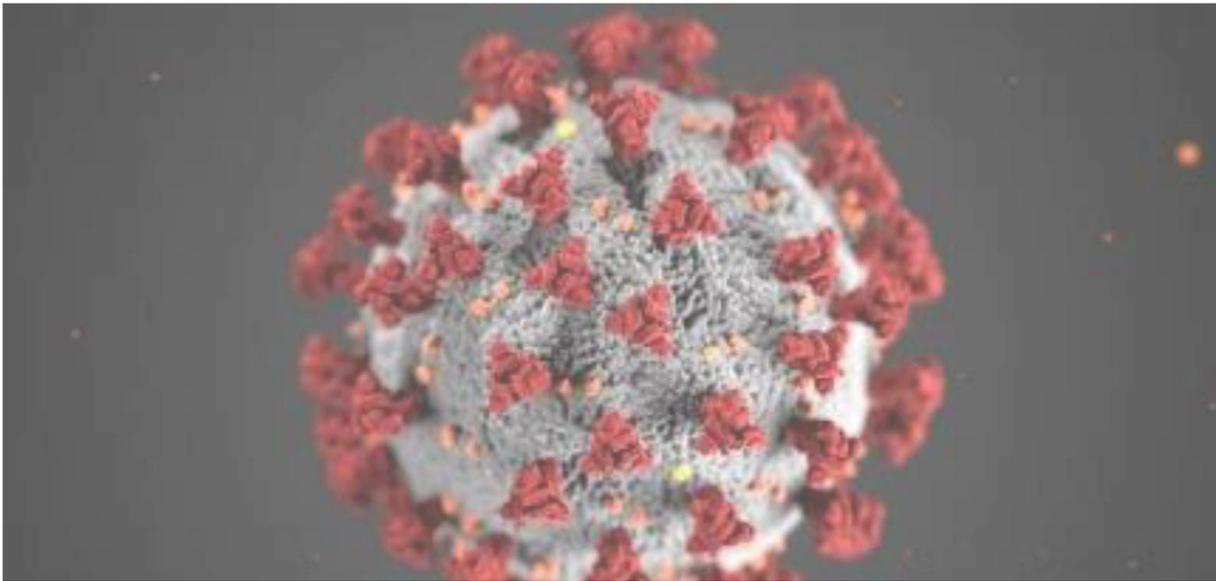




TEXAS
Health and Human
Services

Texas Department of State
Health Services

TEXAS COVID-19 VACCINE PROGRAM PROVIDER MANUAL



VERSION 2.0

Texas Department of State Health Services

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SECTION ONE: INTRODUCTION

The Texas Department of State Health Services (DSHS) Immunization Unit has prepared the COVID-19 Vaccine Program Provider Manual. Consultation on the policies in this manual have been conducted with the Centers for Disease Control and Prevention (CDC), the Center for Medicare and Medicaid Services (CMS), DSHS, and other organizations.

The purpose of the COVID-19 Provider Manual is to consolidate COVID-19 Vaccine Program policies, procedures, and information into one source. You may consult the manual as needed, for the handling and management of the COVID-19 vaccine. This manual is not all inclusive and as information evolves, the DSHS Immunization Unit will publish updated policy information on DSHS website at

<https://www.dshs.texas.gov/coronavirus/immunize/vaccine-manage-resources.aspx>.



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SECTION TWO: PROVIDER ENROLLMENT REQUIREMENTS

A. Enrollment Requirements

A licensed signing clinician will be required to enroll in the COVID-19 Vaccine Program. Licensed signing clinicians include:

- Medical Doctors (MD)
- Doctor of Osteopathic Medicine (DO)
- Nurse Practitioners (NP)
- Advanced Practice Nurses (APN)
- Physician Assistants (PA)
- Certified Nurse Midwives (CNM)
- Dentists (DDS)
- Registered Pharmacists (RPh)
- Optometrists (OD)
- Podiatrists (DPM)
- Veterinarians (DVM)

All provider types, other than veterinarians, must have an Individual National Provider Identification Number (NPI), and must complete the COVID-19 Vaccine Program Provider Agreement through the [EnrollTexasIZ.dshs.texas.gov](https://enrolltexasiz.dshs.texas.gov) web site.

The EnrollTexasIZ site has detailed information on the registration process and requirements. Enrolling providers must have the following information available to complete enrollment:



- ImmTrac2 Org Code (if registered)
- Texas Vaccines for Children (TVFC) / Adult Safety Net (ASN) PIN, if enrolled
- Facility Name
- Facility Physical, Administering, and Shipping Address
- Facility Phone Number
- Facility Fax Number
- Facility Primary COVID-19 Vaccine Coordinator and Back-up COVID-19 Vaccine Coordinator information
 - First Name, Last Name, Phone Numbers, and a unique email address.
- Chief Medical Officer (or equivalent) and Chief Executive Officer information
 - First Name, Last Name, Phone Number, a unique email address, Texas Medical License, License Type, Individual National Provider Identification Number (NPI), Specialty, Medicaid ID.
- Patient Population (number and type of patients served)
- Storage capacity (refrigerated/frozen/ultra-cold)
- Data logger make/model and certificates of calibration

As part of the enrollment process, providers will be required to register with the Texas Immunization Information System (ImmTrac2). If the enrolling provider already has an ImmTrac2 Org Code, this information can be prepopulated in the enrollment form. Upon completion of the enrollment form, providers will be assigned a six-digit provider identification number



(PIN). **It is important that this number be kept near the provider for ordering vaccines and for reporting vaccines administered.**

This is further discussed in [Section Four: Vaccine Management](#) and [Section Five: Reporting Requirements](#). For more information visit <https://www.dshs.texas.gov/coronavirus/immunize/provider-enrollment.aspx>.

Facility Type - Private Residence

Due to strict temperature storage and monitoring requirements of vaccines, the Texas DSHS does not permit the COVID-19 vaccine to be stored at a private residence.

Private Residences include, but not limited to, the part of a structure used as a dwelling, including, without limitation: a private home, townhouse, condominium, apartment, mobile home, vacation home, cabin, or cottage. DSHS reserves the right to decline to send vaccine to providers as it deems appropriate.

For questions about the COVID-19 Vaccine Program enrollment, contact the DSHS COVID-19 Vaccine Provider Help Desk at by phone at (833) 832-7068, 8 a.m. to 5 p.m., Monday through Friday or by email at COVID19VacEnroll@dshs.texas.gov.



B. Specific Terms of the Agreement

The COVID-19 Vaccine Program Provider Enrollment Form includes a provider agreement. This agreement must be completed by all providers to receive and administer COVID-19 vaccines. By signing the COVID-19 Vaccine Program Provider Agreement, the office and all practitioners associated with the medical site agree to:

- Administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and the Advisory Committee on Immunization Practices (ACIP)¹
- Record in the vaccine recipient's record and report required information to ImmTrac2 and any other required database *within 24 hours of vaccine administration*²
- Retain all records relating to COVID-19 vaccine for a minimum of three (3) years following vaccination
- Not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to organization
- Administer COVID-19 vaccine to everyone regardless of the vaccine recipient's ability to pay the administration fees ([see Section Six: Billing for more information](#))
- Provide an approved Emergency Use Authorization (EUA) fact sheet to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative, prior to the administering COVID-19 vaccine
- The provider's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services during the COVID-19 Pandemic for safe delivery of vaccines³



- Comply with DSHS Immunization Unit requirements for COVID-19 vaccine management. Those requirements include:
 - Proper storage and handling⁴
 - Monitoring of vaccine storage unit temperatures⁴
 - Complying with the guidance for handling temperature excursions⁴
 - Monitoring and complying with COVID-19 vaccine expiration dates
 - Maintaining all COVID-19 records for a minimum of three (3) years
- Report the number of doses of COVID-19 vaccine and adjuvants that are unused, spoiled, or expired, or wasted as required. [See Section Four: Vaccine Management](#)
- Comply with federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses⁵
- Report moderate and severe adverse events following vaccination to Vaccine Adverse Event Reporting System (VAERS)⁶ [See Section Five: Reporting Requirements.](#)
- Provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative
- Comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 vaccine

¹ <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>

² <https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html>

³ <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>

⁴ <https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html>

⁵ <https://dshs.texas.gov/immunize/covid19/COVID19-Vaccine-Disposal-Guidelines.pdf>

⁶ <https://vaers.hhs.gov/reportevent.html>



More information can be found on the DSHS website at <https://www.dshs.texas.gov/coronavirus/immunize/provider-enrollment.aspx>.

