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DEPT. OF HEALTH AND HUMAN SERVICES

Vaccines for Adults

Immunization Program Clinic Provider Manual

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Overview of State Programs

Vaccines for Adults (VFA) Program

The VFA Program provides select adult vaccines at free or reduced cost to uninsured adults aged 19 and older. To participate in the VFA Program, clinics are required to also be Vaccines for Children (VFC) providers. VFA programs are partnered with VFC. This partnership ensures vaccine access to vulnerable populations, improving public health outcomes.

Nebraska Department of Health and Human Services (NDHHS) Immunization Program

Vaccine funding for the VFA program is distributed by the Centers for Disease Control and Prevention (CDC) to the NDHHS Immunization Program. NDHHS is responsible for:

- Supplying vaccines at no cost to enrolled clinics
- Monitoring program adherence and vaccine stewardship.
- Safeguarding vaccine viability at all times.

Nebraska State Immunization Information System (NESIIS)

NESIIS is a **confidential**, population-based computerized database that tracks immunization records. NESIIS is an important software that participating providers can use to document all immunization doses administered to Nebraska residents. Benefits include:

- Consolidated immunization histories for patients.
- Assistance with clinical decision-making.
- Support for public health initiatives to reduce vaccine-preventable diseases.

Overview of Federal Programs

Centers for Disease Control and Prevention (CDC)

The CDC is a federal agency focused on improving public health through health promotion, prevention, and preparedness activities. It collaborates with local, state, and national partners to monitor and prevent disease outbreaks (including bioterrorism), implement prevention strategies, and maintain national health statistics.

The CDC also works to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. Key areas of focus include supporting health departments, improving global health, reducing leading causes of death, strengthening surveillance, and reforming health policies.

Advisory Committee on Immunization Practices (ACIP)

The ACIP is made up of medical and public health experts who develop vaccine recommendations for the U.S. civilian population. These recommendations provide public health guidance on the safe use of vaccines and related biological products.

All VFA providers must adhere to the immunization schedules, dosages, and contraindications set by ACIP.

Federal Law Requirements

National Childhood Vaccine Injury Act Documentation

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

All VFA providers must adhere to NCVIA requirements, including:

1. Providing Vaccine Information Statements (VIS) to patients before vaccination.
    a. Current VIS copies in multiple languages are available at:
        i. http://www.immunize.org/vaccines/vis/about-vis/
2. Allowing patients time to review the VIS and ask questions.
3. Recording essential vaccine details including:
    a. Vaccine name
    b. Date vaccine was administered
    c. Vaccine manufacturer
    d. Lot number
    e. Clinic or facility address
    f. Name and title of individual administering vaccination
    g. VIS publication date
    h. Date VIS was provided to patient, parent, or legal guardian

**Note: More information regarding NCVIA can be found at: https://www.hrsa.gov/vaccine-compensation/about

Vaccine Adverse Event Reporting System (VAERS)

VAERS is a national surveillance program that collects information about adverse events following the administration of licensed vaccines. This data is used to monitor side effects and identify potential safety concerns.

Anyone can file a VAERS report, including healthcare providers, vaccine 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 vaccine information statement (VIS).

Provider Requirements:

- Report any event(s) listed in the “Reportable Events” table occurring within a specified time period after vaccination.
    - https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf
- Report any event(s) identified by the vaccine manufacturer as a contraindication to subsequent doses of that vaccine.
- Link to VAERS website.

Provider Recommendations:

- Report any clinically significant adverse event(s), even if unsure whether the vaccine caused the event.
- Report vaccine administration errors.
- Visit the MedWatch Online Voluntary Reporting Form to report any unexpected side effects or adverse events

Clinics, Roles, and Responsibilities

Clinics

Enrolled Clinics

An enrolled clinic is one with an active VFA program.

Eligible Clinics:

- Federally Qualified Health Centers (FQHCs)
- Local Health Departments
- Community Clinics
- Public Immunization Clinics

Public Clinics in Nebraska

The NDHHS Immunization Program defines a public clinic as one operated by a public or non-profit agency, such as:

- County or district health departments
- Tribal health facilities
- Community action agencies
- Federally Qualified Health Centers

*Public clinics serve as a “safety net” for populations with unmet healthcare needs.

Key Characteristics:

- Sponsoring physician who is located off-site
- Serve healthy clients without contraindications
- Have the capacity to serve all eligible patients
- Must accommodate walk-in patients.

Roles and Responsibilities

Enrolled Clinics:

- Secure a sponsoring physician.
- Implement appropriate policies and procedures to govern clinic operations.
- Provide appropriate staff and adequate training.
- Ensure immunization records are entered manually into NESIIS or are provided via data exchange (Electronic Health Record (EHR) connectivity is at the expense of the clinic)
- Clinics must have appropriate vaccine storage units and temperature monitoring devices to ensure compliance with program requirements.

Sponsoring Physicians:

- Provide annual written vaccine administration standing orders and emergency protocol to staff.
- Acknowledge and signing the annual recertification form.
- Be on call, or designate a back-up physician, during vaccination clinic hours to provide consultation.

