

# NEBRASKA

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DEPT. OF HEALTH AND HUMAN SERVICES

# COVID-19 Vaccine Provider Manual

NDHHS Immunization Program  
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## Overview of Programs

### *COVID-19 Program*

The COVID-19 Vaccine Program is a federally funded program that provides vaccine, at no cost, to people throughout the United States. The Centers for Disease Control and Prevention (CDC) has determined that vaccination is an important tool to help stop the COVID-19 pandemic and up until recently, ACIP recommendations for phased allocation have provided guidance for federal, state, and local jurisdictions while vaccine supply was limited. However, given substantial increases in the supply of vaccines, programs are now transitioning beyond priority groups and allow broad eligibility for receipt of COVID-19 vaccines consistent with applicable Emergency Use Authorizations (EUA). CDC buys vaccine and distributes them to grantees, such as NDHHS, which in turn distributes them at no charge to private physicians' offices, public health clinics, hospitals, pharmacies, and others enrolled as COVID-19 providers.

### *NDHHS Immunization Program*

Vaccine funding for the COVID-19 program is distributed by CDC to the NDHHS Immunization Program. NDHHS supplies vaccine at no cost to enrolled providers, and is responsible for ensuring enrolled providers adhere to program requirements, are good stewards of resources given, and are ensuring vaccine viability at all times.

### *Nebraska State Immunization Information System*

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

### *Centers for Disease Control and Prevention*

The Centers for Disease Control and Prevention (CDC) is a federal agency that conducts and supports health promotion, prevention, and preparedness activities in the United States, with the goal of improving overall public health. The CDC works with partners at the local, state, and national levels to monitor and prevent disease outbreaks (including bioterrorism), implement disease prevention strategies, and maintain national health statistics. The agency also leads public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats. The CDC focuses on the following five strategic

areas: increasing support to local and state health departments, improving global health, decreasing leading causes of death, strengthening surveillance and epidemiology, and reforming health policies.

#### *Advisory Committee on Immunization Practices*

The Advisory Committee on Immunization Practices (ACIP) is comprised of medical and public health experts who develop recommendations on the use of vaccine in the civilian population of the United States. The recommendations stand as public health guidance for the safe use of vaccine and related biological products. All COVID-19 providers must comply with immunization schedules, dosages, and contraindications established by ACIP.

#### *Vaccine Adverse Event Reporting System*

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

## Requirements and Recommendations

Providers must...

- Provide current EUA fact sheets to patients prior to vaccine administration
- Complete and/or update vaccination record card
- Provide V-safe information to vaccine recipients or caregivers each time a vaccine is administered
- Report core data elements to NESIIS within 24 hours of administration
- Rectify inventory daily including:
  - Spoiled, wasted, and expired vaccines
  - Redistribution (transfer)
- Report temperature excursions to NDHHS Immunization Program immediately
- Assure all staff who receive, handle, manage, prepare, or administer COVID-19 vaccine are trained on and have documentation of the training on specific storage, handling, preparation, and administration requirements for each vaccine product used
- Report vaccine inventory daily to Vaccines.gov and NESIIS
- Have a plan for proper waste disposal
- Vaccine documentation (COVID-19 vaccination card and or patient record) must include the following:
  - Patient demographics such as name, DOB, etc.
  - Vaccine name
  - Date vaccine was administered
  - Vaccine manufacturer
  - Lot number
  - Clinic or facility address
  - Name and title of individual administering vaccination
- Report the following items to Vaccine Adverse Event Reporting System (VAERS)
  - Vaccine administration errors whether or not associated with an adverse event,
  - Serious adverse events\* (irrespective of attribution to vaccination)
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children
  - Cases of COVID-19 that result in hospitalization or death

\*\*Please note Healthcare providers are encouraged to report to VAERS any additional clinically significant adverse events following vaccination, even if providers are not sure if vaccination caused the event.

## Records Retention

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

This includes...

- Vaccine administration verification
- Vaccine packing slips, borrowing reports, monthly transaction summaries, and waste reports
- Temperature logs

## Fees and Billing

- Providers cannot
  - Charge for the cost of vaccine
  - Bill uninsured or underinsured individuals
  - Bill patient for co-pay or balance
  - Accept a donation
- Providers can bill for administration fee
  - Insurance
  - Medicare and Medicaid
  - Seek reimbursement through HRSA

## Storage Units and Vaccine Storage

Pfizer:

<https://www.cdc.gov/vaccines/COVID-19/info-by-product/pfizer/downloads/storage-summary.pdf>

Moderna:

<https://www.cdc.gov/vaccines/COVID-19/info-by-product/moderna/downloads/storage-summary.pdf>

Janssen/Johnson and Johnson:

<https://www.cdc.gov/vaccines/COVID-19/info-by-product/moderna/downloads/storage-summary.pdf>

CDC recommends the following storage unit types in order of preference:

- Pharmaceutical-grade stand alone or combination
- Household/commercial stand-alone unit
- Household/commercial combination unit, using the refrigerator section only

**\*\*Note:** No dormitory-style or bar-refrigerators under any circumstances. Consult the assigned community health nurse prior to purchase.

