

**DEPT. OF HEALTH AND HUMAN SERVICES** 

# Birth Dose Hospital Provider Manual

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# Overview of State Programs

## Birth Dose Hospital Program

The State of Nebraska provides the hepatitis B vaccine for the birth dose at no cost to participating birthing hospitals. The vaccine is available for all newborns, regardless of insurance status, to reduce barriers and emphasize the importance of vaccinations to parents. This vaccine is specifically designated for use as the birth dose.

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

Vaccine funding for the BDH program is distributed by the State of Nebraska 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 BDH 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 BDH 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. <a href="http://www.immunize.org/vaccines/vis/about-vis/">http://www.immunize.org/vaccines/vis/about-vis/</a>
- 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

## 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\_Vac cination.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.

<sup>\*\*</sup>Note: More information regarding NCVIA can be found at: <a href="https://www.hrsa.gov/vaccine-compensation/about">https://www.hrsa.gov/vaccine-compensation/about</a>

# Clinics, Roles, and Responsibilities

#### Clinics

## **Enrolled Clinics**

An enrolled hospital is defined as one actively participating in the BDH program and meeting the following criteria:

- Successfully completed provider re-enrollment
- Submitted the completed BDH Questionnaire Form

## **Eligible Clinics:**

Must be a birthing hospital located in Nebraska.

## 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.

## Key Characteristics:

- Serve healthy clients without contraindications
- Have the capacity to serve all eligible patients
- Must accommodate walk-in patients.

## 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.

## BDH Coordinators and Back-Up Coordinators

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

## BDH 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:
  - o Perform monthly vaccine counts:
    - Complete accurate physical counts of BDH vaccines on the last day of each month.
  - O 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:

- BDH 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

## Provider Enrollment Form

All providers must complete the annual re-enrollment process:

- Submit a form indicating the number of births per year.
- Agree to comply with enrollment requirements.
- Ensure the enrollment form is signed annually by a person with prescribing authority.
- Notify the Nebraska Immunization Program promptly if there is a change in the designated contact person or NESIIS user.
- Complete the Annual Questionnaire no later than March 31, 2025.

Re-enrollment forms will be distributed electronically in late January/ early February and must be submitted by February 28, 2025.

# Eligibility for Vaccine and Screening

## Screening Eligibility

The Immunization Program requires patient eligibility screening to account for doses provided by state funding.

State-supplied hepatitis B vaccines may be administered to all infants; however:

- Hospitals must screen each infant for eligibility
- Eligibility criteria must be documented on the date of service.

## **Fees and Donations**

#### Fees

Prohibition on Vaccine Charges: Hospitals cannot charge for the cost of BDH vaccines.

- Administration Fee
  - Hospitals may charge an administration fee of up to \$19.82 per vaccination.
  - Hospitals 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**

- Hospitals 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 BDH 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:
  - o 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

- State vaccines 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 <u>temperature logs</u> 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.
- Calibration testing on non-should be done every 2 to 3 years or according to the manufacturer's suggested timeline.
- Place probes in the central section of 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. Temperature excursions may also be called "cold chain failures". 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**

- Contact the Manufacturer:
  - a. Call the <u>vaccine manufacturer</u> to determine vaccine's viability.
  - Request written documentation from the manufacturer regarding the vaccine's status.
- 5. Contact NDHHS Immunization Program Staff
  - 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.

# 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 BDH 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 BDH Enrolled Providers

NDHHS requires that all BDH-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 BDH vaccine.
- Monthly vaccine transaction summary reports.
- Annual re-enrollment for BDH participation.

#### NESIIS Recommendations for BDH Enrolled Providers

NDHHS highly recommends that all BDH-enrolled providers:

Document private vaccine administration records accurately and promptly

## **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:** maintain enough vaccine for one to two months.
- Ensure ordered quantities reflect the populations served.
- 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:
  - o Orders marked "approved" in NESIIS are not received within:
    - 5 days for HepB vaccine

## 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 autopopulate 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 <u>temperature excursion</u> <u>guidelines</u>.
- 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 <a href="mailto:Andrew.d.reinhard@nebraska.gov">Andrew.d.reinhard@nebraska.gov</a> 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 BDH 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.
- o Ensure this will not impact a VFC eligible child's ability to receive vaccine.

