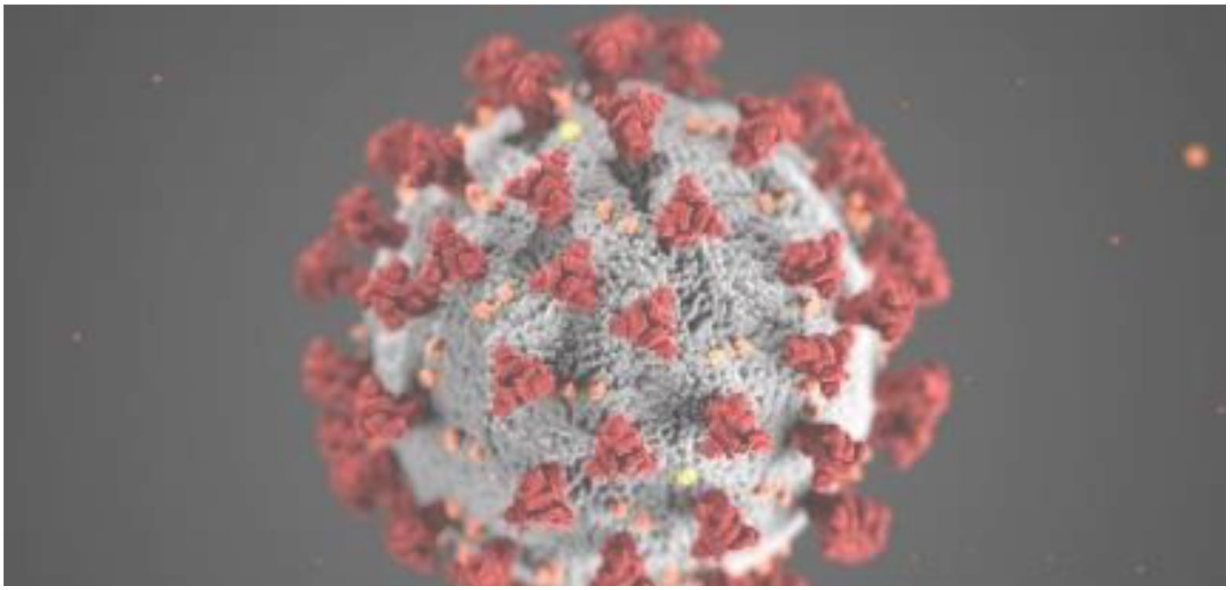
TEXAS Health and Human Services | Texas Department of State Health Services

TEXAS COVID-19 PROVIDER MANUAL



VERSION 1.0

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 Vaccination 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 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, DSHS Immunization Unit will publish policy information on DSHS website 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), and
- Registered Pharmacists (RPh).

They must have an Individual National Provider Identification Number (NPI), and they must register though the EnrollTexasIZ.dshs.texas.gov web site. The EnrollTexasIZ site has detailed information on the registration process and requirements. For questions about registration, please call the DSHS COVID-19 Vaccine Provider hotline at (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or email COVID19VacEnroll@dshs.texas.gov.

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 Address,

- Facility Phone Number,
- Facility Fax Number,
- Facility Point of Contact and Primary Registry Point of Contact,
    - First Name, Last Name, Phone Numbers, and a unique email address.
- Responsible Medical Professional,
    - 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), and
- Storage capacity (refrigerated/frozen/ultra-cold).

As part of the enrollment process, providers will be required to register with Texas' Immunization Registry, ImmTrac2. If the enrolling provider already has an ImmTrac2 Org Code, this information will prepopulate in the enrollment form. Upon completion of the enrollment, providers will be assigned a six-digit provider identification number (PIN). **It is important that this number be kept near the provider for ordering and for reporting vaccines administered** as 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.

B. Specific Terms of the Agreement

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

- Administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC's 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.
- Will 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).
- Prior to administering COVID-19 vaccine, providers must provide an approved Emergency Use Authorization (EUA) fact sheet to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
- 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 vaccines.[3]
- Comply with DSHS Immunization Unit requirements for COVID-19 vaccine management. Those requirements include:
    - Proper storage and handling;[4]
    - Monitoring of vaccine storage unit temperatures;[4]

[1] https://www.cdc.gov/vaccines/hcp/acip-recs/index.html
[2] https://www.cdc.gov/vaccines/programs/iis/index.html
[3] https://www.cdc.gov/vaccines/pandemic-guidance/index.html

  - Comply with the guidance to handling temperature excursions;[4]
  - Monitor and comply with COVID-19 vaccine expiration dates; and
  - Maintain all COVID-19 records for a minimum of three (3) years.
- Report the number of doses of COVID-19 vaccine and adjuvants that were 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 doses.[5]
- 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.