### Safeguarding the Electrical Supply

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

### Storing Vaccine

- Shorter expiration dates must be kept in front to be utilized first.
- Short dated vaccine must be reported to NDHHS at least three to six months in advance.
- Providers must contact NDHHS regarding vaccine that won't be used prior to expiration.
- Immediately remove expired or wasted vaccine from storage units.
- Store vaccine away from cold air vents, drawers, floors, and walls.

- Allow enough space for proper air circulation around vaccines.
- If using containers to organize vaccines, use open and ventilated types.
- Keep vaccines in original boxes, with lids intact, until administration to protect from light.
- Store diluents according to manufacturer's instructions.

## Temperature Monitoring and Devices

### Vaccine Storage

- Vaccine must be stored at appropriate temperatures from the time of manufacture to the time of administration.
  - Refrigerators 2°C to 8°C (36°F to 46°F)
  - Freezers -15°C to -50°C (5°F to -58°F)
  - Ultra-cold freezers -60°C to -80°C (-76°F to -112°F)
- Unit temperatures must be documented daily each day the facility is open. Electronic temperature documentation is allowable. Providers can also utilize temperature logs provided in the appendix to record the following:
  - Date
  - Time
  - Temperature
  - Initials of staff member assessing temperatures

**\*\*Note:** Backup temperature monitoring device is encouraged.

CDC recommends the following temperature monitoring devices in order of preference:

- Digital data loggers
- Min/Max thermometer
- Digital thermometer

**\*\*Note:** Place probes in the central section of storage units where vaccine is located.

## Temperature Excursions

A temperature excursion is defined as any time temperatures go out of acceptable ranges, even by one tenth of a degree. The protocol below must be initiated for each temperature excursion:

- Mark the vaccine “DO NOT USE - AWAITING GUIDANCE”, and store at appropriate temperatures.
- Move to another refrigerator, freezer, or cooler per the emergency vaccine protocol.
- Call the assigned community health nurse or NDHHS. If after hours, proceed to the next step.
- Call the vaccine manufacturer to determine vaccine viability. Clinic staff must request manufacturer documentation be sent regarding vaccine viability.
- Document excursion details, action steps taken, and outcome. Email or fax documentation, along with manufacturer information, to the assigned community health nurse and retain a copy at the clinic.

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

\*\*Note: Place probes in the central section of storage units where vaccine is located

## Ordering and Receiving Vaccine

### Ordering Vaccine

- All vaccine orders are placed in NESIIS.
  - Providers must submit a completed COVID-19 Provider Agreement to DHHS Immunization Program.
  - At this time, approved providers must work with Local Health Departments to receive COVID-19 vaccine allocation through NDHHS.
  - In addition, allocations will be contingent on appropriate storage and vaccine monitoring. Electronic temperature documentation is allowable.
- Clinics should ensure that quantities ordered are reflective of populations served.
- Clinics are allowed to be depots for COVID-19 vaccines. A depot is defined as a site that redistributes vaccines to more than one other location. If COVID-19 vaccine is transferred to another facility, the receiving facility must be enrolled in the COVID-19 program.
- The CDC requires NDHHS to monitor expiration dates to ensure appropriate vaccine use. If excessive waste activity is noted, orders can be placed on hold until the clinic has been contacted for clarification and or technical support.
- Vaccine ordering privileges may be suspended for non-compliance with NDHHS requirements.

## Receiving Vaccine

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

COVID-19 vaccination providers must report any issues with supplies contained in the ancillary kits that are shipped with their federal vaccine orders. The reporting process has four steps to ensure enough information is gathered so trends in packaging and shipping problems can be identified. Please photograph any identified deficiencies to support the reported deficiencies and possible investigation.

- Report deficiencies to McKesson directly; the customer service desk is charged with responding to problems and identifying trends.

McKesson Customer Service

Phone #: 833-272-6634

Email: SNSSupport@McKesson.com

- Report deficiencies to the DHHS Immunization Program to help identify trends in problem equipment.
- If a deficiency leads to an error or injury during vaccine administration, include the event in the report to VAERS.
- Because syringes and needles are classified as medical devices, providers are encouraged to report any deficiencies by completing US Food and Drug Administration (FDA) form 3500:
  - Per the FDA guidelines: If the case report involves more than one (1) faulty medical device, please prepare a complete copy of Form FDA 3500 that identifies one device and attach an additional copy of Form FDA 3500, with only Section E filled in, for each additional device. Be prepared to provide photos, lot number, order number, date ordered, and date received when filing a report.