VFA Coordinators and Back-Up Coordinators

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

VFA and Back-Up Coordinators Must:

- Daily and Weekly Responsibilities
  - **Daily Temperature Records**
    - Manually record minimum, maximum, and current temperatures each day the clinic is open.
  - **Monitor temperature trends**:
  - Download data loggers weekly (preferably) and review for any temperature trends.
- Monthly Responsibilities:
  - **Perform monthly vaccine counts**:
    - Complete accurate physical counts of VFA vaccines on the last day of each month.
  - **Update NESIIS**:
    - Adjust vaccine inventory in NESIIS.
  - **Submit transaction summaries**:
    - Send monthly summaries to NDHHS by the 15th of the following month.
- Training and Compliance:
  - **Complete required training**:
    - Review and/or complete the CDC's "You Call the Shots: Vaccine Storage and Handling" training annually and submit the certificate to NDHHS within 60 days (required for new coordinators).
  - **Report clinic or personnel changes**:
    - Immediately notify NDHHS of any updates, such as changes in coordinator, address, phone number, shipping hours, or medical director.

Records Retention

All records related to the NDHHS Immunization Program must be kept for at least 3 years, as required. This applies even if a provider retires or the location closes. Clinics may maintain records in either electronic or paper format, based on their preference. Providers must ensure these records are accessible and available to NDHHS upon request. Blank Clinic Line Listing.

Required Records Include:

- VFA screening and eligibility documentation
- Billing records
- Vaccine administration verification
- Vaccine-related documentation, such as:
  - Packing slips
  - Borrowing reports
  - Monthly transaction summaries,
  - Waste reports
- Temperature logs

Eligibility for Vaccine and Screening

Eligibility Requirements:

VFA vaccines are available to:

- 19 years of age and older
- Uninsured

Screening for Eligibility

Screening is required for every patient before vaccine administration. Providers must:

- Document eligibility at each visit.
- Maintain accurate records in NESIIS to ensure compliance with program guidelines.

Fees and Donations

Fees

Prohibition on Vaccine Charges: Clinics cannot charge for the cost of VFA vaccines.

- Administration Fee
  - Clinics may charge an administration fee of up to $19.82 per vaccination.
  - Clinics must not deny vaccine administration to eligible patients who are unable to pay the administration fee.
- Billing for Administration Fees:
  - Providers who bill for the administration fee after the date of service may issue **only one bill** to the patient, which must be sent within 90 days of vaccine administration.
  - **Unpaid administration fees** cannot be sent to collections.

Donations

- Clinics may collect a donation of up to $19.82 per vaccination, instead of an administration fee.
- No patient may be denied vaccination due to an inability or unwillingness to donate. Funds received from donations or administration fees are to be used to support the public immunization clinic.

Storage Units and Storage Safety

Vaccine Storage Unit Requirements

To ensure proper vaccine storage, all units used in the VFA program must meet the following criteria:

General Requirements

- Must maintain required vaccine storage temperatures.
- Must be large enough to accommodate the largest inventory volume and allow for adequate air circulation.
- Must be in good working order, with frost build-up addressed per CDC's Storage and Handling Toolkit.
- Must not contain food or drink.
- May hold both biologicals and vaccine but must be stored below vaccine.
- Must have water bottles or cold packs labeled "DO NOT DRINK" placed throughout in refrigerators and freezers to keep temperatures stable.
    - Unless otherwise specified by manufacturer.
- ALL units must have a digital data logger or continuous temperature monitoring system

Unit Type

- Freezers:
    - 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.
    - Pharmaceutical-grade units are recommended as best practice.
- Prohibited Units:
    - Dormitory-style refrigerators are not permitted, per CDC requirements.

**Note:

- Clinics must notify NDHHS before using any new storage unit or an existing unit that has been repaired.

Safeguarding the Electrical Supply

To ensure reliable power for vaccine storage:

- Direct Connection:
    - Plug storage units directly into electrical outlets. **Extension cords are not allowed.**
- Prevent Accidental Unplugging:
    - Use safety lock plugs, if available
    - Clearly label refrigerators, freezers, electrical outlets, fuse boxes, and circuit breakers with "DO NOT UNPLUG" or "WARNING" stickers.
- Backup Power:
    - Whenever possible, connect storage units to an outlet backed by a generator.

**Note:

- In hospitals or large health care systems with comprehensive written policies and standard operating procedures; detailed measures to prevent accidental disconnection of vaccine storage units may replace the need for "WARNING" stickers on circuit breakers.

Vaccine Storage

General Storage Guidelines

- Vaccines from VFC, VFA, and private stock may be stored together but must be labeled clearly.
- Arrange vaccines with shorter expiration dates in front to ensure they are used first.

Organizing Vaccine Storage

- Store vaccines away from cold air vents, drawers, floors, and walls.
- Never store vaccine in drawers, crisper drawers of household-type units, or the space where the drawers have been removed.
- Allow enough space for proper air circulation.
- Store in their original boxes with lids intact to protect them from light.
- Containers should be open and ventilated for proper air circulation.
- Use labeled containers, color-coded baskets, or separate shelves to distinguish vaccines.
- Store diluents per manufacturer's instructions and **never in freezers.**

Managing Expiring or Wasted Vaccine

- Report soon-to-expire vaccine to NDHHS 3-6 months in advance.
- All clinics should contact NDHHS for guidance on unused vaccine nearing expiration.
- Remove **expired or wasted vaccine** immediately from storage units.