More information can be found on 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-enrolled site to maintain correct demographics, days and hours available to receive vaccine

[4] https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html
[5] The disposal process for remaining unused COVID-19 vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in CDC's Vaccine Storage and Handling Toolkit until CDC provides disposal instructions; website URL will be made available.
[6] https://vaers.hhs.gov/reportevent.html

shipments, and profile information in Vaccine Allocation and Ordering System (VAOS). For changes to provider information please contact the DSHS COVID-19 Vaccine Helpdesk via email COVID19VacEnroll@dshs.texas.gov. Emails must include:

- Facility Name and address
- ImmTrac2 Org Code

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

Enrollment 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 Approval

Contact the COVID-19 Vaccine Helpdesk toll-free at (877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or email COVID19VacEnroll@dshs.texas.gov to have your enrollment unlocked to make the updates. You must provide your site name (including address) and your ImmTrac2 Org Code.

Enrollment Approved

Complete the Patient Population Adjustment Form as accurately as possible on DSHS website https://www.dshs.texas.gov/coronavirus/immunize/provider-enrollment.aspx and email it to COVID19VacEnroll@dshs.texas.gov including 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 request an update to the population with website administrator.

D. Vaccine Coordinators Responsibilities

The COVID-19 Vaccination Program requires the vaccine coordinator be the Point of Contact (POC) for receiving vaccine shipments, monitoring storage

unit temperatures, managing vaccine inventory, responding to DSHS inquiries, etc.

- Set up data loggers in storage units.
- Ensure staff are familiar with the operations of the data loggers including how to download the data (recommended weekly, on Mondays).
- Monitor and record the temperatures of units (refrigerator and freezer) two times each workday.
- Read and record the minimum and the maximum temperatures at the beginning of each workday.
- Reset the minimum and maximum temperatures at the end of each workday.
- Monitor the operation of storage equipment and systems.
- Maintain all documentation, such as vaccine inventory and temperature logs.
- Document COVID-19 vaccine inventory information.
- Place orders for additional COVID-19 vaccine in VAOS.
- Track and document doses administered.
- Oversee proper receipt and storage of vaccines deliveries.
- Organize vaccines to monitor expiration dates.
- Ensure vaccine is stored and handled appropriately to safeguard vaccine viability.
- Respond to out-of-range temperature excursions and notify DSHS Immunization Unit.
- Notify 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 CDC's "You Call the Shots Module 10 – Storage and Handling", located on CDC's

website, 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 three (3) year record retention policy for COVID-19 vaccine.

F. Withdrawing from the COVID-19 Program

Facilities that wish to discontinue as a COVID-19 provider will need to submit an official request in writing. The notice must be signed by the Chief Executive Officer (CEO) or the Chief Medical Officer (CMO) and emailed to COVID19VacEnroll@dshs.texas.gov. The email must state that the facility is electing to have their enrollment withdrawn. Sending this email 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.

SECTION THREE: COVID-19 VACCINE OVERVIEW

In the United States, the federal government's Operation Warp Speed (OWS) has contracted with six different 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.

Manufacturer	Doses needed	Timing	Storage/Handling
Moderna	2	0, 28 days	Frozen 30 days refrigerated
Pfizer/BioNTech	2	0, 21 days	Ultra-Cold Frozen 5 days refrigerated
AstraZeneca/Oxford	2	0, 28 days	Refrigerated
Novavax	2	0, 21 days	Refrigerated
Sanofi/GSK	2	TBD	Refrigerated
Johnson/Johnson & Johnson	1	N/A	Frozen 3 months refrigerated

Table 3.1

Table 3.1 above shows COVID-19 vaccines currently being produced by manufacturers. However, Moderna and Pfizer/BioNTech are the only vaccines that have been approved for emergency use. As additional vaccines are released for use, this manual will be updated to include more information.

In addition to the vaccine, OWS will ship the following ancillary supplies per 100 doses of the order.

- 105 needles for vaccine administration
- 105 syringes
- 210 alcohol prep pads

- 4 surgical masks and 2 face shields
- 100 COVID-19 vaccination record cards
- Vaccine needle guide
- Reconstitution Kit with necessary supplies for vaccines requiring dilution

Each vaccine has unique storage requirements ranging from ultra-cold (-70°C/-90°F) to refrigerated (2-8°C/35-40°F). See *Table 3.2.*

Manufacturer	Storage/Handling
Moderna	Frozen (-20°C/-4°F) 30 days refrigerated (2-8°C/35-40°F)
Pfizer/BioNTech	Ultra-Cold Frozen (-70°C/-90°F) 5 days refrigerated (2-8°C/35-40°F)
AstraZeneca/Oxford	Refrigerated (2-8°C/35-40°F)
Johnson/Johnson & Johnson	Frozen(-20°C/-4°F) 3 months refrigerated (2-8°C/35-40°F)
Novavax	Refrigerated (2-8°C/35-40°F)
Sanofi/GSK	Refrigerated (2-8°C/35-40°F)

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".

CDC has also published several resources for providers that are available on their website. To get more resources for training your staff, educating your patients, or frequently asked questions see the CDC website at https://www.cdc.gov/vaccines/covid-19/hcp/faq.html.

Determining Vaccine Administration Priority / Patient Eligibility and Patient Rights

Phase 1A

Protecting health care workers is essential to keeping the health care system intact and able to care for COVID-19 and other patients, so phase 1A of vaccine distribution, when the vaccine supply is most limited, will focus on making vaccine available to health care workers. To support this distribution, the Expert Vaccine Allocation Panel (EVAP) has recommended, and Dr. Hellerstedt has approved, a tiered definition of health care workers specific to Phase 1A. During this phase, the EVAP will make recommendations based on the priority order in the Health Care Workers definition.