## Clinic Roles and Responsibilities

It is a requirement that all clinics have a designated primary and back-up COVID-19 vaccine coordinator. Both roles must be able to assume oversight of all responsibilities.

Primary and back-up vaccine coordinators must...

- Reviewing and monitoring temperatures of storage units daily.
- Rotate stock to assure oldest vaccine is used first.
- Download data loggers weekly, if applicable, and review for temperature trends.
- Perform accurate physical counts of COVID-19 vaccine daily.
- Adjust inventory in NESIIS daily.
- Immediately report personnel or clinic changes to NDHHS, such as coordinator, address, phone number, shipping hours, and/or medical director.

Required Reporting

- Record waste in NESIIS.
- COVID-19 Provider Agreement and Redistribution Agreements per CDC requirement.
- Contact NDHHS at least ninety days prior to vaccine expiration dates, or if quantities on hand exceed populations served.

## Emergency Vaccine Management Plan and Transportation

Providers must have an Emergency Vaccine Management Plan (EVMP)

- The plan must be written (template in the appendix).
- Review, date and initial annually.

Transporting Vaccine

- Any COVID-19 vaccine provider transport vaccine from main clinic to provide outreach to an off-site location must:
  - Pack only enough vaccine needed for the day.
  - Stored vaccine in containers with the functionality to maintain appropriate temperatures.
  - Ensure digital data logger is used to monitor and document temperatures hourly while in transport.

## Nebraska State Immunization Information System – NESIIS

NDHHS requires all COVID-19 vaccine enrolled providers use NESIIS for:

- Entering administered vaccines into patient records.
- Generating required reports.
- Managing inventory.

**\*\*Note:** Any patient presenting for immunizations under the COVID-19 vaccine programs must have immunization entered into NESIIS, unless the patient and/or the parent or guardian “opts-out.” The NESIIS Opt-out Form must be completed, signed, and submitted to NDHHS.

NESIIS provides...

- Vaccine transfers from one enrolled clinic to another enrolled clinic to reduce waste, and encourage use before expiration.
- Patient privacy and confidentiality.
- Support for clinical decision-making.
- Reminders for families when immunizations are due, or have been missed.
- Vaccine may be reported by using:
  - Real time data exchange,
  - Flat files,
  - Manual data entry , or
  - Vaccine Registration and Administration System (VRAS).

**\*\*Note:** All enrolled COVID-19 providers will receive NESIIS training and ongoing technical support by the NDHHS NESIIS staff. Questions should be directed to the assigned community nurse, or refer to NESIIS webpages.

## Visits

### Compliance Site Visits

NDHHS staff will periodically conduct on-site compliance site visits with enrolled providers.

- Ensures compliance with CDC COVID-19 clinic requirements.
- Clinics must have COVID-19 contact personnel present, and billing staff may be called upon.
- Must have COVID-19 vaccine in stock.
- Will include assessment of the following:
  - Verification of demographics and contact information
  - Billing practices
  - Vaccine and supply accountability
  - COVID-19 vaccine documentation in patient medical record

- Storage and handling practices
- Observation of COVID-19 vaccine administration
- Technical assistance will be provided, as needed
- If issues are identified, the assigned NDHHS staff will develop a corrective action plan.
  - Clinics must address any issues of non-compliance.
  - Timeframes may vary.

Follow-up types can include:

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

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

## Fraud and Abuse

### Fraud

- Is the intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state laws.

### Abuse

- Includes provider practices that are inconsistent with sound fiscal, business, or medical practices, and results in an unnecessary cost to the CDC COVID-19 Vaccination Program (and/or including actions that result in an unnecessary cost to the immunization program, a health insurance company, or patient), or in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care. Abuse also includes, but is not limited to, recipient practices that result in unnecessary cost to the CDC COVID-19 Vaccination program, diversion of COVID-19 vaccine, prohibited direct or indirect inducements to the provider or another part, and misuse of data collected in the course of participation in the DCDC COVIW-19 Vaccination Program.