Vaccine Storage Requirements

Temperature Guidelines

- **Refrigerators:** 2°C to 8°C (36°F to 46°F)
- **Freezers:** -15°C to -50°C (5°F to -58°F)
- **Ultra-Cold Freezers:** -60°C to -90°C (-76°F to -130°F)

Monitoring and Documentation

- At the start of each workday:
    - Review and record temperature readings from NDHHS-approved continuous temperature monitoring devices.
    - Log the following details using temperature logs provided in the appendix:
        - Date
        - Time
        - Staff member's initials
        - Minimum/maximum and current temperatures for both refrigerator and freezer
    - Clinics may create their own temperature logs, as long as the above criteria are included.
- Weekly
    - Download data from digital data loggers (DDLs)
        - https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/

Temperature Monitoring Devices, and Excursions

Temperature Monitoring Devices

Required Features for Continuous Monitoring Devices

Continuous temperature monitoring devices must:

- Be **certified as calibrated** and recalibrated per the certificate of calibration.
- Feature a **digital display** that is easily readable from outside the storage unit.
- Show the **current, minimum and maximum temperatures**.
- Place probes in the central section of the storage units where vaccine is located.
- Units pre-approved by NE DHHS Immunization Program Staff 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.

Recommended Features

Temperature monitoring devices should:

- Include a **temperature probe in buffered material** to mimic vaccine temperatures.
    - Buffered materials can be:
        - Glycol
        - Glass beads
        - Sand
        - Teflon®
- Have an **alarm** for out-of-range temperatures.
- Include a **low battery indicator**.
- Maintain an accuracy of ±0.5°C (±1°F).
- Provide memory storage for at least **4,000 readings**.

Temperature Excursions

A temperature excursion occurs when vaccine storage temperatures fall outside the acceptable range, even by as little as 0.1°C. Follow this protocol for every temperature excursion:

Immediate Actions

1. Communicate with Staff
    a. Ensure the primary and backup vaccine coordinators both know of the temperature excursion. **Do not discard vaccine.**
2. Isolate the Vaccine:
    a. Label the vaccine "**DO NOT USE"** and ensure it is stored at the appropriate temperature.
3. Separate the Vaccine:
    a. If space allows, relocate the vaccine to another refrigerator, freezer, or cooler.
    b. Otherwise, separate the vaccine from vaccine currently in use.

Notifications

4. Contact the Manufacturer:
    a. Call the vaccine manufacturer to determine vaccine's viability.
    b. Request written documentation from the manufacturer regarding the vaccine's status.
5. Contact NDHHS
    a. Call the assigned community health nurse or NDHHS for guidance.

Documentation

6. Record Details:
    a. Document the excursion, using the Vaccine Troubleshooting Form
        i. Temperature excursion details
        ii. Actions taken
        iii. Outcome of the manufacturer's evaluation
    b. Send documentation, along with manufacturer information, to the assigned community health nurse via email or fax. Retain a copy for clinic records.

Correction

7. If the temperature alarm sounds repeatedly, do not disconnect the alarm until the issue is identified and resolved. Follow these steps to address the problem:
    a. Check the Basics:
        i. Verify the power supply.
        ii. Ensure the unit doors are securely closed.
        iii. Confirm thermostat settings are correct.
    b. Address Fluctuations:
        i. If the excursion was due to a temperature fluctuation, refer to the "Vaccine Storage and Temperature Monitoring Equipment" section in the CDC's Vaccine Storage and Handling toolkit for guidance on adjusting storage unit temperatures to the appropriate range.
    c. Manage Equipment Failures:
        i. If you suspect the storage unit has failed, implement your emergency vaccine storage and handling Standard Operating Procedures (SOPs).
        ii. **Never allow vaccines to remain in a nonfunctioning unit** following a temperature excursion.

**Note: If a vaccine is deemed unviable due to a temperature excursion and has been administered to patients, consult with the primary provider to determine whether revaccination is necessary.

Vaccine Inventory

Limited Adult Vaccine Inventory

The NDHHS Immunization Program has limited adult vaccine funding, allocated based on provider demand. Funding is available starting in Quarter 1. Once funds are exhausted, additional orders cannot be placed. A federal redistribution period may occur based on state demand, but it is not guaranteed.

- Quarter Breakdown:
    - 1st Quarter: October, November, December
    - 2nd Quarter: January, February, March
    - 3rd Quarter: April, May, June
    - 4th Quarter: July, August, September

Nebraska State Immunization Information System (NESIIS)

NESIIS Features

- Data exchange: Facilitates information transfer through electronic medical records, supported by State statutes 71-539 to 71-544.
- Vaccine transfers: Enables transfers between enrolled clinics to reduce waste and encourage vaccine use before expiration.
- Patient privacy: Ensures confidentiality of patient information.
- Clinical decision support: Assists with clinical decision-making.
- Reminders: Sends reminders to families when immunizations are due or missed.

**Note:

- All enrolled VFA providers will receive NESIIS training and ongoing technical support from the NDHHS NESIIS staff.
- For questions, contact the assigned community health nurse or refer to the NESIIS webpages.

NESIIS Requirements for VFA Enrolled Providers

NDHHS requires that all VFA-enrolled providers use NESIIS for the following:

- Entering administered vaccines into patient records.
- Generating required reports for tracking and compliance.
- Managing inventory of vaccines.
- Ordering VFC/VFA vaccine.
- Monthly vaccine transaction summary reports.
- Annual re-enrollment for VFA participation.

NESIIS Recommendations for VFA Enrolled Providers

NDHHS highly recommends that all VFA-enrolled providers:

- Document private vaccine administration records accurately and promptly

**Note:

- Any patient receiving immunizations under the VFA program must have their immunization records entered into NESIIS, unless the patient or their guardian “opts-out.”
- The NESIIS Opt-out Form must be completed, signed, and submitted to NDHHS.

NESIIS Help Desk

- The NESIIS Help Desk provides training and grants system access upon completion.
- For assistance, contact **dhhs.nesiis@nebraska.gov**.

