MMR	Pro Quad	Prevnar	Rota	Td	Tdap	Varicella

This is a blank grid/chart template with two labeled columns.

Date	Name																									

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency

Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. **It's critical to have an up-to-date emergency plan with steps you should take to protect your vaccine.** In any emergency event, activate your emergency plan immediately. Ideally, vaccine should be transported using a portable vaccine refrigerator or qualified pack-out. However, if these options are not available, you can follow the emergency packing procedures for refrigerated vaccines below:

1 Gather the Supplies

Hard-sided coolers or Styrofoam™ vaccine shipping containers
- Coolers should be large enough for your location's typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

Conditioned frozen water bottles
- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand (this normally takes less than 5 minutes).

Insulating material — You will need two of each layer
- **Insulating cushioning material** – Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard** – Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

Temperature monitoring device – Digital data logger (DDL) with buffered probe. Accuracy of +/-1°F (+/-0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 5 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?

Conditioned frozen water bottles and corrugated cardboard used along with one inch of Insulating cushioning material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. **Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.**
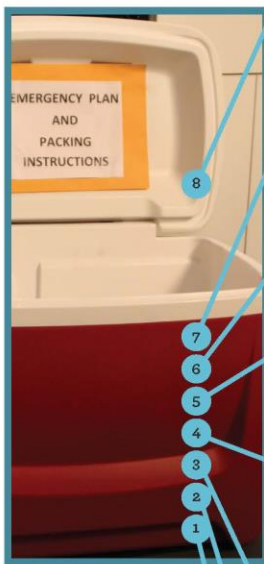

Packing Vaccines for Transport during Emergencies

2 Pack for Transport

Conditioning frozen water bottles (this normally takes less than 5 minutes)
- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice "sticks," put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.
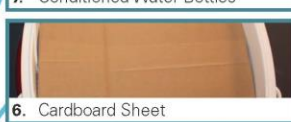
EMERGENCY PLAN AND PACKING INSTRUCTIONS

8. Temperature Monitoring Device Display (on lid)

Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.

7. Conditioned Water Bottles

Conditioned frozen water bottles – Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

6. Cardboard Sheet

Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.

5. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™

4. Vaccines, Diluents, and Temperature Monitoring Device Probe

Vaccines – Add remaining vaccines and diluents to cooler, covering DDL probe.
Temperature monitoring device – When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.
Vaccines – Stack boxes of vaccines and diluents on top of insulating material.

3. Bubble wrap, packing foam, or Styrofoam™

Insulating cushioning material – Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

2. Cardboard Sheet

Insulating material – Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

1. Conditioned Water Bottles

Conditioned frozen water bottles – Line bottom of the cooler with a single layer of conditioned water bottles.

NOTE:
This pack-out can maintain appropriate temperatures for up to 8 hours, but the container should not be opened or closed repeatedly.

3 Arrive at Destination

Before opening cooler – Record date, time, temperature, and your initials on vaccine temperature log.

Storage – Transfer boxes of vaccines quickly to storage refrigerator.

Troubleshooting – If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines "Do Not Use" and store at appropriate temperatures until a determination can be made.

Emergency Vaccine Management Plan

Provider Site Name: _____

Provider Site Address: _____

Primary Vaccine Coordinator: _____

Emergency Phone Number: _____

Back-up Vaccine Coordinator: _____

Emergency Phone Number: _____

Transporting Vaccine
- In the event of a power failure or storage unit failure, vaccine will need to be moved to a pre-designated location.
- Ensure that all appropriate staff have instructions on what to do during an emergency. This may include where to go, how to transport vaccine to ensure the cold chain is maintained, and what supplies are needed such as frozen water bottles, bubble wrap, cardboard, flashlights, and keys. Refer to the Packing Vaccines for Transport during Emergencies located in the Appendix of this manual.
- Keep a copy of this Emergency Vaccine Management Plan along with a copy of the Packing Vaccines for Transport during Emergencies.
- All refrigerated vaccine must be kept between 36°F/2°C and 46°F/8°C.
- Varicella and MMRV (ProQuad) need to be transferred on frozen cold packs with a thermometer and topped with frozen cold packs. MMR can be transported frozen. Keep temperatures between -58°F/-50°C and 5°F/-15°C.
- Once vaccine is transported to alternate refrigeration and freezer units, keep them at the proper temperatures.

The back-up refrigerator and/or freezer unit is located: _____

Alternate facility phone number: _____

Signature of primary vaccine coordinator: _____

This plan must be initialed and updated annually.
____/____/2022 ____/____/2023   ____/____/2024
_____initials   _____initials   _____initials

Acknowledgement of Policies and Signature Page

As an enrolled provider, it is a federal requirement that each provider has written vaccine management policies adopted into practice for the management of publicly purchased vaccine. This manual serves to fulfill federal requirements of vaccine management policies.

- The primary vaccine coordinator and their back-up(s) read and sign this page, certifying that the manual has been reviewed and take responsibility for adopting policies into clinic processes.
- An Emergency Vaccine Management Plan must be developed and implemented.
- This manual is reviewed and signed annually.

By signing below, I hereby certify that I have read the Nebraska Immunization Program Provider Manual Revised 2022, and take responsibility for adopting all policies into clinic processes. I acknowledge that this is my legal signature.

Primary Vaccine Coordinator Name: _____   Date: _____

Back-up Vaccine Coordinator Name: _____   Date: _____

Additional Trained Staff (Optional): _____   Date: _____

**Note: Insert additional signatures, as necessary.