#### Fraud and Abuse Examples\*

- Failing to comply with any part of the Provider Agreement
- Providing COVID-19 vaccine to non-eligible persons
- Selling or otherwise misdirecting COVID-19 vaccine
- Billing a patient or third party for COVID-19 vaccine, constituent products, or ancillary supplies
- Collecting donations for COVID-19 vaccine, constituent products, or ancillary supplies
- Intentional or excessive waste of COVID-19 vaccine
- Denying eligible persons COVID-19 vaccine
- Reporting falsified COVID-19 vaccine administration or inventory data
- Failing to maintain COVID-19 Vaccination Program-related records for a minimum of three years
- Failing to properly store and handle COVID-19 vaccine
- Mixing more or less than the authorized volume of diluent with its respective COVID-19 vaccine
- Administering more or less than the authorized dosage of a COVID-19 vaccine

*\*This list provides examples and should not be considered comprehensive.*

#### NDHHS must...

- Conduct preliminary investigations and refer all suspected cases of fraud and abuse directly to the Office of the Inspector General
- Follow the federal regulatory scheme at 42 CFR §455.15 and 42 CFR §455.23
- Direct unanswered questions and concerns to: [Medicaid Integrity Program@cms.hhs.gov](mailto:Medicaid_Integrity_Program@cms.hhs.gov)
- Make referrals within ten working days from the initial assessment

Referrals should be made within 10 working days from the notification of potential fraud and abuse, and the following information must be included:

- Contact information for the immunization program manager or designee
- Provider name, Medicaid provider ID (if known), address, and provider type (e.g., private provider)
- Source of complaint (e.g., provider office, awardee staff, anonymous caller)
- Date NDHHS received information that the provider might be putting the CDC COVID-19 Vaccination Program at risk of loss due to fraud and abuse
- Specific, detailed description of suspected misconduct, persons involved, contact information (if available), and quantity of vaccine, constituent products, or ancillary supplies involved, when available
- All available communication between NDHHS and the provider concerning the suspected misconduct, including the signed Provider Agreement, education given to the provider as a result of previous compliance problems, and any general provider communication about program implementation

NDHHS will make a referral to any other state agency as mandated by state law and send a copy to the CDC.

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

## Leaving the Program

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

Termination will commence...

- If a provider is determined to be abusive or fraudulent.
- If a vaccine order has not been placed within the past twelve months.

Prior to termination...

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

Voluntary Disenrollment

- Providers must submit written notice.

Any NDHHS equipment must be returned.

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## Quick Reminders

### Daily

- Read and record storage unit temperatures, time, date and initial at least once per day when the clinic opens. Electrical temperature documentation is allowable.
- Temperature excursions must be handled immediately to protect vaccine.
- Reconcile manual and electronic inventory.

### Weekly

- If applicable, download data loggers.
- Review and assess reports for temperature trends on storage units.
- Check vaccine expiration dates and rotate stock, placing vaccine expiring soonest up front.

### Annually

- Review, date and initial emergency plan.
- Review manual, update acknowledgement of Policies and Signature page.

### On Going

- Providers should track, maintain documentation, and monitor the status of the training received by each vaccination staff.

## Provider Resources

- DHHS Immunization Program:  
<http://dhhs.ne.gov/Pages/Immunization.aspx>
- DHHS Reporting Concerns or Complaints:  
<http://dhhs.ne.gov/Pages/complaints.aspx>
- Nebraska State Immunization Information System:  
<http://dhhs.ne.gov/Pages/Nebraska-Immunization-Information-System.aspx>
- Immunization Action Coalition:  
<https://www.immunize.org/>
- Immunization Action Coalition Standing Orders Templates for Administering Vaccines:  
<https://www.immunize.org/standing-orders/>
- CDC COVID-19 Landing Page:  
For providers:  
<https://www.cdc.gov/vaccines/COVID-19/index.html>  
For patients:  
<https://www.cdc.gov/vaccines/COVID-19/index.html>
- Packing Vaccines for Transport during Emergencies:  
<https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf>
- CDC Storage and Handling Toolkit:  
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>

## Staff Training

### Required

NESIIS

[Dhhs.nesiis@nebraska.gov](mailto:Dhhs.nesiis@nebraska.gov)

You Call the Shots – Storage and Handling  
New Vaccination Provider Trainings:

<https://www.cdc.gov/vaccines/COVID-19/downloads/Vaccinator-Resource-provider-training-508.pdf>

### Suggested Training

Vaccination Training Programs and Reference Materials for Healthcare Professionals:

<https://www.cdc.gov/vaccines/COVID-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf>

Vaccine Administration Competencies Assessment Form:

<https://www.cdc.gov/vaccines/COVID-19/downloads/competencies-screening-checklist.pdf>

Training and Education Resources for Healthcare Providers:

<https://www.cdc.gov/vaccines/COVID-19/training-education/index.html>

CDC You Call The Shots, all modules:

<https://www.cdc.gov/vaccines/ed/youcalltheshots.html>

### Storage and Handling

Quick Reference Guide for Health Professionals:

[https://www.cdc.gov/vaccines/COVID-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf?ACSTrackingID=USCDC\\_2120-DM53231&ACSTrackingLabel=New%20Reference%20Tools%20Are%20Available%21&deliveryName=USCDC\\_2120-DM53231](https://www.cdc.gov/vaccines/COVID-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf?ACSTrackingID=USCDC_2120-DM53231&ACSTrackingLabel=New%20Reference%20Tools%20Are%20Available%21&deliveryName=USCDC_2120-DM53231)