On Dec. 4, following guidance issued by the CDC's Advisory Committee on Immunization Practices, Dr. Hellerstedt approved the EVAP's recommendation to include residents of long-term care facilities in the first tier of Phase 1A so they can be among the first Texas residents to receive the COVID-19 vaccine.

Phase 1A: Health Care Workers Definition

First Tier

1. Paid and unpaid workers in hospital settings working directly with patients who are positive or at high-risk for COVID-19. Such as but not limited to:
    a. Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.),
    b. Additional clinical staff providing supporting laboratory, pharmacy, diagnostic and/or rehabilitation services, and
    c. Others having direct contact with patients or infectious materials.

2. Long-term care staff working directly with vulnerable residents. Includes:
   a. Direct care providers at nursing homes, assisted living facilities, and state supported living centers.
   b. Physicians, nurses, personal care assistants, custodial, food service staff.
3. EMS providers who engage in 9-1-1 emergency services like pre-hospital care and transport.
4. Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients.
5. Residents of long-term care facilities.

Second Tier

1. Staff in outpatient care settings who interact with symptomatic patients. Such as but not limited to:
   a. Physicians, nurses, and other support staff (custodial staff, etc.),
   b. Clinical staff providing diagnostic, laboratory, and/or rehabilitation services.
   c. Non-9-1-1 transport for routine care, and
   d. Health care workers in corrections and detention facilities.
2. Direct care staff in freestanding emergency medical care facilities and urgent care clinics.
3. Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individuals who may have COVID-19 infection.
4. Public health and emergency response staff directly involved in administration of COVID-19 testing and vaccinations.

5. Responders who provide mortuary or death services to decedents with COVID-19. Includes:
   a. Embalmers and funeral home workers who have direct contact with decedents, and
   b. Medical examiners and other medical certifiers who have direct contact with decedents.
6. School nurses who provide health care to students and teachers.

For more information visit CDC's website https://www.cdc.gov/vaccines/covid-19/implementation-strategies.html.

Important Information for Vaccine Administration

Prescreening 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 prescreening 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.

I. Pfizer-BioNTech COVID-19 Vaccine Overview

General Information

Diluent: 0.9% sodium chloride (normal saline, preservative-free), multi-dose vial: 5 doses per vial, dosage: 0.3 mL.

Age Indications: 16 years of age and older.

Schedule: 2-dose series separated by 21 days. Both doses must be the same COVID-19 vaccine (Pfizer).

Administer: Intramuscular (IM) injection in the deltoid muscle.

Storage and Handling

- 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. A signature will be required when the vaccine is delivered.
- The diluent and ancillary supply kits will arrive separately from the vaccine.
- Unpack the thermal shipping container following the manufacturer's direction.

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 or see Figure 4.1.

II. Moderna Vaccine Overview

General Information

Multidose vial: 10 doses per vial, dosage: 0.5 mL.

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.

Administer: Intramuscular (IM) injection in the deltoid muscle.

Storage and Handling

- The vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F). A signature will be required when the vaccine is delivered.
- The ancillary supply kit will arrive separately from the vaccine.
- Unpack shipment following the manufacturer's direction.

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.

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SECTION FOUR: VACCINE MANAGEMENT

I. Vaccine Allocation & Ordering

COVID-19 vaccine is ordered through VAOS after registration and approval is complete. If you do not receive your vaccine shipment, please contact us at COVID19VacEnroll@dshs.texas.gov and DSHS Immunization will investigate and provide a response and/or update. Please include your six-digit PIN and facility name in the email.

A. Vaccine Allocation

To deploy the vaccine effectively as possible, DSHS has created an Expert Vaccine Allocation Panel (EVAP) to make recommendations on vaccine allocation decisions; including identifying groups that should be vaccinated first to provide the most protection to vulnerable populations, and critical state infrastructure. The panel has recommended and the Commissioner of Health John Hellerstedt, MD, has approved the following guiding principles that provide the foundation for the Texas vaccine allocation process.

Vaccine Allocation Guiding Principles

Texas will allocate COVID-19 vaccines in limited supply based on:

- **Protecting health care workers** who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the health care infrastructure for all who need it.
- **Protecting front-line workers** who are at greater risk of contracting COVID-19 due to the nature of their work providing critical services and preserving the economy.
- **Protecting vulnerable populations** who are at greater risk of severe disease and death if they contract COVID-19.

- **Mitigating health inequities** due to factors such as demographics, poverty, insurance status, and geography.
- **Data-driven allocations** using the best available scientific evidence and epidemiology at the time, allowing for flexibility for local conditions.
- **Geographic diversity** through a balanced approach which considers access in urban and rural communities in addition to affected ZIP codes.
- **Transparency** through sharing allocations with the public and seeking public feedback.