C. Provider Change of Information

It is the responsibility of the staff at the COVID-19 Vaccine Program enrolled site to maintain correct patient demographics, days and hours available to receive vaccine shipments, and profile information in the Vaccine Allocation and Ordering System (VAOS).

To make updates to your enrollment, including patient population, follow the instructions below based on your enrollment status:

Enrollment In-Progress

If the COVID-19 Vaccine Program provider enrollment is in-progress, the provider can log into their enrollment and update any information as needed.

NOTE: The entire enrollment form must be completed to be reviewed for approval. The username is the **firstname.lastname** of the person who registered the enrollment.

Enrollment Pending Signature or Pending Approval

Contact the COVID-19 Vaccine Provider Help Desk by phone at (833) 832-7068, 8 a.m. to 5 p.m., Monday through Friday or email at COVID19VacEnroll@dshs.texas.gov to have your enrollment unlocked to make the updates.

Emails must include:

- Facility Name and address
- ImmTrac2 Org Code



Enrollment Approved

Complete the Patient Population Adjustment Form as accurately as possible on the DSHS website at

<https://www.dshs.texas.gov/coronavirus/immunize/provider-enrollment.aspx> and email the completed form to

COVID19VacEnroll@dshs.texas.gov. Include the following information:

- Site name (including physical mailing address)
- ImmTrac2 Org Code
- The updated population totals by category as listed below:
 - Long-term care facilities residents [nursing facility (NF), assisted living facility (ALF), or independent living facility (ILF)]
 - General adult population
 - General pediatric population
 - Adults 65 years of age or older
 - Health care workers
 - Critical infrastructure/essential workers
 - People experiencing homelessness
 - Pregnant women
 - Racial and ethnic minority groups
 - Tribal communities
 - People who are incarcerated/detained
 - People living in rural communities
 - People who are under-insured or uninsured
 - People with disabilities



- People with underlying medical conditions that are at risk for severe COVID-19 illness
- Military - veteran
- Military – active duty/reserves
- Other people at higher risk for COVID-19

Once your email has been received, DSHS will update the information as needed.

D. Vaccine Coordinators Responsibilities

The COVID-19 Vaccine Program requires Primary or Back-up Vaccine Coordinators to be the Point of Contact (POC) for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, responding to DSHS inquiries, as well as responsible for the following:

- Setting up data loggers in storage units
- Ensuring staff are familiar with the operations of the data loggers including how to download the data (recommended weekly, on Mondays)
- Monitoring and recording the temperatures of vaccine storage units (refrigerator and freezer) two times each workday
- Reading and recording the minimum and the maximum temperatures at the beginning of each workday
- Resetting the minimum and maximum temperatures at the end of each workday
- Monitoring the operation of storage equipment and systems
- Maintaining all documentation, such as vaccine inventory and temperature logs
- Documenting COVID-19 vaccine inventory information



- Placing orders for additional COVID-19 vaccine in VAOS
- Tracking and documenting doses administered
- Overseeing proper receipt and storage of vaccines deliveries
- Organize vaccines to monitor expiration dates
- Ensuring vaccine is stored and handled appropriately to safeguard vaccine viability
- Responding to out-of-range temperature excursions and notifying DSHS Immunization Unit
- Notifying the DSHS Immunization Unit when there are changes to enrollment information

E. COVID-19 Provider Training

It is highly recommended that COVID-19 vaccine providers take the CDC's "You Call the Shots Module 10 – Storage and Handling" training, located on the CDC website at

<https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>. This module explains proper storage and handling of COVID-19 vaccines. Should providers choose to complete the highly recommended CDC training, providers are required to keep all training certificates on hand in accordance with the CDC three (3) year record retention policy for COVID-19 vaccine.

F. Withdrawing from the COVID-19 Vaccine Program

Providers who choose to not continue with their current enrollment, or choose to withdraw from the COVID-19 Vaccine Program, must complete the following steps below:

1. Download the COVID-19 Vaccine Program Withdrawal Form on the DSHS website at
<https://dshs.texas.gov/coronavirus/immunize/provider->



[enrollment.aspx](#)

2. Complete the COVID-19 Vaccine Program Withdrawal form in its entirety.

Note: Submissions with blank fields will be returned for corrections and will delay withdrawal completion.

3. Email the completed withdrawal form to COVID19VacEnroll@dshs.texas.gov.
4. Once the withdrawal form is processed by DSHS, you will receive a confirmation email from the COVID-19 Vaccine Provider Help Desk (COVID19VacEnroll@dshs.texas.gov).

Completing the form and submitting the withdrawal request will prevent future vaccine allocations of the COVID-19 vaccine. Facilities can continue to administer current vaccine inventory and are still required to report doses administered as described in [Section Five: Reporting Requirements](#).

For questions about the COVID-19 Vaccine Program withdrawal process, contact the DSHS COVID-19 Vaccine Provider Help Desk by phone at (833) 832-7068, 8 a.m. to 5 p.m., Monday through Friday or by email at COVID19VacEnroll@dshs.texas.gov.



SECTION THREE: COVID-19 VACCINE OVERVIEW

In the United States, the federal government’s Countermeasures Acceleration Group contracted with vaccine manufacturers to begin manufacturing their vaccine prior to receiving FDA approval or Emergency Use Authorization (EUA). The table below (Table 3.1) provides an overview of the COVID-19 vaccines who have EUA.

Manufacturer	Doses Needed	Timing	Storage/Handling
Moderna	2	At least 28 days	Frozen/ Refrigerated
Pfizer/BioNTech	2	At least 21 days	Ultra-Cold/ Frozen/ Refrigerated
Johnson & Johnson/Janssen	1	N/A	Refrigerated

Table 3.1

Table 3.1 above shows COVID-19 vaccines currently under EUA for the following manufacturers: Moderna, Pfizer/BioNTech, and Johnson & Johnson/Janssen. As additional vaccines are released for use, this manual will be updated accordingly.

A. Pfizer-BioNTech COVID-19 Vaccine Overview

General Information:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>

Vaccine: Pfizer-BioNTech COVID-19 Vaccine

Diluent: 0.9% sodium chloride (normal saline, preservative-free)

Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Vaccine MUST be mixed with diluent before administration.



Multidose vial: 6 doses per vial

Dosage: 0.3 mL

Age Indications:

12 years of age and older

Schedule:

2-dose series separated by 21 days

A series started with Pfizer COVID-19 Vaccine should be completed with this product.

Administer:

Intramuscular (IM) injection in the deltoid muscle

Storage and Handling

- A. Vaccine will arrive at a temperature between -80°C and -60°C (-112°F to -76°F) in a thermal shipping container with dry ice. Diluent and an ancillary supply kits will arrive separately from the vaccine.
- B. Unpack the thermal shipping container following the manufacturer's directions.

For more information on specific storage and handling requirements for this vaccine, see CDC's website, <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html>.

B. Moderna Vaccine Overview

General Information:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html>

Dosing Information:

Multidose vial: 11-15 doses per vial

Dosage: 0.5 mL

Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.



Age Indications:

18 years of age and older

Schedule:

2-dose series separated by 28 days

A series started with COVID-19 vaccine (Moderna) should be completed with this product.