## Temperature Logs

Refrigerator Vaccine Temperature Log: Celsius

<https://www.cdc.gov/vaccines/COVID-19/downloads/refrigerator-storage-logger-celsius.pdf>

Refrigerator Vaccine Temperature Log: Fahrenheit

<https://www.cdc.gov/vaccines/COVID-19/downloads/refrigerator-storage-logger-fahrenheit.pdf>

Vaccine Storage Troubleshooting Record:

<https://immunize.org/catg.d/p3041.pdf>

## Vaccine Administration Data

Healthcare Provider EUA Fact Sheets:

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-COVID-19/COVID-19-vaccines>

EUA Fact Sheets for Recipients and Caregivers:

<https://www.cdc.gov/vaccines/COVID-19/eua/index.html>

V-Safe information Sheets

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html>

Summary Document for Interim Clinical Considerations:

<https://www.cdc.gov/vaccines/COVID-19/downloads/summary-interim-clinical-considerations.pdf>

Core Vaccine Administration Data Elements:

<https://www.cdc.gov/vaccines/COVID-19/reporting/downloads/appendix-C-vaccine-data-requirements.xlsx>

## Adverse Events

Managing Anaphylaxis:

<https://www.cdc.gov/vaccines/COVID-19/clinical-considerations/managing-anaphylaxis.html>

VAERS Form:

<http://vaers.hhs.gov/esub/index.jsp>

COVID-19 Vaccine Administration Errors and Deviations:

<https://www.cdc.gov/vaccines/COVID-19/downloads/covid19-vaccine-errors-deviations.pdf>

Vaccine Administration: Preventing Vaccine Administration Errors:

<https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-preventing-errors.pdf>

## Pfizer Vaccine Manufacturer Contact Information

- Pfizer, Inc.
  - 800-438-1985, Option 3
  - <https://www.pfizerpro.com/>
  - <https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-COVID-19-vaccine>
  - [COVID-19 Vaccine](#)
  
- Pfizer-BioNTech Temperature Log: Celsius
- <https://www.cdc.gov/vaccines/COVID-19/info-by-product/pfizer/downloads/temp-log-ultra-cold-storage-celsius.pdf>
  
- Pfizer-BioNTech Temperature Log: Fahrenheit
- <https://www.cdc.gov/vaccines/COVID-19/info-by-product/pfizer/downloads/temp-log-ultra-cold-storage-fahrenheit.pdf>
  
- Pfizer Thermal Shippers:
- <https://www.cdc.gov/vaccines/COVID-19/info-by-product/pfizer/downloads/storage-summary.pdf>
- 
- COVID-19 Vaccine Shipper and Logger Return Instructions
- <https://contlogo.s3.eu-central-1.amazonaws.com/Pfizer/Thermal%20Shipper%20Return%20Guidance.pdf>
  
- Tracking Use-By Times:
- Pfizer-BioNTech BUD Tracking Labels:
- <https://www.cdc.gov/vaccines/COVID-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf>

## Moderna Manufacturer Contact Information

- [Moderna Inc.](#)
  - 1-866-MODERNA (1-866-663-3762). 24 hours, 7 days a week.
  - [Moderna, Inc. | Home \(modernatx.com\)](#)
  - COVID-19 Vaccine
  - <https://www.cdc.gov/vaccines/COVID-19/info-by-product/moderna/downloads/Moderna-Vaccine-Transport.pdf>
- Moderna Storage and Handling Labels:
  - <https://www.cdc.gov/vaccines/COVID-19/info-by-product/moderna/downloads/storage-handling-label.pdf>
- Moderna Temperature Log: Celsius
  - <https://www.cdc.gov/vaccines/COVID-19/info-by-product/moderna/downloads/temp-log-freezer-storage-celsius.pdf>
- Moderna Temperature Log: Fahrenheit
  - <https://www.cdc.gov/vaccines/COVID-19/info-by-product/moderna/downloads/temp-log-freezer-storage-fahrenheit.pdf>

## Janssen/Johnson & Johnson Manufacturer Contact Information

- [Janssen/ Johnson & Johnson](#)
  - 1-800-565-4008
  - [Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use | Johnson & Johnson \(jnj.com\)](#)
  - COVID-19 Vaccine

Janssen Storage and Handling Labels:

<https://www.cdc.gov/vaccines/COVID-19/info-by-product/janssen/downloads/janssen-storage-handling-label.pdf>