Ordering and Receiving Vaccine

Ordering Vaccine

General Guidelines

- All vaccine orders must be placed via NESIIS.
- **Best Practice:** Order lean, as adult vaccine inventory is limited.
- Ensure ordered quantities reflect the populations served.
- When possible, orders should be placed when vaccine inventory is reduced to a four-week supply to ensure there is enough stock to allow for potential delays.
- Avoid maintaining a stockpile or building up an excess amount of vaccine.

Pre-Order Requirements

- Adjust inventory in NESIIS.
- Complete and submit monthly transaction summaries to NDHHS.

Monitoring and Compliance

- Providers are responsible for annual training on proper storage and handling procedures for all staff involved in the receipt, management, administration, or transport of vaccines.
- The CDC requires NDHHS to monitor vaccine ordering patterns to ensure appropriate quantities are ordered.
    - **Unusual Ordering Activity:** If flagged, orders will be placed on hold until clarification is obtained.
- Non-compliance with NDHHS requirements may result in suspension of vaccine ordering privileges.

Follow-Up

- Contact the Vaccine Ordering Specialist if:
    - Orders marked “approved” in NESIIS are not received within:
        - **4 days** for flu vaccine
        - **5 days** for other vaccines

Special Ordering Circumstances

- **Influenza Vaccine:** May be ordered independently of other vaccines.
- **Td Vaccine:** May be ordered as a single dose.
- **PPSV23 (VFA Program)**: May be ordered as a single dose. Contact the NDHHS Immunization Program.

Receiving Vaccine

Shipment Details

- Shipments will arrive based on days and times indicated in the clinic’s NESIIS Profile
- Update shipping or profile changes immediately in NESIIS and notify NDHHS.
    - Clinics are liable for non-viable vaccine due to unreported changes in operating days, hours, or address
- Allow up to **two weeks** for vaccine receipt
    - If not received within two weeks, contact NDHHS.

Shipment Acceptance and Inspection

- Always accept vaccine shipments, even if damaged or incorrect.
    - Place damaged or incorrect vaccines in appropriate storage, label "**DO NOT USE",** and contact NDHHS immediately.
    - Please see "Problems with Receiving a Shipment" below to troubleshoot.
- Inspect vaccine condition and check temperature monitor cards (if enclosed).
- Compare the NESIIS order, packing slip, and package contents.
    - Check the shipment log against the vaccine in the box as well as against the order.
    - Keep packing slips for at least 3 years.

Storage and Documentation

- Store vaccines in appropriate storage unites with the earliest expiration dates at the front.
- In NESIIS:
    - Go to "**Inventory**" → "**Manage Transfers**" → "**Accept Transfer**" to auto-populate shipment information into inventory.

**Note:

- **Varicella** arrives frozen separately from Merck
- **MMR Vaccine** arrives refrigerated but can be stored in the freezer as best practice to prevent warming.

Problems with Receiving a Shipment

- Report any discrepancies immediately to the Nebraska Immunization Program if the vaccine received does not match the packing slip or the order that was placed in NESIIS.
- If the condition of the vaccine is questionable (temp monitor card is activated, ice packs are thawed), mark the vaccine "Do Not Use" and store at appropriate temperature and contact the Nebraska Immunization Program
- If a temperature excursion occurred in transit, please follow the temperature excursion guidelines.
- For any other shipment issues, call the Nebraska Immunization Program at (402) 471-6423. You can also contact our Inventory Ordering Specialist, Andrew Reinhard, at Andrew.d.reinhard@nebraska.gov or (402)-471-3435 to explain the issues.

**Note:

- Have your packing slip readily available when contacting NDHHS Immunization Program staff.

Vaccine Accountability and Documentation

Vaccine Accountability

- **Ensure staff awareness:** All staff administering vaccine must know which vaccine stock to use based on eligibility.
- **Accurate Tracking:** Track administered, returned, and/or wasted doses in NESIIS.
- **Private Vaccine Doses:** Promote the entry of private vaccine doses into NESIIS.
- **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 VFA dose when an insurance plan did not cover vaccine.

**Note:

- 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 VFA eligible patient's ability to receive 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 (Vaccine Waste Report)
    - 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.
    - VFA and private patient numbers must be included with the provider profile.
- Temperature Excursion Documentation
    - Submit Vaccine Storage Troubleshooting Record 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.

Vaccine Handling and Management

Wasted Vaccine

Wasted vaccine refers to vaccine that cannot be returned due to:

- Broken syringes or vials.
- Syringes or vials that were uncapped or drawn-up and not administered by end of day.
- Lost or unaccounted for vaccine.
- Doses remaining in an open multi-dose vial after expiration, beyond use date, or involved in a temperature excursion.
- Vaccine disposed of in a Sharps container.

**Note:

- Vaccine waste must be rare.

Vaccine Waste Reporting:

- Any wasted or spoiled vaccine must be reflected in the provider inventory in NESIIS before running a waste report.
- Run a waste report in NESIIS and submit it to the Nebraska Immunization Program by the 15th of the following month.
    - You can submit via fax at (402)-471-6426 or email: DHHS.Immunization@nebraska.gov.
- The vaccine should then be discarded in a sharp's container, or other approved waste disposal method.

Returned Vaccine

Returned vaccine refers to vaccine sent back to NDHHS due to exposure to a temperature excursion or expiration, rendering it unviable.

- 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 return to NDHHS at room temperature and packaged to prevent breakage.
- Return vials with **plastic lids intact, and syringes with rubber stoppers**.