Administration:

Intramuscular (IM) injection in the deltoid muscle

Storage and Handling

- A. Vaccine will arrive at a temperature between -50°C and -15°C (-58°F to 5°F). Ancillary supply kits will arrive separately from the vaccine.
- B. Unpack the shipping container following the manufacturer's directions.

For more information on specific storage and handling requirements for this vaccine, see CDC's website, <https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html> or [see Figure 4.2](#).

C. Janssen Vaccine Overview

General Information:

<https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html>

Dosing information:

Multidose vial: 5 doses per vial

Dosage: 0.5mL

Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Age Indications:

18 years of age and older



Schedule:

Single dose

Administration:

Intramuscular (IM) injection in the deltoid muscle

Storage and Handling

Store vaccine in a refrigerator. Do NOT freeze.

The vaccine will arrive at a refrigerated temperature of 2°C to 8°C (36°F and 46°F).

- Unpack the vaccine shipment following the manufacturer’s directions.
 - Check both temperature monitoring devices in the box (3M MonitorMark and FreezeMark)
- An ancillary supply kit will arrive separately from the vaccine

D. Vaccine Ancillary Kits

The United States Department of Health and Human Services (HHS) is providing ancillary supply kits for the administration of COVID-19 vaccine. The Strategic National Stockpile (SNS), managed by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), is partnering with McKesson Corporation to produce, store, and distribute these vaccine ancillary supply kits on behalf of the SNS.

COVID-19 vaccination providers do not need to order ancillary kits. When ordering COVID-19 vaccine, ancillary supplies will automatically be ordered in amounts to match the vaccine orders at no cost to the COVID-19 vaccination provider.



Moderna Vaccine

New Presentation (available May 2021): This presentation of the Moderna COVID-19 Vaccine contains vials authorized for 13-15 doses (maximum 15-dose vial). Associated ancillary kit contains supplies to support administration of 14 doses per vial. If a provider draws a 15th dose, they will need to do so using their own supplies.









Possible Ancillary Kits—COVID-19 Vaccine Supporting 140 Doses (Moderna)

The following tables list the contents of each possible ancillary kit by product and quantity. All kits are configured for 140 doses with 5% surplus.

*Needle and Syringe Sizes for **Adult** Ancillary Kits*

PRODUCT	QUANTITY
Needle (22–25G x 1")	75
Syringe (1 mL or 3mL, LDV)	75
Needle (22–25G x 1")	50
Syringe (1 mL or 3mL)	50
Needle (22–25G x 1.5")	25
Syringe (1 mL or 3 mL)	25
Alcohol Pad (sterile, individually sealed)	300
Vaccination Record Card	150
Needle Gauge and Length Chart	1
Face Shield	3
Surgical Mask	6

*Needle and Syringe Sizes for **Pediatric** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	75
Syringe (1 mL or 3 mL, LDV)	75
Needle (25G x 1")	75
Syringe (1 mL or 3 mL)	75
Alcohol pads (sterile, individually sealed)	300
Vaccination Record Card	150
Needle Gauge and Length Chart	1
Face Shield	3
Surgical Masks	6
Face Shield	3
Surgical Mask	6



Pfizer Vaccine

Pfizer will direct ship the following ancillary supplies per 450-dose pack size.



Possible Ancillary Kits—COVID-19 Vaccine Supporting 450 Doses (Pfizer-BioNTech)

*Needle and Syringe Sizes for Large Combined **Adult** Ancillary Kits*

PRODUCT	QUANTITY
Needle (22–25G x 1")	315
Syringe (1 mL, LDV)	315
Needle (22–25G x 1")	75
Syringe (1 mL)	75
Needle (22–25G x 1.5")	85
Syringe (1 mL)	85
Needle, Mixing (21–25G x 1.5")	80
Syringe, Mixing (3 mL or 5 mL)	80
Alcohol Pad (sterile, individually sealed)	1,200
Vaccination Record Card	450
Needle Gauge and Length Chart	4
Face Shield	10
Surgical Mask	20
Diluent	75

*Needle and Syringe Sizes for Large Combined **Pediatric** Ancillary Kits*

PRODUCT	QUANTITY
Needle (25G x 1")	315
Syringe (1 mL, LDV)	315
Needle (25G x 1")	160
Syringe (1 mL)	160
Needle, Mixing (21–25G x 1.5")	80
Syringe, Mixing (3 mL or 5 mL)	80
Alcohol Pad (sterile, individually sealed)	1,200
Vaccination Record Card	450
Needle Gauge and Length Chart	4
Face Shield	10
Surgical Mask	20
Diluent	75



Johnson & Johnson/Janssen

Johnson & Johnson/Janssen distributed vaccines will ship the following ancillary supplies per 100 doses.



Possible Ancillary Kits—COVID-19 Vaccines Supporting 100 Doses (Moderna and Janssen*)

The following tables list the contents of each possible ancillary kit by product and quantity. All kits are configured for 100 doses with 5% surplus.

Needle and Syringe Sizes for **Adult** Ancillary Kits

PRODUCT	QUANTITY
Needle (22–25G x 1")	85
Needle (22–25G x 1.5")	20
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Needle and Syringe Sizes for **Pediatric** Ancillary Kits

PRODUCT	QUANTITY
Needle (25G x 1")	105
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4

Needle and Syringe Sizes for **Mixed (Pediatric/Adult)** Ancillary Kits

PRODUCT	QUANTITY
Adult/Pediatric Needle (22–25G x 1")	95
Adult Needle (22–25G x 1.5")	10
Syringe (1 mL or 3 mL)	105
Alcohol Pad (sterile, individually sealed)	210
Vaccination Record Card	100
Needle Gauge and Length Chart	1
Face Shield	2
Surgical Mask	4



Vaccine Storage Temperatures

Each COVID-19 vaccine has unique storage requirements ranging from ultra-cold (-75°C/-65°F) to refrigerated (2-8°C/39-41°F). See *Table 3.2*.

			Refrigerated 2°C to 8°C (36°F to 46°F)		Room Temperature Up to 25°C (77°F)	
	Ultra-low temperature freezer -80°C to -60°C (-112°F to -76°F)	Freezer -25°C to -15°C (-13°F to 5°F)	Undiluted/ Unpunctured	Diluted/ Punctured	Undiluted/ Unpunctured 8°C and 25°C (46° and 77°F)	Diluted/ Punctured
Pfizer-BioNTech COVID-19 Vaccine	Expiration date	2 weeks*	1 month	---	2 hours	6 hours (2°C to 25°C)
Moderna COVID-19 Vaccine	---	Expiration date -50°C and -15°C (-58°F and 5°F)	30 days	---	24 hours	12 hours (2°C to 25°C)
Janssen (J&J) COVID-19 Vaccine	---	---	90 days	6 hours	12 hours	6 hours (2°C to 8°C) 2 hours (9°C to 25°C)

Table 3.2

It is critical providers review and understand the manufacturers requirements for each individual vaccine. Improper storage temperatures will result in a non-viable vaccine supply. All COVID-19 vaccine supply is temperature-sensitive and needs to meet proper cold chain requirements to maintain and ensure efficacy and maximize shelf life. For more information on proper vaccine storage and handling, visit the [CDC "Vaccine Storage and Handling Toolkit"](#).

To find more resources for training staff, educating patients, or frequently asked questions see the CDC website at <https://www.cdc.gov/vaccines/covid-19/hcp/faq.html>.



E. Vaccine Procedures: Vaccine Preparation

Proper preparation is critical for maintaining the integrity of the vaccine during transfer from the vial to the syringe. Always use aseptic technique and follow infection prevention guidelines when preparing vaccines. Aseptic technique refers to the manner of handling, preparing, and storing medications and injection equipment/supplies (e.g., syringes, needles) to prevent microbial contamination and infection.