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

Clinic Name: \_\_\_\_\_ Month/Year: \_\_\_\_\_

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

### Once/ Twice Daily Freezer Temperature Log

-15°C to -50°C (5°F to -58°F)

Clinic Name: \_\_\_\_\_ Month/Year: \_\_\_\_\_

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

Once/ Twice Daily Ultra-Cold Freezer Temperature Log

-60°C to -80°C (-76°F to -112°F)

Clinic Name: \_\_\_\_\_ Month/Year: \_\_\_\_\_

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

### Vaccine Transport Log

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

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

Clinic Name: \_\_\_\_\_ Date: \_\_\_\_\_

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

**\*\*Notes:**

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## Vaccine for Children Program and CDC COVID-19 Vaccination Program Comparison

As Emergency Use Authorization of COVID-19 vaccine products expand to include adolescents and children, providers enrolled in the Vaccines for Children (VFC) program are well situated to enroll in the COVID-19 Vaccination Program to ensure equitable access to COVID-19 vaccination services. VFC providers have direct access to the younger patient population and are familiar with vaccine administration and federal vaccine

programs. Though the VFC and COVID-19 Vaccination programs are both federal government programs, each have distinct requirements based on the associated funding legislation. For this reason, the provider agreements remain separate, and VFC providers must sign and adhere to the requirements of the CDC COVID-19 Vaccination Program Provider Agreement in order to receive and administer COVID-19 vaccines. The table below will assist VFC providers in understanding the differences in the programs' requirements. **Program differences are in bold.**

Category	VFC Program	COVID-19 Vaccination Program
<b>Provider Enrollment</b>	<p>Providers enroll via state/local immunization program enrollment system and procedures.</p> <p><b>Providers must complete and sign state/local immunization program Vaccines for Children Program Provider Agreement and VFC Program Provider Profile Form.</b></p>	<p>Providers enroll via state/local immunization program enrollment system and procedures.</p> <p><b>Providers must complete and sign CDC COVID-19 Vaccination Program Provider Agreement, Sections A and B.</b></p>
<b>Vaccine Ordering</b>	<p>Providers order routine childhood vaccines via state/ local immunization program-designated ordering system and procedures.</p> <p>Providers must be fully trained in vaccine management and storage/handling procedures prior to receiving vaccine supply.</p> <p>Providers must have the proper equipment <b>(as defined by the state/local immunization program)</b> for storing and monitoring vaccine prior to receiving vaccine supply.</p>	<p>Providers order COVID-19 vaccines via state/local immunization program-designated ordering system and procedures.</p> <p>Providers must be fully trained in vaccine management, storage/handling, preparation, and administration prior to receiving vaccine supply.</p> <p>Providers must have the proper equipment <b>(as defined in the <u>Vaccine Storage and Handling Toolkit-March 2021 [cdc.gov]</u>)</b> for storing and monitoring vaccine prior to receiving vaccine supply.</p>
<b>Vaccine Recipient Eligibility</b>	<p><b>VFC vaccines<sup>*</sup> may be administered to any child ages 0 through 18 years who is:</b></p> <p><b>Medicaid-eligible</b></p> <p><b>Uninsured</b></p> <p><b>Underinsured</b></p> <p><b>American Indian/Alaska Native (AI/AN)</b></p>	<p><b>Federally purchased COVID-19 vaccines may be administered to any person, regardless of health benefit coverage status. The age of the vaccine recipient must align with the U.S. Food and Drug Administration (FDA) Emergency Use Authorization or Approval of the vaccine administered.</b></p>

\*VFC vaccines do not include COVID-19 vaccines

**Consent/Assent**

The federal government does not have specific requirements for medical consent for vaccination. Providers should adhere to the medical consent laws of their state/jurisdiction and may also be subject to policy requirements for consent within their own organizations.

The federal government does not have specific requirements for medical consent for vaccination. Providers should adhere to the medical consent laws of their state/jurisdiction and may also be subject to policy requirements for consent within their own organizations.

**Category**

VFC Program

COVID-19 Vaccination Program

**Provision of Vaccine Information**

Providers must give the appropriate vaccine information statement to the patient (or parent or legal representative) prior to every dose of specific vaccines covered under the National Vaccine Childhood Injury

Providers must give the vaccine product-specific Emergency Use Authorization Fact Sheet for Recipients and Caregivers to the patient or their caregiver prior to every dose of COVID-19 vaccine. Providers must provide a COVID-19 Vaccination Record Card to the patient or their caregiver after vaccination (cards are included in the ancillary supply kits provided with the vaccines).

**Administration Fee Reimbursement**

Providers may charge a vaccine administration fee up to the regional maximum established for each state by the Centers for Medicare and Medicaid Services (CMS). Providers may not deny access to vaccine for a VFC-eligible child if the patient or parent is unable to pay. Providers may bill vaccine administration fees to patient/parent for uninsured or underinsured patients as well as Medicaid or other third-party payers for Medicaid-eligible or AI/AN patients.