Initial Vaccine Allocation

Initial vaccine allocations are received after completion of the pandemic provider registration. Allocations are given based on the provider population that was entered in the registration. Once allocations are received, it is the responsibility of the provider to accept them in VAOS. Notifications and tracking information will be sent after doses have been shipped. The notification will be sent via email from CDCCustomerService@McKesson.com. The notification will contain information about the vaccine shipment, including the specific vaccine, quantity ordered, and the tracking number. The provider will receive a separate notification for each vaccine cooler (box) in the shipment, as each cooler (box) has its own unique tracking number.

II. 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 VAOS. Appropriate staff must be on site and available to receive vaccine shipments. Each site

establishes the hours available to accept vaccine shipments during the completion of the COVID-19 Vaccine Program Enrollment. Vaccine delivery MUST include at least one (1) weekday other than a Monday, which has a four (4) hour designated window for delivery of your vaccine shipment (e.g., Thursday, 8 a.m. to 12 p.m.). The staff at the COVID-19 enrolled site may not change available hours in VAOS once an order is placed. The signing clinician is responsible for incomplete or erroneous information entered in VAOS which can result in vaccine loss.

Sites will receive an allocation notification when they are slotted to receive vaccines. The shipment of COVID-19 vaccines may vary depending on if the allocation is for the first or second dose. The shipment should occur within approximately two weeks of receiving the allocation notification. Once shipment is initiated by DSHS, VAOS will send a shipment notification to the provider; however, there is not a significant amount of lead time between this notification and receipt. 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.

For questions, please call the DSHS COVID-19 Vaccine Provider toll-free hotline at (877) 835-7750, or email COVID19VacEnroll@dshs.texas.gov. 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 and Moderna 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 and then contact DSHS Immunization as well, to ensure their replacement order is tracked and input into VAOS for inventory reasons. Providers are required to enter the number 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.

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 questionable (potentially non-viable 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.
- Vaccine is received damaged.

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

	Moderna COVID-19 Vaccine	Pfizer 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.	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.

	Moderna COVID-19 Vaccine	Pfizer COVID-19 Vaccine
2	Separate the questionable vaccine in a vaccine quarantine bag and place the questionable vaccines in the freezer, until viability can be determined. Do not write on the vaccine itself.	Separate the questionable vaccine until viability can be determined. Do not write on the vaccine itself.
3	Contact McKesson at **1-833-343-2703** to report the Moderna vaccine temperature excursion.	Contact Pfizer at **1-800-438-1985** to report the 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.
5	Inform DSHS of the vaccine temperature excursion at 1-877-835-7750 or COVID19VacEnroll@dshs.texas.gov.	Inform DSHS of the vaccine temperature excursion at 1-877-835-7750 or COVID19VacEnroll@dshs.texas.gov.