1. Prepare vaccines in a clean, designated medication area away from where the patient is being vaccinated and away from any potentially contaminated items. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment.
2. Health care personnel should ensure their clinic has the supplies needed to administer vaccines.
3. Health care personnel should complete proper hand hygiene before preparing vaccines.
4. Use a separate needle and syringe for each injection.
5. Always check the expiration dates on the vaccine and diluent. Some syringes and needles have expiration dates, so check those, too. NEVER use expired vaccine, diluent, or equipment.
6. Prepare vaccines only when you are ready to administer them.
7. Only administer vaccines you have prepared. This is a medication administration best practice standard. If vaccine is drawn up by one person but administered by another, the person administering the vaccine cannot be sure what is in the syringe and whether it is safe.

For more information about vaccine preparation, visit the CDC website:

<https://www.cdc.gov/vaccines/hcp/admin/prepare-vaccines.html>



Emergency Use Authorization (EUA) Fact Sheet

Before administering COVID-19 vaccine, administrators must provide an approved Emergency Use Authorization (EUA) fact sheet to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. To obtain a copy of EUA fact sheets use the following links:

Pfizer/BioNTech COVID-19 vaccine: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine>

Moderna COVID-19 vaccine: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine>

Johnson & Johnson/Janssen COVID-19 vaccine: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine>

Observation periods following vaccination

CDC recommends the following observation periods after COVID-19 vaccination:

- 30 minutes:
 - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
 - People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination)
 - History of anaphylaxis due to any cause
- 15 minutes: All other people



For more information on the CDC interim clinical considerations for the use of COVID-19 vaccine, visit the website at:

<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html>

F. Important Information for Vaccine Administration

Pre-vaccination screening patients prior to vaccine administration is required for providers to determine if the patient should not get the COVID-19 vaccine. CDC has created a pre-vaccination screening form that is available for use at <https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf>.

Here are a few things to remember for vaccine administration:

- Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost
- Vaccine recipients are not required to be tested for COVID-19 prior to administration of the vaccine. However, providers must prescreen to determine if the COVID-19 vaccine should be given to a patient
- Vaccine administrators must provide the vaccine recipient or caregiver with a COVID-19 vaccination record card which includes the name of the vaccine administered, the date of administration, and the name/location of the administering clinic. These cards are included in the ancillary supply kits
- COVID-19 vaccination providers are encouraged to label or clearly mark vaccine vials to clearly indicate thaw as well as “use by” times



SECTION FOUR: VACCINE MANAGEMENT

A. Vaccine Ordering

The COVID-19 vaccine is ordered through Vaccine Allocation & Ordering System (VAOS) once your COVID-19 Vaccine Program Provider Enrollment has been approved. Starting on August 16, 2021, all COVID-19 vaccine order requests will be fulfilled using an improved ordering timeline, which will allow providers to receive vaccine in a timelier manner.

1. If you place a minimum pack size order of a given presentation COVID-19 vaccine your order will be placed through the CDC.
 - a. Please allow 2 business days for all pending orders to be processed and confirmed for accuracy and validity prior to being placed with the CDC.
 - b. If your order is denied for any reason, you will receive an email notification.
 - c. The new timeline for receiving CDC deliveries will be 5-7 calendar days.
2. If you place a "less than a minimum pack size" order of a given COVID-19 vaccine, your order will be processed and shipped through the State of Texas by one of our state authorized shipping partners.
 - a. Please allow 2 business days for all pending small dose orders to be processed and confirmed for accuracy and validity prior to being shipped by the state.
 - b. The new timeline for receiving "less than minimum pack size" order deliveries is 7-10 business days.

If you have questions or need additional information about your shipment, please contact the COVID-19 Vaccine Shipments team at COVID19VacShipments@dshs.texas.gov. Please be sure to include your facility name and six-digit PIN in the email.



B. Receiving Vaccine Orders

The COVID-19 Program requires vaccine shipments always be accepted and never refused or returned without specific instructions from the DSHS Immunization Unit.

The staff at COVID-19-enrolled sites must ensure the accurate clinic address and delivery hours are entered in the COVID-19 Vaccine Program Provider Agreement. Each site establishes the hours available to accept vaccine shipments during the completion of the COVID-19 Vaccine Program Enrollment. Vaccine delivery hours **MUST** include four (4) consecutive hours on one (1) or more days (e.g., Thursday, 8 a.m. to 12 p.m.). The staff at the COVID-19 enrolled site may not change available hours in the provider enrollment once an order is placed. The signing clinician is responsible for incomplete or erroneous information entered in the COVID-19 Vaccine Program provider enrollment which can result in vaccine loss. Appropriately trained staff must also be on site and available to receive vaccine shipments.

It is important to store vaccine shipments immediately upon receipt to ensure vaccine viability. All staff at COVID-19- enrolled sites are required to train other clinic staff on what a vaccine shipment looks like and must maintain a completed vaccine management plan in place to ensure the vaccine is stored quickly and correctly upon arrival.

Each vaccine is shipped and stored at different temperatures. See the Storage and Handling Requirements section below for a summary of storage and handling for both the Pfizer, Moderna, and Johnson & Johnson/Janssen COVID-19 vaccines.



Inspecting Vaccine Shipments

Providers must inspect vaccines upon arrival. If the vaccines are warm, missing, broken, or if the inspection fails, they should contact McKesson and request a replacement shipment. They should then contact DSHS Immunization, to ensure their replacement order is tracked and input into VAOS. Providers are required to enter the number of doses that pass and fail inspection in the Provider Community

Portal within 24 hours. The total of doses passing the inspection and the doses that failed the inspection must equal the total number of doses in the vaccine shipment. This information will automatically be uploaded into VAOS when complete.

Vaccine Distribution

Always store COVID-19 vaccines in their original packaging with lids closed until ready for administration unless vaccines are stored in an auto-dispensing unit that requires vaccines to be removed from the original packaging. Place COVID-19 vaccines with the earliest expiration dates in front of those with later expiration dates.

Refrigerators and freezers that store COVID-19 vaccines are to be dedicated to storing vaccine only. Food or drinks in the same refrigerator or freezer as vaccines is not allowed. If other biologics must be stored in the same unit, store them below the vaccines to avoid contamination.

Temperature Excursions

A temperature excursion occurs when any temperature reading is outside the recommended range for vaccine as defined in the manufacturer's package insert. Vaccines must always be stored properly, even if viability is questionable. Vaccines that are received warm, damaged, or in an otherwise questionable state require immediate attention.



Listed below are examples of possible temperature excursions or questionable vaccines:

- Vaccine shipment received with temperature indicator strip showing out of range
- Vaccine is warm to touch
- Ice/gel packs are melted
- Ice/gel packs are missing, or vaccine is received damaged

If vaccine viability is questionable upon receipt, the facility/site must immediately follow the steps below:

Steps	Moderna COVID-19 Vaccine	Pfizer COVID-19 Vaccine	Johnson & Johnson/ Janssen COVID-19 Vaccine
1	Place the probe of a data logger in the questionable shipment, near the vaccine and replace the lid to gain the current temperature. Temperatures must be checked frequently to see when the temperature stabilizes.		
2	Separate the questionable vaccine and vaccine quarantine bad and place the questionable vaccines in the freezer, until viability can be determined. Do not write on the vaccine itself.		
3	Contact Moderna at 1-866-663-3762 or email excursions@moderna.tx.com to report the Moderna vaccine temperature excursion.	Contact Pfizer at 1-800-438-1935 or email PfizerMedicalInformation@pfizer.com to report the Pfizer vaccine temperature excursion.	Contact Johnson & Johnson/Janssen at 1-800-565-4008 or email JSCCOVIDTEMPEXCURSION@its.jnj.com to report the J&J/Janssen vaccine temperature excursion.
4	McKesson will initiate a process for sending a replacement order for the vaccine.	Pfizer will initiate a process for sending a replacement order for the vaccine.	McKesson will initiate a process for sending a replacement order for the vaccine.
5	Inform DSHS of the vaccine temperature excursion at (833) 832-7068 or COVID19VacEnroll@dshs.texas.gov		

For questions about vaccine shipments, please email the DSHS COVID-19 Vaccine Shipments team at COVID19VacShipments@dshs.texas.gov.