All organizations and providers participating in the CDC COVID-19 Vaccination Program:  
Must administer COVID-19 vaccine at no out-of-pocket cost (including through balance billing) to the recipient  
May not deny anyone vaccination based on the vaccine recipient's coverage status or network status  
May not charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided and may not require additional medical services to receive COVID-19 vaccination  
May seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient,

such as: Vaccine recipient's private insurance company  
Medicare or Medicaid  
Health Resources & Services Administration (HRSA) programs for underinsured and uninsured patients

**Reporting Vaccine Administration**

Providers must document vaccine administration using the designated system and timeline required by the state/local immunization program, state/jurisdiction law, or organization policy.

Providers must document CDC-defined core data elements of vaccine administration in their medical record systems within 24 hours of administration, and use their best efforts to report administration data to the relevant system for the jurisdiction (i.e., immunization information system [IIS]) as soon as practicable and no later than 72 hours after administration.

**Reporting Vaccine Inventory**

Providers must report vaccine inventory with every vaccine order, using the system and procedures designated by the state/local immunization program.

All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into Vaccines.gov. In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into Vaccines.gov.

**Vaccine Wastage**

Providers must document and report vaccine wastage, using the system and procedures designated by the state/local immunization program.

Providers must document and report vaccine wastage, using the system and procedures designated by the state/local immunization program.

## Vaccine Adverse Event Reporting System (VAERS)

Providers are required to report to VAERS: Any adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine; or  
Any adverse event listed in the [VAERS Table of Reportable Events Following Vaccination](#) that occurs within the specified time period after vaccination.

CDC encourages providers to report any clinically significant adverse event that occurs in a patient following a vaccination, even if the provider is unsure whether a vaccine caused the event.

**Providers are required to report to VAERS the following adverse events (AEs) after COVID-19 vaccination, under Emergency Use Authorization (EUA), and other adverse events if later revised by CDC: Vaccine administration errors, whether or not associated with an AE**

**Cases of COVID-19 that result in hospitalization or death**

**Serious AEs regardless of causality. Serious AEs are defined as: Death;**

**A life-threatening AE;**

**Inpatient hospitalization or prolongation of existing hospitalization;**

**A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;**

**A congenital anomaly/birth defect;**

**An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.**

### **Cases of Multisystem Inflammatory Syndrome**

Providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if vaccination might not have caused the event.

**Providers should also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 vaccine being authorized under a EUA.**

## Vaccine Redistribution

VFC vaccines should routinely be shipped directly from the CDC distributor to the provider location where the vaccine will be administered. (Note: Exceptions made in Alaska and the United States-Associated Pacific Islands)

If approved by the state/local immunization program: **Large healthcare systems that use a centralized pharmacy may have vaccine shipped to the pharmacy for redistribution to the clinic(s) only if both the pharmacy and the clinic(s) are on the same campus. It is not acceptable for a large health care system to use one centralized pharmacy to ship vaccine to clinics throughout the jurisdiction.**

If approved by the state/local immunization program and validated cold-chain procedures are in place according to the manufacturer's instructions and CDC guidance on COVID-19 vaccine storage and handling, **providers may be allowed to routinely redistribute vaccine to other provider locations.**

**There must be a signed *CDC COVID-19 Vaccine Redistribution Agreement* for the provider conducting redistribution and a fully completed *CDC COVID-19 Vaccination Provider Profile Information* form (Section B of the *CDC COVID-19 Vaccination Program Provider Agreement*) for each receiving vaccination location.**

CDC cannot reimburse costs of redistribution beyond the initial designated primary CDC ship-to site(s), nor for purchase of any vaccine-specific refrigerators or qualified containers. Therefore, organizations planning for redistribution of COVID-19 vaccine must carefully assess the associated risks and costs (e.g., vaccine loss due to temperature excursions, purchase of vaccine-specific portable refrigerators and/or containers) before planning this activity.

## Vaccine Transfers

VFC vaccine transfers can occur only: With the approval and under direct guidance of the state/local immunization program

When a process is in place to ensure vaccine viability during transfer, as outlined in CDC's *Vaccine Storage and Handling Toolkit*. The process must include the use of a digital data logger (DDL) with a current and valid Certificate of Calibration Testing for temperature monitoring during transport, as well as other appropriate equipment.

When temperature monitoring documentation validates the vaccine has not been exposed to a temperature

COVID-19 vaccines may be transported: With the approval and under direct guidance of the state/local immunization program.