I. 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.

II. Storage and Handling Requirements

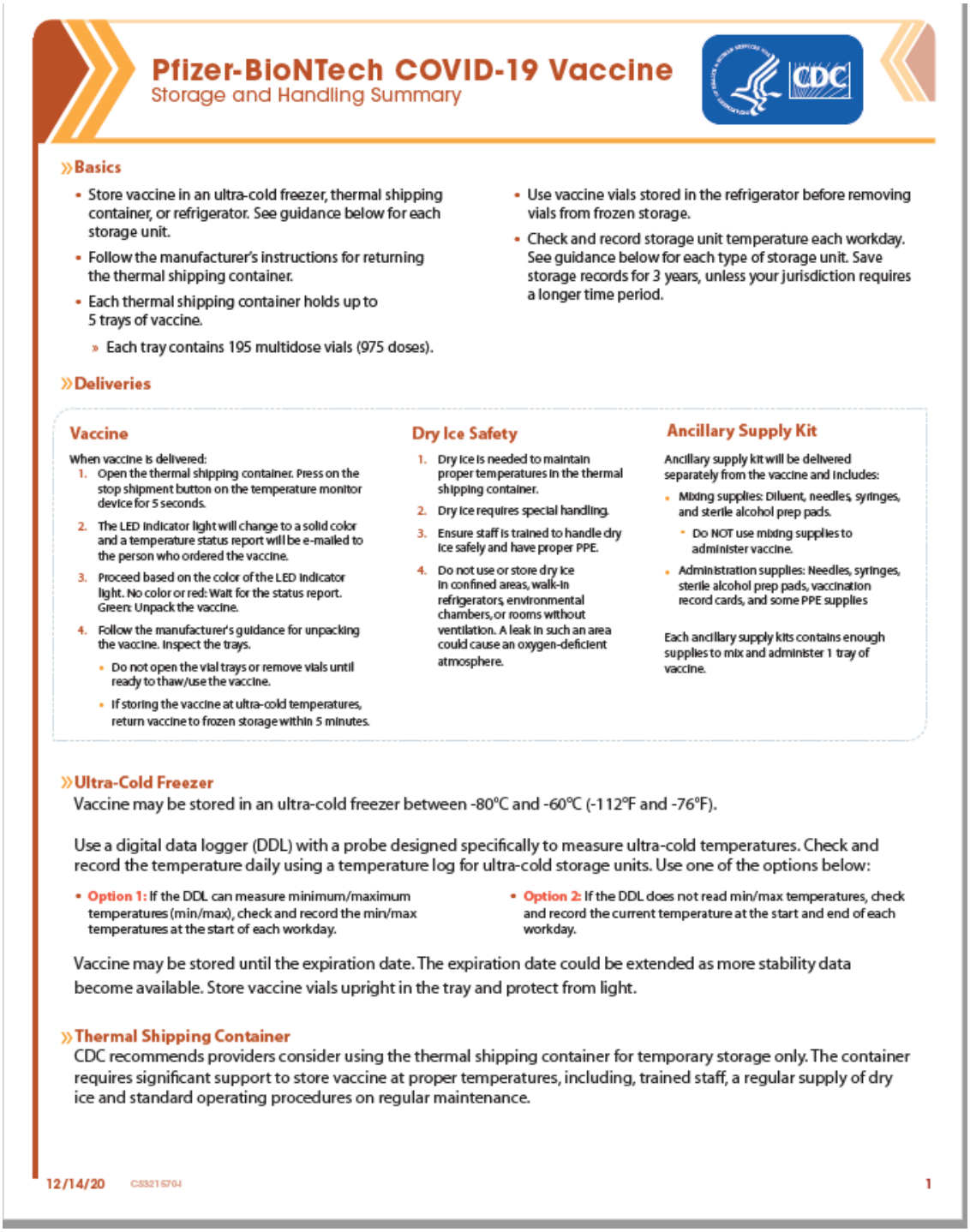
Storage Unit Requirements

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, and 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.

The DSHS Immunization Unit recommends 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 is strongly encouraged to obtain a stand-alone freezer. Refrigerated vaccine is to be stored in the household unit and frozen vaccine will be stored in the stand-alone freezer.
- Combination units, if used to store both refrigerated and frozen vaccine, must have separate thermostats for each compartment.
- Dorm-style and small combination refrigerator and freezer units with a single external door are never allowed for the storage of COVID-19 vaccine.

Each vaccine requires different processes for storage and handling. See Figure 4.1 for storage and handling summary of Pfizer COVID-19 vaccine and Figure 4.2 for a storage and handling summary of the Moderna vaccine.



Pfizer-BioNTech COVID-19 Vaccine
Storage and Handling Summary

Basics

- Store vaccine in an ultra-cold freezer, thermal shipping container, or refrigerator. See guidance below for each storage unit.
- Follow the manufacturer's instructions for returning the thermal shipping container.
- Each thermal shipping container holds up to 5 trays of vaccine.
  - Each tray contains 195 multidose vials (975 doses).
- Use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- Check and record storage unit temperature each workday. See guidance below for each type of storage unit. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

Deliveries

Vaccine

When vaccine is delivered:

1. Open the thermal shipping container. Press on the stop shipment button on the temperature monitor device for 5 seconds.
2. The LED indicator light will change to a solid color and a temperature status report will be e-mailed to the person who ordered the vaccine.
3. Proceed based on the color of the LED indicator light. No color or red: Wait for the status report. Green: Unpack the vaccine.
4. Follow the manufacturer's guidance for unpacking the vaccine. Inspect the trays.
   - Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
   - If storing the vaccine at ultra-cold temperatures, return vaccine to frozen storage within 5 minutes.

Dry Ice Safety

1. Dry ice is needed to maintain proper temperatures in the thermal shipping container.
2. Dry ice requires special handling.
3. Ensure staff is trained to handle dry ice safely and have proper PPE.
4. Do not use or store dry ice in confined areas, walk-in refrigerators, environmental chambers, or rooms without ventilation. A leak in such an area could cause an oxygen-deficient atmosphere.

Ancillary Supply Kit

Ancillary supply kit will be delivered separately from the vaccine and includes:

- Mixing supplies: Diluent, needles, syringes, and sterile alcohol prep pads.
  - Do NOT use mixing supplies to administer vaccine.
- Administration supplies: Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE supplies

Each ancillary supply kits contains enough supplies to mix and administer 1 tray of vaccine.

Ultra-Cold Freezer

Vaccine may be stored in an ultra-cold freezer between -80°C and -60°C (-112°F and -76°F).

Use a digital data logger (DDL) with a probe designed specifically to measure ultra-cold temperatures. Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- **Option 1:** If the DDL can measure minimum/maximum temperatures (min/max), check and record the min/max temperatures at the start of each workday.
- **Option 2:** If the DDL does not read min/max temperatures, check and record the current temperature at the start and end of each workday.

Vaccine may be stored until the expiration date. The expiration date could be extended as more stability data become available. Store vaccine vials upright in the tray and protect from light.

Thermal Shipping Container

CDC recommends providers consider using the thermal shipping container for temporary storage only. The container requires significant support to store vaccine at proper temperatures, including, trained staff, a regular supply of dry ice and standard operating procedures on regular maintenance.