**Note:

- Do not return vials that are missing their lids, or if a syringe is missing its rubber stopper
- Any unused vaccine in open vial must be documented as wasted vaccine in NESIIS and disposed of appropriately.

Return Process

- All expired or spoiled vaccines must be returned to the Nebraska Immunization Program within 3-6 months after expiration/ spoiling.
- Use NESIIS to create a return transaction summary, selecting “return only” and include the date range when the vaccine had expired.
- Complete the vaccine return transaction summary and keep a copy.
- NESIIS automatically marks expired vaccines as “returned”, so providers do not need to adjust inventory.
- Place the vaccine in a box with bubble wrap or a padded envelope with the return form (packing slip).
- NDHHS Mailing Address:

  Nebraska Immunization Program
  PO Box 95026, 301 Centennial Mall S
  Lincoln, NE 68509

**Note:

- Contact NDHHS at least 90 days prior to vaccine expiration dates, or if quantities on hand exceed populations served.
- **Failure to do so may result in provider being responsible for restitution.**

Borrowed Vaccine

Borrowed vaccine refers to vaccine borrowed between VFA and private stock within a clinic.

Guidelines:

- **Prior approval needs to be obtained by NDHHS program staff for VFC and VFA vaccines to be borrowed.**
- Borrowing is appropriate only in unexpected circumstances, such as:
  - Delayed vaccine shipments.
  - Vaccine spoiled during transit to a clinic.
- May occur for short-dated vaccine between VFA and private stock.
- Must be replaced on a dose-for-dose basis within 30 days.
- Record any borrowed vaccines on the borrowing report and submit to nurse.

**Note:

- Vaccine borrowing is never to be used as a continuous replacement system of a provider’s privately purchased vaccine inventory.
- It should be rare, and strategies to maintain adequate inventories must be discussed with NDHHS, prior to borrowing.

Restitution Policy

The restitution policy refers to the replacement of VFA vaccine lost due to provider negligence. NDHHS will request replacement vaccine on a dose-for-dose basis

Situations Requiring Vaccine Replacement

- **Failure to rotate,** leading to expiration
- **Failure to provide a list** of vaccine set to expire within 90 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

Vaccine replacement will not be requested in the following situations:

- **Natural disasters**, including power failures.
- **Storage unit failures** not caused by negligence.
- **Shipments of non-viable vaccine** received.
- **Accidental breakage** of vaccine vials.
- **Vaccine drawn** but not administered due to parental refusal.

**Note:

- Extenuating circumstances must be discussed between the provider and NDHHS

Restitution Process

1. Contact the assigned community health nurse.
2. Reconcile inventory in NESIIS, indicating vaccine replacement within 90 days.
3. Send a follow-up email to the assigned community health nurse confirming doses have been replaced.

**Note:

- If vaccine is deemed non-viable by NDHHS, the prescribing authority will be notified.
- Responsibility for revaccinating patients will be at the discretion of the clinic's medical director.

Emergency Vaccine Management Plan and Transportation

Emergency Vaccine Management Plan (EVMP)

- Providers must have a written Emergency Vaccine Management Plan (EVMP).
    - Include what to do in event of a power outage or equipment failure.
- The plan must be reviewed, dated, and initialed annually.

Transporting Vaccine

Eligibility for Vaccine Transportation

- Actively enrolled Public Clinics may transport vaccine from their main clinic to provide outreach at off-site locations.
- Redistribution of Vaccine is permitted **only by contacting NDHHS program staff**
    - Examples of situations where redistribution may occur include:
        - Overordering
        - Natural Disasters
        - Fluctuating demand

Transportation Requirements

- Only transport the amount of vaccine needed for the day.
- Store vaccines in containers designed to maintain appropriate temperatures.
    - Follow this guide.
- Monitor and record temperatures hourly during transport, using a certified/ calibrated thermometer using our Vaccine Transport Log.

**Note:

- Please contact NDHHS if a public clinic decides to provide a new outreach opportunity.

Visits

Compliance Site Visits

- Occur on an annual basis.
- Ensures compliance with VFA requirements.
- 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

Follow-Up

- 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.
- Types of Follow-Up
    - Additional training
    - Call/email
    - Follow-up visit
    - Submission of requested materials
    - Develop plan for improvement

Consequences of Non-compliance

- Providers and coordinators must adhere to the program requirements detailed in this manual.
- If issues remain unresolved, **ordering privileges may be suspended** or **program participation terminated.**

**Note:

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

Fraud and Abuse

Fraud

- **Definition**: Intentional deception or misrepresentation by a person, knowing that the deception could result in unauthorized benefits to themselves or another person.
- **Includes**: Any act constituting fraud under applicable federal or state laws.
- **Example**:
    - A provider administers federally purchased vaccine to all patients regardless of eligibility.
    - A provider administers federally purchased vaccine to an insured person and then bills the insurance company for the cost of the vaccine.
    - A provider charges more than $19.82 for administration fees to the patient.

Abuse

- **Definition**: Practices inconsistent with sound fiscal, business, or medical practices that result in unnecessary costs, including costs to the immunization program, health insurance companies, patients, or reimbursements for non-medically necessary services.
- **Example**:
    - Vaccine not maintained according to CDC standards, deemed non-viable, resulting in patients needing revaccination.
    - A provider does not accurately account for federally purchased vaccine and cannot determine how many doses were used for eligible patients.

NDHHS Responsibilities

- **Preliminary Investigations**: NDHHS is required to conduct preliminary investigations into potential fraud or abuse.
- **Referrals**: NDHHS must make referrals within ten working days from the initial assessment.
- NDHHS must…
    - Conduct preliminary investigations
    - 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** when an investigation is opened.
- Future participation in the program will depend on the investigation outcome.