C. Vaccine Loss

Inspection of the shipment is important to complete the total vaccine loss. All vaccine losses must be reported within 24 hours of the loss in VAOS.



Vaccine loss due to shipment errors or expiration will be replaced.

COVID-19 Vaccine Disposal

The Centers for Disease Control and Prevention (CDC) states that COVID-19 vaccines should be treated as regulated medical waste in its disposal requirements from their [Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage](#) notice. The CDC advises providers to waste COVID-19 vaccines in accordance with local regulations.

The State of Texas Department of State Health Services (DSHS) follows the Texas Commission on Environmental Quality (TCEQ) guidance on proper medical waste disposal of wasted COVID-19 vaccine. Please see [attached PDF](#) for reference. The TCEQ and DSHS define medical waste as special waste from health care-related facilities ([25 TAC 1.132\(46\)](#) and [30 TAC 326.3\(23\)](#)), which includes: treated and untreated animal waste, bulk human blood and body fluids, microbiological waste, pathological waste, and sharps.

Following the TCEQ's guidance on disposal of COVID-19 medical waste, dispose of needles and associated vials in a clearly labeled sharps container, treating it as a contaminated biohazard container. Wipe down and sanitize work area. After disposing of vaccine, take off and dispose gloves, and thoroughly wash hands with soap and water for at least 20 seconds or use an alcohol-based hand sanitizer that contains at least 60% alcohol.

Additional information on local regulations for how to treat and dispose medical waste in Texas, can be found on TCEQ's website at <https://www.tceq.texas.gov/response/covid-19/waste-disposal-guidance> or by emailing info@tceq.texas.gov.

If your facility participates in the Texas Vaccines for Children (TVFC) or Adult Safety Net (ASN) Programs, follow the guidance provided in the [TVFC and ASN Program Provider Manual, Chapter 3 Section IV: Vaccine Loss](#).



D. Storage and Handling Requirements

Storage Unit Requirements

Proper receipt and storage of vaccine delivery is important to maintain the vaccine cold chain. The cold chain, or temperature monitoring, begins with the cold storage unit at the manufacturing plant, extends through transport of vaccines to the distributor, continues through the delivery and storage at the enrolled facility, and ends with administration of vaccine to the patient. Exposure to heat, cold, or light at any step in the cold chain can damage vaccines, resulting in loss of vaccine viability. Once lost, vaccine viability cannot be restored. Refrigerators and freezers that store COVID-19 vaccines are to be dedicated to storing vaccine only. Food or drinks in the same refrigerator or freezer as vaccines is not allowed. If other biologics must be stored in the same unit, store them below the vaccines to avoid contamination. A "Do Not Unplug" sign is required to be posted on or near all outlets where units are plugged in. A "Do Not Disconnect" sign must be posted on or near each circuit breaker.

The CDC and DSHS Immunization Unit recommend the following types of units, listed in preferential order:

- Pharmaceutical/purpose-built units
- Stand-alone, single-purpose refrigerator and stand-alone single purpose freezer
- Combination household unit
 - In the event a combination household unit is used, the site should only use the refrigerator section and obtain a separate stand-alone freezer. Refrigerated vaccine is to be stored in the refrigerator component of the combination unit and frozen vaccine will be stored in the stand-alone freezer



- Dorm-style and small combination refrigerator and freezer units with a single external door are never allowed for the storage of the COVID-19 vaccine

For current vaccine storage and handling information of each vaccine, visit the [COVID-19 Vaccine Management Resources website](#).

Digital Data Logger Requirements

COVID-19 vaccine providers must have proper storage and temperature monitoring equipment to meet the specific needs of the COVID-19 vaccine product(s) they have in their inventory. It is essential for each vaccine storage unit to have a continuous temperature monitoring device to ensure vaccines are stored within the correct temperature range. DSHS requires a digital data logger (DDL) for each storage unit that contains the COVID-19 vaccine. A digital data logger provides the most accurate continuous storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range. Digital data loggers using a buffered temperature probe provide the most accurate way to measure actual vaccine temperatures.

Each digital data logger must be current with a valid Certificate of Calibration Testing.

The following are requirements for data loggers:

- An active temperature display that can be easily read by all staff from the outside of the unit, without having to open the door
- The data logger must have functionality that does not require a computer password to access the temperature display
- The display must remain active for temperature readings (i.e., must not have sleep mode turned on)
- Alarm for out-of-range temperatures



- A display which shows the current temperature, as well as minimum and maximum temperatures. (e.g., for refrigerated vaccines, the minimum temperature would be 36°F and the maximum temperature would be 46°F; for frozen vaccines, the minimum temperature would be -25°C and the maximum temperature would be -15°C; and for ultra-cold vaccines, the minimum temperature would be -80°C and the maximum temperature would be -60°C)
- Low battery indicator
- Accuracy of +/-1°F (+/-0.5°C)
- Detachable probe in buffered material
- Memory storage of at least 4,000 readings (device must not rewrite over old data and must stop recording when the memory is full), and
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes

NOTE: Not all data loggers can measure ultra-cold temperatures (see product box for additional requirements for ultra-cold temperature monitoring).

Additional Requirements for Ultra-Cold Temperature Monitoring

Digital data loggers using a buffered temperature probe provide the most accurate measurement of vaccine temperatures. However, many manufacturers use pure propylene glycol (freezing point -59° C) or a glycol mixture with a warmer freezing point. For accurate ultra-cold temperature monitoring, it is essential to use an air-probe, or a probe designed specifically for ultra-cold temperatures with the data logger.

Probes must be in buffered material so that they measure temperatures that are more representative of the temperature of the vaccine in the vial rather than the air temperature of the storage unit.



Examples of buffers include the following:

- A vial filled with liquid (glycol, ethanol, glycerin)
- A vial filled with loose media (sand, glass beads)
- A solid block of material (Teflon®, aluminum)
- The COVID-19 Program does not allow the following temperature monitoring devices:
 - Alcohol or mercury thermometers, even if placed in fluid-filled bio-safe liquid vial
 - Bi-metal stem temperature monitoring devices
 - Food temperature monitoring devices
 - Household mercury temperature monitoring devices
 - Chart recorders
 - Infrared temperature monitoring devices, or
 - Thermometers

These devices can have significant limitations, can be difficult to read, and generally only provide information on the temperature at the precise time they are read. Therefore, temperature fluctuations outside the recommended range may not be detected.

NOTE: In pharmaceutical or purpose-built units, the digital data logger probe is recommended to be placed in a central location; however, other placements may be suitable because these units maintain more consistent temperatures throughout the unit.

To better help COVID-19 providers, DSHS Immunization Unit has created a Best Practice for Data Loggers resource document. This document can be found online at <https://www.dshs.texas.gov/immunize/covid19/Best->



[Practices-for-Data-Loggers.pdf](#).

Best Practices for Monitoring COVID-19 from Vaccine

- Develop an organizational standard operating procedure for the reporting and documentation of temperatures
- Check temperatures using a certified calibrated data logger twice daily
- Record the minimum/maximum temperature (do not convert temperatures from Fahrenheit to Celsius or Celsius to Fahrenheit), date, time, the name of the person checking and recording temperature, and action taken if a temperature excursion occurred
- Reset minimum and maximum temperature readings from the day before at the end of each business day
- Download the data their digital data loggers at least once per week, on Mondays, to ensure that any excursions are identified and addressed in a timely manner

E. Documentation Requirements

Vaccine Record Keeping Requirements

The CDC and DSHS require all vaccinators to record the following information in the medical record each time a COVID-19 vaccine is administered:

- Name of vaccine administered
- Date vaccine was administered (month, day, year)
- Name of vaccine manufacturer
- Vaccine lot number
- Name and title of the health care professional administering the vaccine
- Address of the clinic where the vaccine was administered



The DSHS Immunization Unit is able provide additional COVID-19 immunization record cards that are designed to capture all required information when a vaccine is administered. To place a request for additional COVID-19 immunization record cards, you must submit the following information to the COVID-19 Vaccine Program Provider Help Desk via email at COVID19VacEnroll@dshs.texas.gov.