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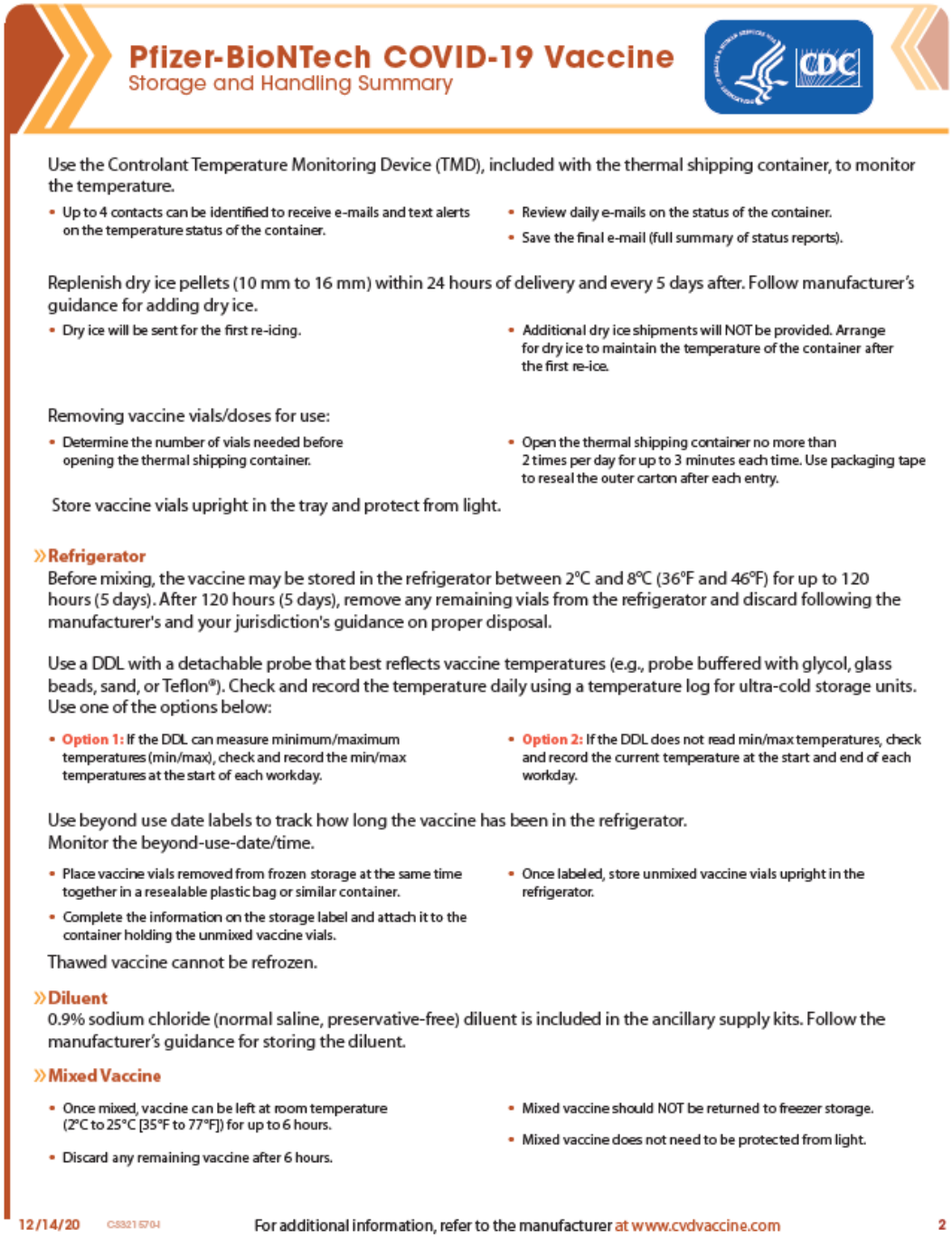
4.1



Pfizer-BioNTech COVID-19 Vaccine
Storage and Handling Summary

Use the Controlant Temperature Monitoring Device (TMD), included with the thermal shipping container, to monitor the temperature.

- Up to 4 contacts can be identified to receive e-mails and text alerts on the temperature status of the container.
- Review daily e-mails on the status of the container.
- Save the final e-mail (full summary of status reports).

Replenish dry ice pellets (10 mm to 16 mm) within 24 hours of delivery and every 5 days after. Follow manufacturer's guidance for adding dry ice.

- Dry ice will be sent for the first re-icing.
- Additional dry ice shipments will NOT be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

Removing vaccine vials/doses for use:

- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than 2 times per day for up to 3 minutes each time. Use packaging tape to reseal the outer carton after each entry.

Store vaccine vials upright in the tray and protect from light.

»Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days). After 120 hours (5 days), remove any remaining vials from the refrigerator and discard following the manufacturer's and your jurisdiction's guidance on proper disposal.

Use a DDL with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log for ultra-cold storage units. Use one of the options below:

- **Option 1:** If the DDL can measure minimum/maximum temperatures (min/max), check and record the min/max temperatures at the start of each workday.
- **Option 2:** If the DDL does not read min/max temperatures, check and record the current temperature at the start and end of each workday.

Use beyond use date labels to track how long the vaccine has been in the refrigerator. Monitor the beyond-use-date/time.

- Place vaccine vials removed from frozen storage at the same time together in a resealable plastic bag or similar container.
- Once labeled, store unmixed vaccine vials upright in the refrigerator.
- Complete the information on the storage label and attach it to the container holding the unmixed vaccine vials.

Thawed vaccine cannot be refrozen.

»Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

»Mixed Vaccine

- Once mixed, vaccine can be left at room temperature (2°C to 25°C [35°F to 77°F]) for up to 6 hours.
- Mixed vaccine should NOT be returned to freezer storage.
- Mixed vaccine does not need to be protected from light.
- Discard any remaining vaccine after 6 hours.