Leaving the Program and Voluntary Disenrollment

Leaving the Program

NDHHS strives to work with providers to find resolutions that allow continued participation. However, the agreement may be terminated at any time due to non-compliance with program requirements.

Termination of Agreement

- Termination will occur if:
  - Providers are determined to be abusive or fraudulent.
  - 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 be given the opportunity to discuss issues of non-compliance.

Voluntary Disenrollment

Providers may choose to voluntarily disenroll by taking the following actions:

1. **Submit written notice** of disenrollment.
2. **Submit a final monthly transaction summary.**
3. **Return all current vaccine stock** that has been exposed to a temperature excursion, with manufacturer(s) documentation provided.
4. **Return all vaccine** to NDHHS.
5. **Return any NDHHS equipment**.

Appendix

Quick Reminders

Link to Form

Daily

- Read and record storage unit minimum, maximum, and current 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/VFA/BDH 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.
- Check data logger calibration expiration dates and contact Immunization Program staff if expiration date is due so replacements can be sent out.
- Contact NDHHS at least 90 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 the CDC developed training module, “You Call the Shots: Vaccine Storage and Handling” every year, and as new guidance emerges.
- Review and update the Emergency Vaccine Management Plan, then initial and sign.
- Complete provider re-enrollment in NESIIS.

Per Diem

- Ensure inventory records are updated before placing orders.
- Notify NDHHS Staff whenever there are changes in personnel, clinic location, or hours of operation.
- Calibration testing on data loggers (including non-NDHHS supplied data loggers) should be done every 2 to 3 years or according to the manufacturer’s suggested timeline.

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.
- Read/review the Nebraska Provider Manual.

Vaccine Manufacturer Contact Information

AstraZeneca

- 800-236-9933, Option 1, Option 4
- https://medicalinformation.astrazeneca-us.com/home/prescribing-information/flumist-quadrivalent.html
- VFC Vaccine:
    - FluMist®

GlaxoSmithKline (GSK)

- 866-475-8222, Option 4
- https://www.gskusmedicalaffairs.com/stability-calculator.html
- VFC Vaccine:
    - BEXSERO®, BOOSTRIX®, ENGERIX-B®, FLUARIX®, FLULAVAL®, HAVRIX®, HIBERIX®, INFANRIX®, KINRIX®, MENVEO®, PEDIARIX®, PRIORIX®, ROTARIX®
- VFA Vaccine:
    - BEXSERO®, BOOSTRIX®, ENGERIX-B®, FLUARIX®, FLULAVAL®, HAVRIX®, MENVEO®, PRIORIX®

Merck & Co., Inc.

- 877-829-6372, Option 3
- www.merckmedicalportal.com
- VFC Vaccine:
    - GARDASIL®9, M-M-R®II, PedvaxHIB®, PNEUMOVAX®23, ProQuad®, RECOMBIVAX HB®, RotaTeq®, VARIVAX®, VAQTA®, VAXNEUVANCE®, VAXELIS®
- VFA Vaccine:
    - GARDASIL®9, M-M-R®II, PNEUMOVAX®23, VARIVAX®, VAQTA®

Moderna Inc.

- 1-866-MODERNA (1-866-663-3762). 24 hours, 7 days a week.
- https://www.modernatx.com/
- VFC Vaccine:
    - COVID-19 (Age 6 months through 11 years), SPIKEVAX®
- VFA Vaccine:
    - SPIKEVAX®

Novavax Inc.

- 844-668-2829, Option 2
- https://us-hcp.novavaxcovidvaccine.com/
- VFC Vaccine:
    - NOVAVAX COVID-19 Vaccine
- VFA Vaccine:
    - NOVAVAX COVID-19 Vaccine

Pfizer, Inc.

- 800-438-1985, Option 3
- https://www.pfizermedicalinformation.com/en-us/stability-calculator
- VFC Vaccine:
    - ABRYSVO™, COMIRNATY®, COVID-19 (Age 5 years through 11 years), COVID-19 (Age 6 months through 4 years) PREVNAR 20®, TRUMENBA®
- VFA Vaccine:
    - ABRYSVO™, COMIRNATY®, PREVNAR 20®, TRUMENBA®

Sanofi Pasteur, Inc.

- 800-822-2463
- https://www.sanofimedicalinformation.com/s/stability-calculator
- VFC Vaccine:
    - ACTHIB®, ADACEL®, BEYFORTUS® DAPTACEL®, FLUZONE®, IPOL®, MENQUADFI®, PENTACEL®, QUADRACEL®, TENIVAC®
- VFA Vaccine:
    - ADACEL®, FLUZONE®, IPOL®, MENQUADFI®, QUADRACEL®, TENIVAC®

Seqirus A CSL Company

- 855-358-8966
- https://www.csl.com/patients-public-health/vaccines
- VFC Vaccine:
    - AFLURIA®, FLUCELVAX®
- VFA Vaccine:
    - AFLURIA®, FLUCELVAX®

Web Links

Nebraska-Specific Resources:

- DHHS Immunization Program:
  - http://dhhs.ne.gov/Pages/Immunization.aspx
- 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
- Nebraska Public Clinics:
  - https://mapsengine.google.com/map/viewer?mid=zUmqOvOqNtwA.k6KVBMFyOBSs
- Map of VFC and VFA Providers:
  - https://experience.arcgis.com/experience/9ba258788e0e4bd4b21bf55da893b194/page/Immunization-Program-Providers
- DHHS Reporting Concerns or Complaints:
  - http://dhhs.ne.gov/Pages/complaints.aspx
- Nebraska Legislature Revised Statute 44-311:
  - https://nebraskalegislature.gov/laws/statutes.php?statute=44-311