When a process is in place to ensure vaccine viability during transfer, as outlined in CDC's *Vaccine Storage and Handling Toolkit*, COVID-19 Vaccine Addendum, pages 53-54. The process must include the use of a digital data logger (DDL) with a current and valid Certificate of Calibration Testing for temperature monitoring during transport, as well as other appropriate equipment.

When temperature monitoring documentation validates the vaccine has not been exposed to a temperature excursion. This documentation must be transported with the vaccine.

excursion. This documentation must be transported with the vaccine.

Transport equal amounts of vaccines, diluents, and ancillary supplies (including vaccination record cards and PPE).

**Vaccine Disposition**

**Spoiled or expired VFC vaccines must be returned in their original container (unopened vial or manufacturer-prefilled syringe) within six months of the spoilage or expiration date.**

Wasted VFC vaccines (e.g., vaccine in an open vial, drawn into a syringe, or compromised because the container was dropped or broken) should be disposed of following state and local disposal requirements.

**Spoiled, expired, and/or wasted COVID-19 vaccine should not be returned to the distributor or manufacturer.** All nonviable or unusable COVID-19 vaccine should be disposed of following state and local disposal requirements.

**Record Retention**

Providers must retain all records related to the VFC program (both hard copy and electronic copy) for a minimum of three years, or longer if required by state/local law, and make these records available upon request.

Providers must retain all hard copy and electronic copy COVID-19 vaccine-related documentation (e.g., vaccine administration documentation, storage and handling records, etc.) for a minimum of three years, or longer if required by state/local law and make these records available upon request.

**Provider Monitoring**

State/local immunization programs are required to conduct VFC compliance site visits with VFC providers every 24 months.

State/local immunization programs are required to conduct CDC COVID-19 Vaccination Program quality assurance site visits with COVID-19 vaccination providers.

## Emergency Vaccine Management Plan

Provider Site Name: \_\_\_\_\_

Provider Site Address: \_\_\_\_\_

Primary Vaccine Coordinator: \_\_\_\_\_

Emergency Phone Number: \_\_\_\_\_

Back-up Vaccine Coordinator: \_\_\_\_\_

Emergency Phone Number: \_\_\_\_\_

### Transporting Vaccine

- In the event of a power failure or storage unit failure, vaccine will need to be moved to a pre-designated location.
- Ensure that all appropriate staff have instructions on what to do during an emergency. This may include where to go, how to transport vaccine to ensure the cold chain is maintained, and what supplies are needed such as frozen water bottles, bubble wrap, cardboard, flashlights, and keys. Refer to the Packing Vaccines for Transport during Emergencies located in the Appendix of this manual.
- Keep a copy of this Emergency Vaccine Management Plan along with a copy of the Packing Vaccines for Transport during Emergencies.
- All refrigerated vaccine must be kept between 2°C/36°F and 8°C/46°F/.
- All frozen need to be transferred on frozen cold packs with a thermometer and topped with frozen cold packs. Keep temperatures between -50°C/-58°F and -15°C/5°F.
- Ultra-cold vaccine must be moved in the original shipping container or ultra-cold designed portable storage unit. Keep temperatures between -80°C/-112°F and -60°C/-76°F
- Once vaccine is transported to alternate refrigeration and freezer units, keep them at the proper temperatures.

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

Alternate facility phone number: \_\_\_\_\_

Signature of primary vaccine coordinator: \_\_\_\_\_

This plan must be initialed and updated annually.

\_\_\_\_/\_\_\_\_/2021      \_\_\_\_/\_\_\_\_/2022      \_\_\_\_/\_\_\_\_/2023

\_\_\_\_\_ initials      \_\_\_\_\_ initials      \_\_\_\_\_ initials

## Acknowledgement of Policies and Signature Page

As an enrolled provider, it is a federal requirement that written vaccine management policies are 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 back-up(s) read and sign this page, certifying that staff have read the manual and take responsibility for adopting policies into clinic processes.
- An Emergency Vaccine Management Plan must be developed and implemented.
- All staff involved with the COVID-19 vaccine has documented training.
- This manual is reviewed and signed annually.

*By signing below, I hereby certify that I have read the Nebraska Immunization Program COVID-19 Provider Manual, and take responsibility for adopting all policies into clinic processes. I acknowledge that this is my legal signature.*

Primary Vaccine Coordinator Name: \_\_\_\_\_  
email \_\_\_\_\_

Date: \_\_\_\_\_

Back-up Vaccine Coordinator Name: \_\_\_\_\_  
email \_\_\_\_\_

Date: \_\_\_\_\_

Additional Trained Staff (Optional): \_\_\_\_\_

Date: \_\_\_\_\_

**\*\*Note: Insert additional signatures, as necessary.**

This plan must be initialed and updated annually.

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___/___/2021	___/___/2022	___/___/2023
_____ initials	_____ initials	_____ initial