The vaccination record card request must be in the following format. Incomplete submissions will not be processed:

(insert number requested here) Vaccination record cards *providers may not exceed 50 cards per request*

Ship To:

Point of contact name:

Name of company:

Address line 1:

Address line 2:

City, State, Zip code:

The COVID-19 Vaccine Program suggests the following recommendations regarding record keeping:

- Designate an immunization staff member to answer immunization questions for staff and patients
- File patient records, keeping the immunization record and Patient Eligibility forms together
- Place immunization records at the front of each patient's chart and make immunizations a priority
- Encourage patients to bring their immunization records with them to facilitate complete documentation of previous immunization history



- If a patient presents with no immunization record, obtain the history through the Texas Immunization Registry (ImmTrac2), or call previous medical facility to obtain the history prior to administering the vaccine
- Empower all staff to become “Immunization Advocates” and have them assess each patient’s immunization status at every encounter
- Give a personal immunization record to each vaccine recipient showing the date (month, day, and year) of when each vaccine was administered

Copies of all DSHS documents must be maintained for five years and made available on request by the COVID-19 Vaccine Program.

F. Vaccine Transfers

Only enrolled COVID-19 Vaccine Program providers can transfer the COVID-19 vaccine to other enrolled COVID-19 Vaccine Program providers with prior approval from the DSHS Immunization Unit. Before requesting a transfer, verify that the facility you want to receive the vaccine is an approved COVID-19 Vaccine Provider. It is the responsibility of the Transferring Provider to ship or physically transport the vaccine while maintaining the cold chain. Transferring Providers are also responsible for any costs incurred in transferring vaccines. Providers are expected to include remaining ancillary supplies that were shipped with vaccine when transferring.

To transfer COVID-19 vaccine, a transfer requests must be completed in VAOS at <https://texasvaccines.dshs.texas.gov/> and include the upload of the completed CDC COVID-19 Vaccine Redistribution Agreement. To prepare for submitting a vaccine transfer request in VAOS, be sure to have the following information ready:

- Transferring Provider information (provider’s contact information)
- Receiving Provider Organization Name and PIN
- Reason for transfer



- Vaccine Type
- Lot ID for the vaccine that is being transferred
- Dose Quantity to transfer

After the request to transfer has been submitted and reviewed by DSHS staff, the requesting person and the Transferring Provider will receive an email notification once the request has been approved or denied. If the request is approved, the primary and backup vaccine coordinators at the Receiving Provider will also receive an email notification. Vaccine is **not** allowed to be transferred prior to receiving approval from DSHS Immunization Unit.

Cold Chain Management and Vaccine Transport

The COVID-19 Vaccine Program requires vaccines to be stored properly from the time they are manufactured until the time they are administered. The system used to maintain and distribute vaccines in optimal condition is called the cold chain.

Sufficient alternative space to store COVID-19 vaccines and maintain the cold chain during any period when the refrigerator or freezer is out of service must be identified. Adequate supplies for packing and transporting the entire COVID-19 vaccine supply/inventory must be available in case of an emergency. These packing supplies must be available to show during the COVID-19 Vaccine Program Clinic Site Visit.

Refrigerated Vaccine Packing Supplies

DSHS recommends transporting refrigerated vaccines with a portable refrigerator unit. If this type of unit is not available, a hard-sided insulated cooler with at least 2-inch walls, Styrofoam vaccine shipping container, or other qualified container may be used as long as it maintains the recommended temperature range (36°F to 46°F [2°C to 8°C]). Using a hard-sided cooler, Styrofoam vaccine shipping container, or other qualified



container requires the following:

- Coolers should be large enough to hold the COVID-19 supply of refrigerated vaccines
- Label the container with the facility name and “Fragile Vaccines – Do Not Freeze” and the date and time the vaccine was removed from the permanent storage unit

NOTE: Do not use soft-sided collapsible coolers for transporting vaccine.

- Conditioned frozen water bottles are required
- Use 16.9 oz. bottles for medium/large coolers and 8 oz. bottles for small coolers
- Before use, condition the frozen water bottles. This is done by placing them in a sink filled with several inches of cool or lukewarm water until there is a layer of water forming near the inner surface of the bottle. The bottle is properly conditioned when the ice block spins freely within the bottle when rotated

NOTE: Do not reuse coolant packs from original vaccine shipping containers.

- Insulating material – two each of the following layers is needed
- Corrugated cardboard – two pieces cut to fit the internal dimensions of the cooler(s) and placed between the insulating cushioning material and the conditioned water bottles
- Insulating cushioning material such as bubble wrap, packing foam, or Styrofoam for a layer at least 2-inches thick above and below the vaccines. Ensure this layer covers the cardboard completely

NOTE: Do not use packing peanuts or other loose material that may shift during transport.

- A data logger with a buffered probe must be used as a temperature



monitoring device

- Prepare the probe by pre-chilling it in the refrigerator for at least five hours prior to transport
- Ensure the data logger has a current and valid certificate of calibration testing
- Ensure the data logger certificate is documented to be accurate within $\pm 1^{\circ}\text{F}$ ($\pm 0.5^{\circ}\text{C}$)
- The data logger currently stored in the refrigerator can be used for transport, as long as there is a device in place to measure the temperature for remaining vaccines

Refrigerated Vaccine Packing for Transport

- Line the bottom of the cooler with a single layer of conditioned water bottles
- Place a sheet of corrugated cardboard over the water bottles
- Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the cardboard
- Stack boxes of vaccines on top of insulating material
- When cooler is halfway full, place the data logger buffered probe in the center of the vaccines, but keep the display outside the cooler
- Cover vaccines with another 2-inch layer of insulating material
- Add the second layer of corrugated cardboard
- Fill the remaining space in the cooler with conditioned water bottles
- Close the lid of the cooler securely and attach the data logger display and a temperature log to the top of the lid to record and monitor the temperature during transport



- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines are removed
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly
- As soon as the destination site is reached, check and record the vaccine temperature

As long as the vaccine temperature is 36°F to 46°F (2°C to 8°C), place the vaccine in the refrigerator.

If the vaccine is below 36°F (below 2°C) or above 46°F (above 8°C), place the vaccine in a quarantine bag in the refrigerator and immediately contact the vaccine manufacturer to determine viability.

Frozen Vaccine Packing Supplies

- Portable Freezer – DSHS recommends transport with a portable freezer
- Unit that maintains the temperature between -58°F and +5°F (-50°C and -15°C). Portable freezers may be available for rent. Label the portable freezer with the facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit
- Temperature Monitoring Device – Use a certified and calibrated data logger with a current and valid certificate of calibration testing. Prepare the data logger by placing it in a freezer unit at least two hours before packing the vaccine
- Cooler – If a portable freezer is unavailable, a hard-sided insulated cooler with at least 2-inch walls, a Styrofoam vaccine shipping container, or other qualified container may be used if temperatures between -58°F and +5°F (-50°C and -15°C) can be maintained. Label the container with the facility name and “Fragile Vaccines – Keep Frozen” and the date and time the vaccine was removed from the permanent storage unit.