CDC Resources

- 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:
  - https://www.cdc.gov/vaccines/hcp/imz-schedules/
- CDC Storage and Handling Toolkit:
  - https://www.cdc.gov/vaccines/hcp/storage-handling/
- CDC You Call The Shots:
  - https://www.cdc.gov/immunization-training/hcp/you-call-the-shots/

Immunization Resources:

- Immunization Action Coalition:
  - https://www.immunize.org/
- Immunization Action Coalition Standing Orders Templates for Administering Vaccines:
  - https://www.immunize.org/standing-orders/
- Vaccine Information Statements
  - https://www.immunize.org/vaccines/vis/about-vis/
- National Childhood Vaccine Injury Act of 1986
  - https://www.hrsa.gov/vaccine-compensation/about

Vaccine Adverse Event Reporting:

- Vaccine Adverse Event Reporting System:
  - https://vaers.hhs.gov/index.html
- MedWatch Online Voluntary Reporting Form
  - https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

Once/Twice Daily Refrigerator Temperature Log

Link to Form

2°C to 8°C (36°F to 46°F)

Clinic Name: _____ NESIIS PIN: _____

Month/Year: _____

Day	Init.	Time		Current	Min	Max	In Range? Yes	No	Comments	Day	Init.	Time		Current	Min	Max	In Range? Yes	No	Comments
Ex.	LJ	8:02	am	39.4 F	36°F	46°F				16			am						
	KR	4:45	pm	40.6 F									pm						
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						

Once/Twice Daily Freezer Temperature Log

Link to Form

-15°C to -50°C (5°F to -58°F)

Clinic Name: _____ NESIIS PIN: _____

Month/Year: _____

Day	Init.	Time		Current	Min	Max	In Range? Yes	No	Comments	Day	Init.	Time		Current	Min	Max	In Range? Yes	No	Comments
Ex.	LJ	8:02	am	-20.2 C	-15°C	-50°C				16			am						
	KR	4:45	pm	-22.0 C									pm						
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						

Once/Twice Daily Ultra-Cold Freezer Temperature Log

Link to Form

-60°C to -90°C (-76°F to -130°F)

Clinic Name: _____ NESIIS Pin: _____

Month/Year: _____

Day	Init.	Time		Current	Min	Max	In Range? Yes	In Range? No	Comments	Day	Init.	Time		Current	Min	Max	In Range? Yes	In Range? No	Comments
Ex.	LJ	8:02	am	-80°F	-76°F	-130°F				16			am						
	KR	4:45	pm	-82°F									pm						
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						
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11			am							27			am						
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12			am							28			am						
			pm										pm						
13			am							29			am						
			pm										pm						
14			am							30			am						
			pm										pm						
15			am							31			am						
			pm										pm						

VACCINE BORROWING REPORT

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

Enrolled providers must ensure borrowing VFC/VFA vaccine will not prevent a VFC/VFA-eligible patient from receiving a needed vaccination. Infrequent exchanging between VFC/VFA 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/ VFA vaccine is administered to a non VFC/VFA-eligible patient
- A dose of privately-purchased vaccine is administered to a VFC/VFA-eligible patient

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 (7 Other or 13 Other) is entered in the Vaccine Borrowing Report Table.

Reason for Vaccine Borrowing and Replacement Coding Legend

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

Reason for Borrowing Private Dose	Code
VFC/ VFA vaccine shipment delay (order placed on time/ delay in shipping)	8
VFC/VFA vaccine not useable on arrival (vials broken, temp monitor out of range)	9
Ran out of VFC/VFA vaccine between orders (not due to shipping delays)	10
Short-dated VFC/VFA dose was exchanged with private dose	11
Accidental use of a Private dose for a VFC/VFA eligible patient	12
Other: Describe:	13 Other

WHAT TO DO WITH THIS FORM:

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

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/VFA 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/VFA vaccine dose borrowing and replacement reported on this form has been accurately reported and conducted in conformance with VFC/VFA provisions for such borrowing and further certify that all VFC/VFA doses borrowed during the noted time period have been fully reported on this form.						
Provider Name:			Provider Signature:			Date:

Facility Name:

Pin #:

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Nebraska Immunization Program
Vaccine Restitution Form

Link to 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 VFA adults.

Clinic Name: _____ NESIIS PIN: _____

Vaccine Type	Loss Date	Lot #	NDC #	VFC/ VFA/ BDH	# 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 VFA 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: _____ Date: _____

Provider Signature: _____

Vaccine Transport Log

Link to Form

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			

Circle: VFC or VFA

**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 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 (2o to 8oC [36o to 46oF] for refrigerator; -50o to -15oC [-58° to 5°F] for freezer; (-90oC to -60oC [-130oF to -76oF]) for ultra-cold freezer.
- Inventory of affected vaccines, including (1) lot numbers and (2) whether purchased with public (for example, VFC) or private funds. Document this information on the *Vaccine Storage Emergency Response Worksheet* (see www.immunize.org/catg.d/p3051) or a separate sheet, and 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!)*