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4.1 (continued)

Moderna COVID-19 Vaccine

Storage and Handling Summary

Basics

- Store vaccine in a freezer or refrigerator. See guidance below for each storage unit.
- Each box contains 10 multidose vials (100 doses).
- Use vaccine vials stored in the refrigerator before removing vials from frozen storage.
- This vaccine does not need to be mixed with a diluent before administration.
- Check and record storage unit temperature each workday. See guidance below for each type of temperature monitoring device. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

Deliveries

Vaccine

1. The vaccine will arrive frozen between -25°C and -15°C (-13°F and 5°F).
2. Examine the shipment for signs of damage.
3. Open the box and remove TagAlert Temperature Monitor from box (placed in the inner box next to vaccine).
4. Check the TagAlert temperature monitoring device by pressing the blue "start and stop" button.
   - Left arrow points to a **green checkmark:** The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
   - Right arrow points to a **red X:** The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label **DO NOT USE!** Call the phone number indicated in the instructions or your jurisdiction's immunization program **IMMEDIATELY!**

Ancillary Supply Kit

An ancillary supply kit will be provided for administering the vaccine and includes enough supplies to administer 100 doses of vaccine.

Administration supplies include needles, syringes, sterile alcohol prep pads, vaccination record cards (shot cards), and some PPE.

The kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities.

Freezer

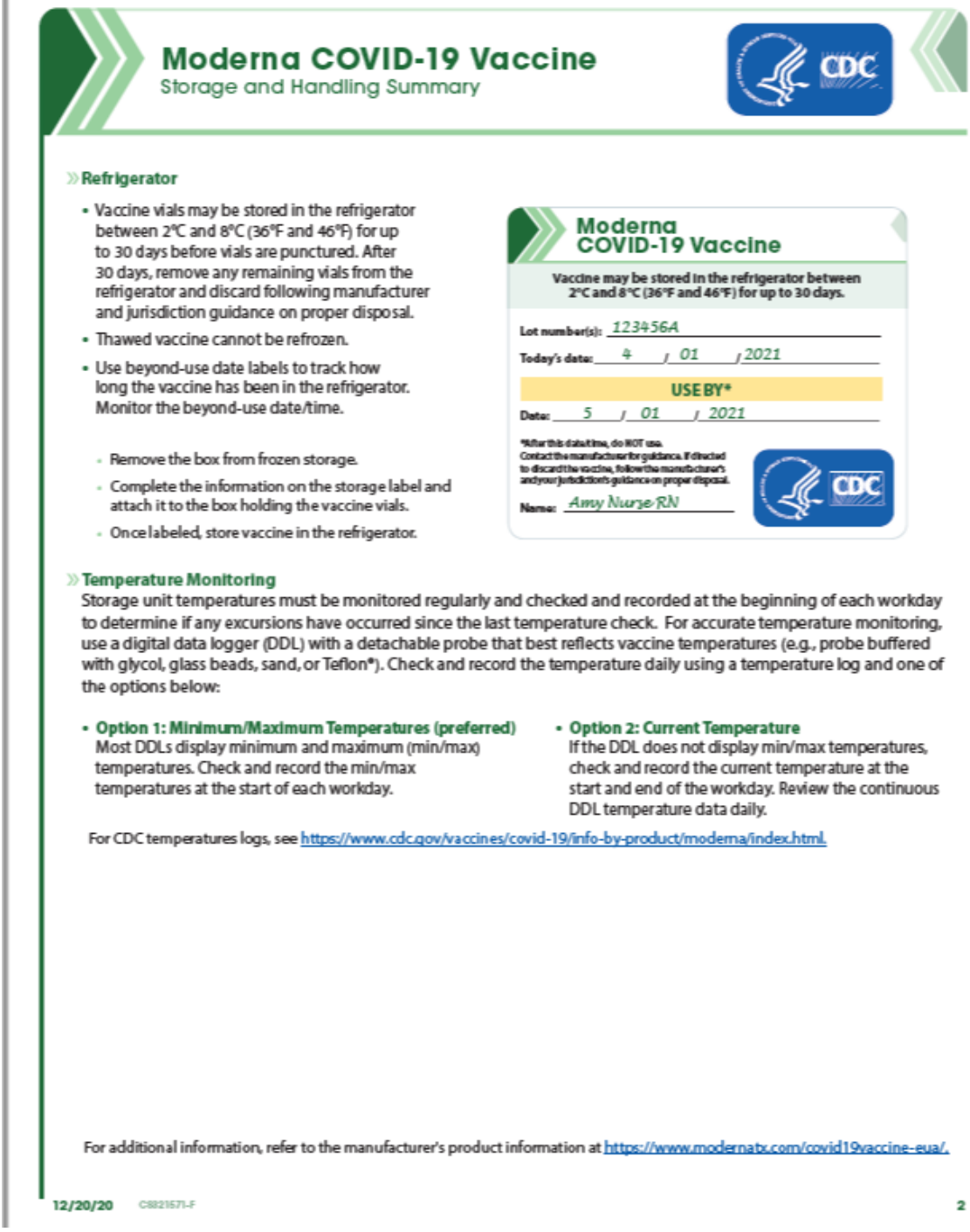
Vaccine may be stored in a freezer between -25°C and -15°C (-13°F and 5°F).