- Use frozen water bottles in the cooler. Dry ice is not allowed to be used for transporting vaccines, even for temporary storage or emergency transport. Dry ice may allow the vaccine to be exposed to temperatures colder than -58°F (-50°C)

Frozen Vaccine Packing for Transport

- Line the bottom of the cooler with a single layer of frozen water bottles
- Place at least a 2-inch layer of insulating material (i.e., bubble-wrap, packing foam, or Styrofoam) over the frozen water bottles
- Stack boxes of vaccines and diluents on top of insulating material
- When the cooler is halfway full, place the data logger probe in the center of the vaccines, keeping the display out of the cooler
- Cover the vaccines with another 2-inch layer of insulating material
- Fill the remaining space in the cooler with frozen water bottles
- Close the lid of the cooler securely and attach the data logger
- Display and a temperature log to the top of the lid to record and monitor the temperature during transport
- Use the temperature recording form to record the time and temperature inside of the storage unit at the time the vaccines are removed
- If vaccines are kept in a transport container for longer than an hour, record the temperatures hourly
- As soon as the destination site is reached, check and record the vaccine temperature
- Place the vaccines in a freezer that maintains a temperature range between -58°F and $+5^{\circ}\text{F}$ (-50°C and -15°C)
- Document the time and temperature the vaccine was removed from the transport container and placed in the alternate storage unit
- Immediately contact the vaccine manufacturer for viability data and guidance when frozen vaccine has been exposed to a temperature above $+5^{\circ}\text{F}$ [-15°C]. Do not discard the vaccine without contacting the



manufacturer. Viability determination will be made on a case-by-case basis

G. Vaccine Management Plan - Routine and Emergency Storage and Handling

The most current Vaccine Management Plan for both Routine and Emergency Vaccine Storage and Handling will be reviewed during COVID-19 Compliance Site Visits and Unannounced Storage and Handling Visits. The documents must be posted on or near the refrigerator or freezer that contains COVID-19 vaccine. The clinic staff involved with vaccine management must be aware of this plan. The DSHS Vaccine Management Plan Template can be downloaded at:

<https://www.dshs.texas.gov/coronavirus/immunize/vaccine-manage-resources.aspx>.

Vaccine Protection in the Event of an Emergency

Staff at enrolled sites must be prepared to provide the following information during an emergency:

- The temperature of the vaccine
- Quantity of vaccine
- Expiration date(s) of the vaccine
- Amount of time the vaccine was exposed to inappropriate temperatures

The following information must be collected when transporting vaccine to an alternate location:

- Temperature of vaccine storage units before removing any vaccine for transportation
- Containers being used and how refrigerated vaccine will be packed for transportation (e.g., conditioned water bottles separated from the vaccine by layered packing materials to prevent freezing and damage)



- Whether a portable freezer or cooler will be used and what packing materials will be used
- Inventory of the vaccine as it is moved into the transport container, documenting the number of doses of each vaccine and the expiration dates. Use a Vaccine Transfer Authorization Form which must be submitted to the RE
- Ensure the Emergency Vaccine Storage and Handling Plan Checklist is available for documenting this process

H. Off-Site and Mass Vaccination Clinics

Off-site and mass vaccinations clinics may be set up for administering COVID-19 vaccines. Routine transport of vaccine is not allowed under the COVID-19 Program because doing so can also compromise the cold chain and vaccine viability. Off-site or mass vaccination clinics are not allowed to operate outside of their jurisdiction of the provider's main office (for example, an enrolled provider in San Antonio is not allowed to transport COVID-19 vaccine to Waco to conduct an off-site/vaccination clinic). Additionally, vaccine transported to an off-site clinic must be returned to the location where it was initially stored.

To ensure vaccine storage and handling for off-site/mass vaccination clinics is managed properly, the following storage and handling practices are recommended:

- COVID-19 vaccine must be properly transported, not shipped to the sites where the mass clinic will take place
- The total time for vaccine transport alone or vaccine transport plus clinic workday should not exceed maximum of eight (8) hours
- Only transport the number of vaccines appropriate for each clinic
- Vaccine should be transported to and from the scheduled clinic at appropriate temperatures to prevent compromising the cold chain and



vaccine viability

- The amount of vaccine being transported should be tracked to maintain accountability
- Upon arrival at the clinic, ensure vaccine is stored to maintain the appropriate temperature throughout the clinic day
- After each clinic day, a physical count of the remaining vaccine should be conducted, and assessment of temperatures performed prior to placing the vaccine back into the storage units to prevent inadvertent administration of the vaccine that may be compromised

Vaccines exposed to temperature excursions must be separated in a vaccine quarantine bag and labeled "Do Not Use" until further information can be gathered from the manufacturer(s). The vaccine should be kept at the appropriate temperatures until the viability determination is made.



SECTION FIVE: REPORTING REQUIREMENTS

A. Vaccine Adverse Events Reporting (VAERS)

Health care providers are required to report to the Vaccine Adverse Events Reporting (VAERS) any adverse events that occur after a COVID-19 vaccination, under Emergency Use Authorization (EUA), and other adverse events if later revised by CDC:

- Vaccine administration errors, regardless of association with an adverse event (AE)
- Serious AEs regardless of causality. Serious AEs are defined as:
 - Death
 - 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 judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for other clinically significant AE, even if unsure



whether a vaccine caused the AE. Complete and submit reports to VAERS online at <https://vaers.hhs.gov/reportevent.html>. For further assistance with reporting to VAERS, call 1-800-822-7967.

B. V-safe

V-safe is a smartphone-based tool which uses text messaging and web surveys to provide personalized health check-ins after a patient receives a COVID-19 vaccination. Providers are encouraged to share information about v-safe with vaccine recipients. Through v-safe, the vaccine recipient or provider can quickly tell CDC if the patient has had any side effects after getting the COVID-19 vaccine. Depending on the answers, someone from CDC may call to check on the patient and get more information. V-safe will remind the patient to get their second COVID-19 vaccine dose if one is needed.

Provider and patient participation in CDC's v-safe make a difference — it helps keep COVID-19 vaccines safe. For more information on v-safe, visit <https://vsafe.cdc.gov>.

C. Reporting to ImmTrac2

[Texas Health and Safety Code Sec. 161.00705](#) states any antiviral, immunization, or medication administration in response to a declared disaster or emergency must be entered in ImmTrac2. Therefore, persons receiving the COVID-19 vaccine are not required to consent to ImmTrac2. Providers are required to document doses administered into ImmTrac2 within 72 hours of administration. For more information on reporting COVID-19 vaccine in ImmTrac2, see the ImmTrac2 disaster reporting training.



SECTION SIX: BILLING/ADMINISTRATION FEE

Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers may be able to charge administration fees for giving the shot. Vaccination providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund. Providers are not allowed to receive cash donations on behalf of vaccine recipients. Please see their website for additional information on vaccine administration fee reimbursements at <https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html>.

SECTION SEVEN: PROGRAM EVALUATION

A. Standards for Adult Immunization Practice

The National Vaccine Advisory Committee (NVAC) revised the Standards for Adult Immunization Practice in 2013. These updated Standards call on **ALL** healthcare professionals – whether they provide vaccinations or not – to take steps to help ensure that their adult patients are fully immunized.

- I. ASSESS** immunization status of all your patients at every clinical encounter.
 - Stay informed. Get the latest CDC recommendations for immunization of adults
 - Implement protocols and policies. Ensure that patients' vaccine needs are routinely reviewed, and patients get reminders about vaccines they need
- II.** Strongly **RECOMMEND** vaccines that patients need.
 - Share tailored reasons why vaccination is right for the patient
 - Highlight positive experiences with vaccination
 - Address patient questions and concerns



- Remind patients that vaccines protect them and their loved ones against a number of common and serious diseases
- Explain the potential costs of getting sick

III. ADMINISTER or REFER your patients to a vaccination provider.

- Offer the vaccines you stock
- Refer patients to providers in the area that offer vaccines you don't stock

IV. DOCUMENT vaccines received by your patients.

- Participate in the Texas Immunization Registry, ImmTrac2. Help your office, your patients, and your patients' other providers know which vaccines your patients have received
- Follow up. Confirm that patients received recommended vaccines that you referred them to get from other immunization providers

B. Clinic Site Visits

The DSHS Immunization Unit is required by the Centers for Disease Control and Prevention (CDC) to conduct COVID-19 vaccine site visits to assure vaccine quality, safe administration to include storage and handling practices, and support in areas of need that are identified during the site visit. The goal of DSHS is to partner with you and provide guidance for safe and effective COVID-19 vaccination practices, through:

- Assessment of your adherence to the COVID-19 Vaccine Program requirements and recommendations
- Identify and address areas where you are doing well and areas needing additional follow-up
- Identify and address your educational needs to help meet program requirements
- Ensure vaccine recipients are receiving properly managed and viable



vaccine

- Ensure that vaccine is distributed according to jurisdictional priorities and ensuring equity in distribution

Prioritization of site visits will be determined based on providers who have vaccine in their inventory. Those who are selected for a site visit will be contacted by a DSHS representative 2-3 weeks in advance to schedule the site visit date and time. The site visit may take up to 4 hours to be completed.