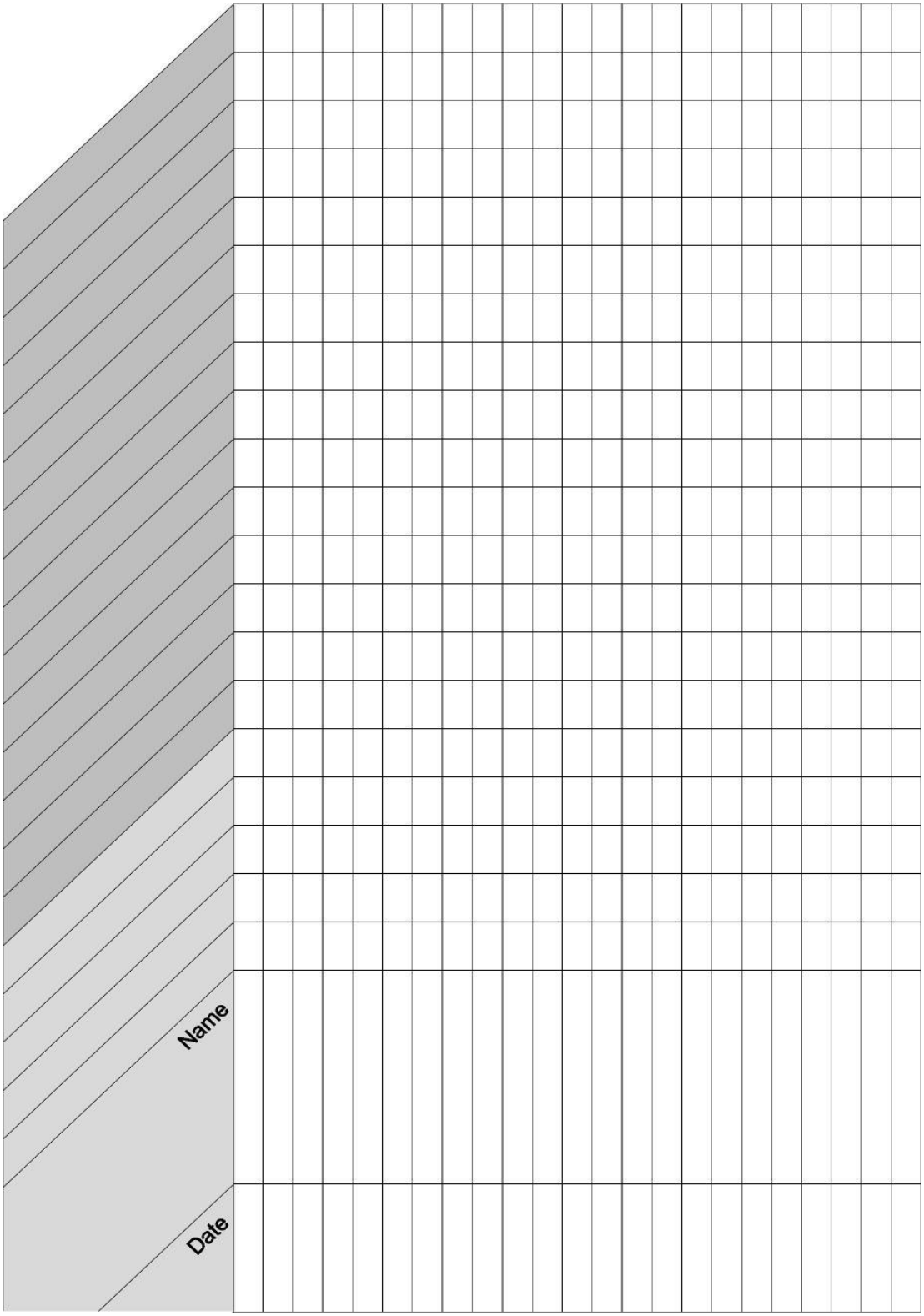
- When were the affected vaccines placed in proper storage conditions? (Note: Do not discard the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state/local health department and/or the manufacturer[s].)
- Who was contacted regarding 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.)

Blank Clinic Listing

Link to Form



Packing Vaccines for Transport During Emergencies (Page 1)

Link to Form

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, and if you can do so safely, follow the emergency packing procedures for refrigerated vaccines.

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.

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 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.**

CS249275-I August 2015

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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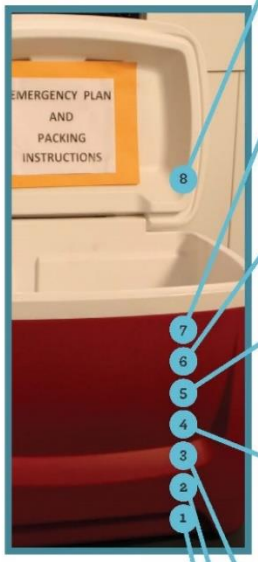
Visit www.cdc.gov/vaccines/Sandl for more information, or your state health department.

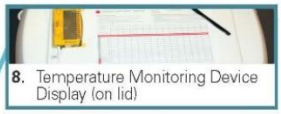
Packing Vaccines for Transport during Emergencies

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.




8. Temperature Monitoring Device Display (on lid)

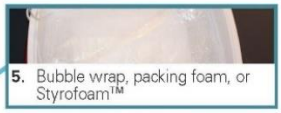
Close lid – Close the lid and attach DDL display and temperature log to the top of the lid.


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

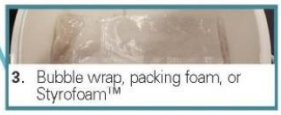
Insulating material – Another sheet of cardboard may be needed to support top layer of water bottles.


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

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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: _____

Signature of back-up vaccine coordinator: _____

Date: _____

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 2025, 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.

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