Note: These temperatures are within the appropriate range for routinely recommended vaccines BUT the temperature range for this vaccine is tighter.

- If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.

Store in the original carton and protect from light. | Do not use dry ice for storage.

4.2



Moderna COVID-19 Vaccine
Storage and Handling Summary

Refrigerator

- Vaccine vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days before vials are punctured. After 30 days, remove any remaining vials from the refrigerator and discard following manufacturer and jurisdiction guidance on proper disposal.
- Thawed vaccine cannot be refrozen.
- Use beyond-use date labels to track how long the vaccine has been in the refrigerator. Monitor the beyond-use date/time.
  - Remove the box from frozen storage.
  - Complete the information on the storage label and attach it to the box holding the vaccine vials.
  - Once labeled, store vaccine in the refrigerator.

Moderna COVID-19 Vaccine

Vaccine may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 30 days.

Lot number(s): 123456A

Today's date: 4 / 01 / 2021

USE BY*

Date: 5 / 01 / 2021

*After this date/time, do NOT use. Contact the manufacturer for guidance. If directed to discard the vaccine, follow the manufacturer's and your jurisdiction's guidance on proper disposal.

Name: Amy Nurse RN

Temperature Monitoring

Storage unit temperatures must be monitored regularly and checked and recorded at the beginning of each workday to determine if any excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures (e.g., probe buffered with glycol, glass beads, sand, or Teflon®). Check and record the temperature daily using a temperature log and one of the options below:

- **Option 1: Minimum/Maximum Temperatures (preferred)**
  Most DDLs display minimum and maximum (min/max) temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: Current Temperature**
  If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

For CDC temperatures logs, see https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html.

For additional information, refer to the manufacturer's product information at https://www.modernatx.com/covid19vaccine-eua/.

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4.2 (continued)

Data Logger Requirements

COVID-19 vaccination 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. This includes the correct vaccine storage unit(s), whether a refrigerator, regular freezer, or ultra-cold freezer. Purpose-built, also referred to as "pharmaceutical-grade," units are preferred and designed specifically for storage of biologics, including vaccines. However, household-grade units can be an acceptable alternative in some situations. Most standard freezer units do not meet ultra-cold freezer requirements for storing vaccine between -60°C and -80°C. However, at this time, DSHS does not recommend COVID-19 vaccination providers purchase ultra-cold storage units because vaccines requiring these storage conditions are expected to be shipped in containers that can maintain ultra-cold temperatures for an extended period.

It is essential for each vaccine storage unit to have a temperature monitoring device to ensure vaccines are stored within the correct temperature range. DSHS recommends a data logger. A data logger provides the most accurate storage unit temperature information, including details on how long a unit has been operating outside the recommended temperature range. Data loggers using a buffered temperature probe provide the most accurate way to measure actual vaccine temperatures. Always use data loggers with a current and valid Certificate of Calibration Testing.

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

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.

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).
- User-programmable logging interval (or reading rate) at a maximum time interval of every 30 minutes.

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.
    - 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, name of 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.

III. Vaccine Transfers

COVID-19 providers can transfer COVID-19 vaccine to another DSHS-enrolled COVID-19 provider with approval from DSHS Immunization Unit. Before requesting a transfer, verify that the facility you want to receive the vaccine is an approved COVID-19 Vaccine Provider. COVID-19 vaccines may only be transferred to 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.

In order to transfer COVID-19 vaccine, transfer requests must be completed in VAOS at https://texasvaccines.dshs.texas.gov/ to 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 info (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.

IV. Off-Site and Mass Vaccination Clinics

Off-site and mass clinics may be set up for COVID-19 vaccine. Routine transport of vaccine is not allowed under the COVID-19 Program. This can also compromise the cold-chain and vaccine viability. Off-site or mass clinics are not allowed to operate outside of their jurisdiction (for example, an enrolled provider in San Antonio is not allowed to transport COVID-19 vaccine to Waco to conduct an off-site/mass clinic). Also, vaccine

transported to an off-site clinic must return 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. 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 the EUA fact sheet 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#additional

B. Vaccine Adverse Events Reporting (VAERS)

Health care providers are required to report to VAERS the following adverse events after COVID-19 vaccination, under Emergency Use Authorization (EUA), and other adverse events if later revised by CDC:

- Vaccine administration errors, regardless of associated 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; and

  - 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 Multi-System Inflammatory Syndrome.
- Cases of COVID-19 that result in hospitalization or death.

Reporting is encouraged for other clinically significant adverse events, whether a vaccine caused the adverse event. 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.

C. 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. 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 makes a difference — it helps keep COVID-19 vaccines safe. For more information on v-safe, visit https://vsafe.cdc.gov.

D. 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 due to the nature of the vaccine. 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 https://www.youtube.com/watch?v=lnqWY7lldQw&feature=youtu.be.

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SECTION SIX: BILLING/ADMINSTRATION 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. 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.