Below is additional guidance that will assist your team in preparing for the site visit:

Who should be present for the visit?

- At least one of the following individuals from your COVID-19 Vaccine Program Provider Agreement:
 - Chief Medical Officer/Chief Executive Officer
 - Primary Vaccine Coordinator
 - Back-Up Vaccine Coordinator

What should you prepare prior to the site visit?

- Have all current COVID-19-related documents, including:
 - COVID-19 Vaccine Program Provider Agreement
 - Data logger temperature report
 - Data logger certificates of calibration
- Internet access with video capability on your computer, tablet, or smartphone for a video conference with your assigned COVID-19 Vaccine Program state representative.



During a COVID-19 vaccine site visit, the reviewer will need access to the following:

- Space to work
- Power source
- Internet connectivity (if available)
- Access to patient records
- Temperature logs/reports or data for the last three months, or longer if deficiencies are found
- Circuit breaker
- Admitting and billing personnel to clarify eligibility screening and billing processes, and
- All vaccine storage units where COVID-19 vaccine is stored

Follow-Up Activities

Upon completion of the site visit, the reviewer will discuss the outcomes of the visit with the vaccine coordinator. The discussion will include a review of the site visit findings and a formal follow-up plan with a timeline that addresses issues of non-compliance or opportunities for improvement.

The vaccine coordinator must sign an Acknowledgement of Receipt (AR) following the visit. The AR is the document that attests to the fact that a site visit was completed, the results of the visit were received, and that both the reviewer and the vaccine coordinator understand all non-compliance issues identified and the actions necessary to address them.

The RE will conduct all required follow-up activities. The purpose of follow-up activities is to ensure that areas for improvement identified by the RE or DSHS contractor are understood by the site's staff and corrective actions



have been identified and implemented. Follow-up activities are conducted as necessary to address all issues and are dependent upon the severity of the non-compliance issues and the follow-up action plan.

Follow-up activities can include, but are not limited to the following:

- Visiting the clinic to observe corrective actions
- Calling the vaccine coordinator at the clinic
- Sending a letter to address the deficient items identified during the site visit; and
- Determining the staff's compliance with the corrective action plans, if applicable

The RE works with clinic staff on non-compliance issues by providing education and guidance regarding corrective actions, including monitoring. If a site exhibits habitual non-compliance and does not follow corrective actions in response to education, the vaccine ordering privileges may be suspended. If non-compliance continues, termination from the COVID-19 Vaccine Program may be implemented.



SECTION EIGHT: FRAUD AND ABUSE

I. Fraud and Abuse

As the complexity of immunizations and immunization programs grow, sites enrolled in COVID-19 Vaccine Program may become more vulnerable to unintentionally committing fraud and/or abuse. Fraud and abuse, whether intentional or not, is subject to all federal fraud and abuse laws.

II. Definitions

A working understanding of what constitutes fraud and abuse is critical for all persons working in the COVID-19 Vaccine Program. The following are definitions of terms related to fraud and abuse:

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

Abuse - Practices that are inconsistent with sound fiscal, business, or medical practices and result in an unnecessary cost to the Medicaid Program (and/or including actions that result in an unnecessary cost to the COVID-19 Vaccine Program, a health insurance company, or a patient) or in reimbursement for services that are not medically necessary, or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary costs to the Medicaid Program.

Oversight - The act of training, monitoring, and providing assistance to clinic staff on COVID-19 Vaccine Program policies and procedures.

Enforcement - Identifying rule and policy violations and ensuring corrective action is taken.

Termination - Action taken when a site or signing authority is no longer eligible for the COVID-19 Vaccine Program due to fraud, abuse, or non-



compliance.

Waste - The careless, inefficient, or unnecessary use of COVID-19 Vaccine Program resources.

III. Examples

Fraud or abuse can occur in many ways. Some types of fraud and abuse are easier to prevent or detect than others. All staff at COVID-19 Vaccine Program enrolled sites should familiarize themselves with the examples below, as they illustrate common practice errors that could result in fraud or abuse allegations. This list provides examples only and should not be considered an exhaustive list of situations that would constitute fraud or abuse.

- Provide COVID-19 vaccine to ineligible patient
- Sell or otherwise misdirect COVID-19 vaccine
- Bill a patient or third party for COVID-19 vaccine (other than administration fees)
- Failure to meet licensure requirements for enrolled clinicians
- Send a patient, parent, or guardian to collections or charge additional fees for non-payment of the administration fee
- Failure to implement COVID-19 Vaccine Program enrollment requirements
- Failure to screen and document COVID-19 Vaccine eligibility at every visit
- Failure to maintain COVID-19 vaccine records for five years
- Failure to fully account for COVID-19 vaccine
- Failure to properly store and handle COVID-19 vaccine
- Order COVID-19 vaccine in quantities or patterns that do not match



population profile or otherwise involve over-ordering of COVID-19 doses, and

- Loss of COVID-19 vaccine due to negligence

IV. Fraud and Abuse Prevention

The COVID-19 Vaccine Program actively works with enrolled clinics to help prevent fraud and abuse in the COVID-19 Vaccine Program. The best methods to prevent fraud and abuse are strong educational components discussed during the initial enrollment process and during the COVID-19 vaccine site visits. Both occasions provide the opportunity to identify and prevent situations that may develop into fraud and abuse.

Reporting Fraud and Abuse

Suspected fraud or abuse can be reported to the COVID-19 Vaccine Program via email, telephone, fax, or letter. Furthermore, newspaper articles and internet pages that indicate potential fraudulent situations are also investigated.

The DSHS COVID-19 Vaccine Program site reviewers must report all cases of alleged or suspected fraud or abuse. Reports received by the DSHS Immunization Unit in any form that merit further investigation may be referred to the Centers for Medicare and Medicaid Services (CMS), Medicaid Integrity Group (MIG) Field Office. The state Medicaid agency will conduct preliminary investigations and, as warranted, refer appropriate cases to the state's Medicaid Fraud Control Unit following the Federal Regulatory scheme at 42 CFR section 455.15 and 42 CFR section 455.23.



SECTION NINE: IMMUNIZATION RESOURCES

Adult Safety Net (ASN) Website

www.dshs.texas.gov/immunize/ASN/

- CDC Immunization Website

www.cdc.gov/vaccines/

- CDC Immunization Schedules

www.cdc.gov/vaccines/schedules/index.html

- CDC Vaccine Storage and Handling Toolkit

www.cdc.gov/vaccines/hcp/admin/storage/toolkit/

- CDC "You Call the Shots" Training

www.cdc.gov/vaccines/ed/youcalltheshots.html

- ImmTrac2, the Texas Immunization Registry

www.dshs.texas.gov/immunize/immtrac/default.shtm

- Immunization Action Coalition

www.immunize.org/

- Standards for Adult Immunization Practice

www.cdc.gov/vaccines/hcp/adults/for-practice/standards/

- Texas DSHS Immunization Website

www.dshs.texas.gov/immunize