## Required Reports

- Transaction Summary
  - Actual inventory and vaccine accountability must be tracked in NESIIS.
  - Submit by the 15<sup>th</sup> of the following month.
- Doses Wasted Summary (Vaccine Waste Report)
  - Submit with Transaction Summary, if applicable.
- 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.
  - o BDH 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 <a href="mailto:dhhs.immunization@nebraska.gov">dhhs.immunization@nebraska.gov</a> 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 <u>email:</u>
     <u>DHHS.Immunization@nebraska.gov.</u>
- 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 <u>at room temperature</u> <u>and packaged to prevent breakage</u>.
- 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.

## **Restitution Policy**

The restitution policy refers to the replacement of BDH 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.
  - o 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).
  - o Include what to do in event of a power outage or equipment failure.
- The plan must be reviewed, dated, and initialed annually.

## Site Review

The Nebraska Immunization Program staff will conduct an annual site review by sending a questionnaire during the re-enrollment process. This questionnaire aims to evaluate vaccine management practices and compliance with state program requirements.

## The review will include:

- Questions about procedures for vaccine management and the use of Vaccine Information Statements (VIS).
- Assessment of storage equipment and temperature monitoring.
- Review of monthly vaccine accountability reports, with any concerns addressed by program staff.

## 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.
  - o 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.

#### \*\*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

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## **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
- <a href="https://medicalinformation.astrazeneca-us.com/home/prescribing-information/flumist-quadrivalent.html">https://medicalinformation.astrazeneca-us.com/home/prescribing-information/flumist-quadrivalent.html</a>
- 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:
  - o 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:
  - o 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 Public Clinics:
  - <a href="https://mapsengine.google.com/map/viewer?mid=zUmqOvOqNtwA.k6KVBMF">https://mapsengine.google.com/map/viewer?mid=zUmqOvOqNtwA.k6KVBMF</a> yOBSs
- Map of VFC and VFA Providers:
  - o <a href="https://experience.arcgis.com/experience/9ba258788e0e4bd4b21bf55da893b">https://experience.arcgis.com/experience/9ba258788e0e4bd4b21bf55da893b</a> 194/page/Immunization-Program-Providers/
- DHHS Reporting Concerns or Complaints:
  - o 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:
  - o 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:
  - o <a href="https://www.immunize.org/">https://www.immunize.org/</a>
- 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:
  - o <a href="https://vaers.hhs.gov/index.html">https://vaers.hhs.gov/index.html</a>

# 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		

							Jin Ra	nge?									In Da	0002	
Day	Init.	Tim	e	Current	Min	Max/	Yes	No	Comments	Day	lnit.	Tim	e	Current	Min	Max	Yes	No	Comments
Ex.	П			39.4 F	36°F	46°É				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						1
14			am							30			am						
П			pm						l				pm						1
15			am							31		$\overline{}$	am						
			pm										pm						1

# 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	lnit.	Tim	ie	Current	Min	Max/	In Ra Yes	nge? No	Comments	Day	Init.	Time		Current	Min	Max	In Ra Yes	nge? No	Comments
Ex.	IJ	8:02		-20.2 C		-50°Ć				16		a	m						
	KR	4:45	pm	-22.0 C								р	m						
1			am							17		a	m						
			pm									р	m						
2			am							18		a	m						
			pm									р	m						
3			am							19		а	m						
			pm									р	m						
4			am							20		а	m						
			pm									р	m						
5			am							21		a	m						
			pm									р	m						1
6			am							22		a	m						
			pm									р	m						1
7			am							23		а	m						
			pm									р	m						
8			am							24		а	m						
			pm									р	m						
9			am							25		a	m						
			pm									р	m						
10			am							26		a	m						
			pm									р	m						
11			am							27		a	m						
			pm									р	m						
12			am							28		а	m						
			pm									р	m						
13			am							29		a	m						
			pm									р	m						
14			am							30		а	m						
			pm									р	m						
15			am							31		а	m						
			pm									р	m						

# 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.	Tim	e	Current	Min	Max/	In Ra Yes	nge? No	Comments	Day	Init.	Time		Current	Min	Max	In Ra Yes	nge? No	Comments
Ex.	Ш	8:02	am		-76°F	-130°F				16		a	m						
	KR	4:45	pm	-82°F					1	П		р	m						1
1			am							17		a	m						
			pm						1	$\Box$		р	m						1
2			am							18		а	m						
			pm						1	П		р	m						1
3			am							19		а	m						
			pm						1			Р	m						1
4			am							20		а	m						
			pm						1	П		Р	m						1
5			am							21		а	m						
			pm						1			Р	m						1
6			am							22		a	m						
			pm						1	П		р	m						1
7			am							23		a	m						
			pm						1	П		р	m						1
8			am							24		a	m						
			pm						1			Р	m						ĺ
9			am							25		a	m						
			pm						1	П		Р	m						1
10			am							26		a	m						
			pm						1			р	m						1
11			am							27		a	m						
			pm						1			р	m						1
12			am							28		a	m						
			pm						1			р	m						1
13			am							29		a	m						
			pm						1			р	m						1
14			am							30		a	m						
			pm						1			р	m						1
15			am							31		_	m						
			pm						1			р	m						1



**DEPT. OF HEALTH AND HUMAN SERVICES** 

# 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

Clinic Name: _			NESI	S PIN:	-	
Vaccine Type	Loss Date	Lot #	NDC #	VFC/VFA/BDH	# Doses Lost	Date Replaced
applicable fed and replaced i	eral and state in conformance	laws, that V e with state	FC and/or VI provisions fo	claims Act (31 U.S.C FA vaccines reporte r restitution, and that ced according to this	d on this form at all doses los	are accurate
Provider Name	e:			_ Date:		
D 11 01						

# Vaccine Storage Troubleshooting Log

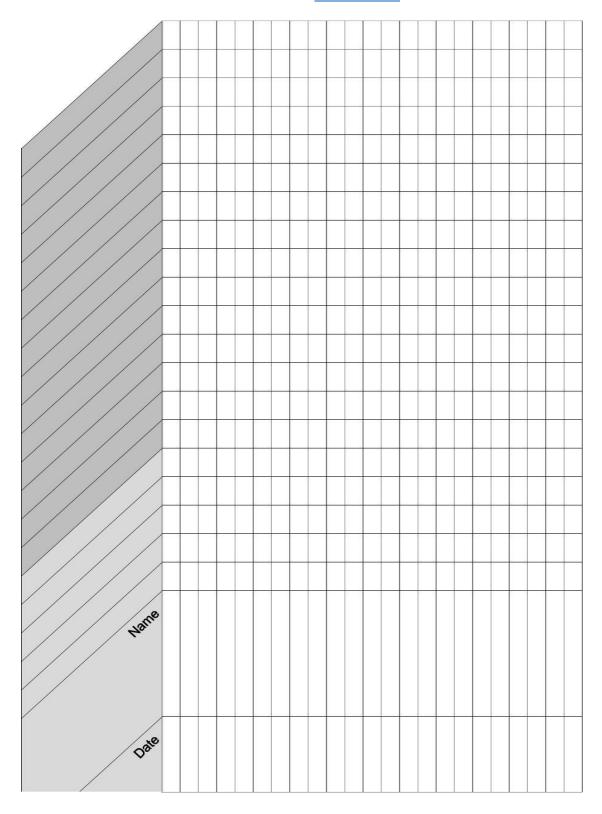
Link to Form

Nebraska Provider Manual 202

see Description of Event Delow.	Date & Time of Event Storage Unit Temperature ff multiple, related cocurred. at the time the problem was discovered	Femperature	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.  General description (i.e., what happened?)  Estimated length of time between event and last documented reading of storage temperature in acceptable (-90oc to -60oc [-130oF to -750F]) for ultra-cold freezer.  (-90oc to -60oc [-130oF to -750F]) for ultra-cold freezer.  Inventory of affected vaccines, including (1) for numbers and (2) whether purchased with public (for examp (see www.immunize.org/catg.d/p3051) or a separate sheet, and maintain the inventory with this troubless to At the time of the event, what elie was in the actorage unit? For example, were three water bottles in the rapid profit or 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.	fiple, related events occurred, pened?) event and last documented reac [5] for ultra-cold freezer. Luding [1] lot numbers and [2] wi 3051, or a separate sheet, and n ewes in the storage unit? For example and storage problems with this feel might be relevant to unders	escription of Event (If multiple, related events occurred, list each date, time, and length of time out of storage. Seneral description (i.e., what happened?) stimated length of time between event and last documented reading of storage temperature in acceptable range (20 to 80 stimated length of time between event and last documented reading of storage temperature in acceptable range (20 to 80 storage) to occ [-13005 to -7505]) for ultra-cold freezer.  Inventory of affected vaccines, including (I) for numbers and (2) whether purchased with public (for example, VFC) or privat (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 bordies in the refrigerator and/or hird to this event, have there been any storage problems with this unit and/or with the affected vaccine?	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 (20 to 80C [300 to 460F] for refrigerator; -500 to -150C [-58° to 5°F] for freezer; (-900C to -500E] for Journal of freezer; (-900C to -500E] for ultra-cold freezer; and maintain the inventory with this troubleshooting record.  • Inventory of affected vaccines, including (1) for 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 tricoubleshooting record.  • At the kinne of the event, where the was the storage problems with this unit and/or with the affected vaccine?  • Prior to this event, have there been any storage problems with and/or with the affected vaccine?  • Include any other information you feel might be relevant to understanding the event.	erator; -50o to -15oC [-58° to 5°F] for freezer; formation on the Vaccine Storage Emergency Re he freezer?	sponse Worksheet
Action Taken (Document thoroughly. This infor • When were the effected vaccines placed in proper sta Incal health denaturement and or the manufacturents	roughly. This information is cri placed in proper storage condition	(Document thoroughly. This information is critical to determining whether the vaccine might still be viable!) the traces placed in exposed vaccine in property that and for the manufacturates.	Action Taken (Document thoroughly. This information is critical to determining whether the vaccine might still be viable!)  When we the affected vaccines in proper storage conditions? (Note: Do not discuss with your state)  Note: the affected vaccine the present of the properties of the vaccine. Store exposed vaccine in proper conditions and label it "do not use" until after you can discuss with your state)	and label it "do not use" until after you can disc	cuss with your sta
local neath repartment almoy or the manuaccuerlable, supervisor, state/local health do  • Mho was contacted regarding the incident? for example, supervisor, state/local health do  • IMPORTANT: What did you do to prevent a similar problem from occurring in the future?	incident? (For example, superviti prevent a similar problem from i	supervisor, state/local health department, manufacturer—list all.) am from occurring in the future?	. manufacturer—list all.)		
Results  What happened to the vaccine? Was it able to be used? If		s it returned to the distributor? (N	not, was it returned to the distributor? (Note: For public-purchase vaccine, follow your state/local health department instructions for vaccine disposition.)	e/local health department instructions for vacc	ine 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 upto-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.

## 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.



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



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

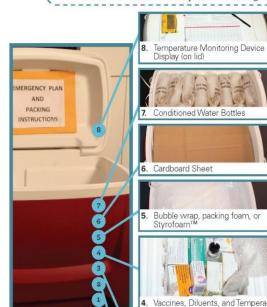
# Packing Vaccines for Transport During Emergencies (Page 2)

# 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.



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

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

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

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

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.

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

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

**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.



1. Conditioned Water Bottles

ture Monitoring Device Probe

# 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

# Emergency Vaccine Management Plan



Provider Site Name:
Provider Site Address:
Primary Vaccine Coordinator:
Emergency Phone Number:
Back-up Vaccine Coordinator:
Emergency Phone Number:
<ul> <li>In the event of a power failure or storage unit failure, vaccine will need to be moved to a pre-designated location.</li> <li>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.</li> <li>Keep a copy of this Emergency Vaccine Management Plan along with a copy of the Packing Vaccines for Transport during Emergencies.</li> <li>All refrigerated vaccine must be kept between 36°F/2°C and 46°F/8°C.</li> <li>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.</li> <li>Once vaccine is transported to alternate refrigeration and freezer units, keep them at the proper temperatures.</li> </ul>
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:

Nebraska Provider Manual 2025

# Acknowledgement of Policies and Signature Page

## 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.

NEBRASKA
Good Life, Great Mission.

**DEPT. OF HEALTH AND HUMAN SERVICES** 

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