COVID-19 Vaccine Provider Questions

(PLEASE NOTE: This document will be updated periodically. Refer to the release date.)

VACCINE

Is there any information regarding severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine?
The CDC has posted details concerning severe allergic reactions. It can be found online at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html.
All recipients should be monitored for an allergic reaction for 15 minutes after vaccine. People with a history of severe allergic reactions should be monitored for 30 minutes.

Where can I find more information about each vaccine?
The CDC has specific pages for each vaccine. Information includes Emergency Use Authorization (EUA), standing orders templates, pre-vaccination screening forms, and storage and handling instructions.
**Pfizer:** https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
**Moderna:** https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
Recipient fact sheets for both vaccines are available at https://www.cdc.gov/vaccines/covid-19/eua/index.html

What are the age indications for each vaccine?
**Pfizer:** 16 years of age and older
**Moderna:** 18 years of age and older

What are some reported adverse reactions to each vaccine?
**Pfizer:** In clinical studies, adverse reactions in participants 16 years of
age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%).

**Moderna:** In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.4%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).

**Both the Pfizer and Moderna vaccines are categorized as mRNA vaccines. How do they work?**

COVID-19 mRNA vaccines give instructions for our cells to make a harmless piece of what is called the “spike protein.” The spike protein is found on the surface of the virus that causes COVID-19.

COVID-19 mRNA vaccines are given in the upper arm muscle. Once the instructions (mRNA) are inside the immune cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them.

Next, the cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn’t belong there and begin building an immune response and making antibodies, like what happens in natural infection against COVID-19.

At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is that those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19.

**PROVIDER ENROLLMENT**

**How do I register to become a COVID-19 vaccine provider? How do I order the COVID-19 vaccine?**

Providers must complete their registration in the registration portal, EnrollTexasIZ.dshs.texas.gov, prior to COVID-19 vaccine allocation. The following steps must also be finalized:
1. Complete Module 10 of the CDC’s “You Call the Shots” Training. (Highly recommended)
2. Evaluate patient population. Identify critical population groups of people that are served by your practice.
3. Complete the COVID-19 Provider Agreement form.
4. Agree to maintain vaccine safety and inventory.
5. Agree to report COVID-19 doses administered in the required timeframe.

**Are healthcare providers able to register multiple clinics at once in the COVID-19 Vaccine Program if they are all under one medical body?**

Healthcare providers who belong to a single organization with multiple sites must enroll each facility individually in the COVID-19 Vaccine Program.

**How can I request to receive COVID-19 vaccine doses?**

You will first need to register your organization by visiting EnrollTexasIZ.dshs.texas.gov. A registration must be completed for each location where COVID-19 vaccine will be administered. Once the registration has been completed, you will have the option to “pre-book” or request to receive the COVID-19 vaccine.

**Who will be my point of contact? Should I reach out to my local health department, to the state, or to the Federal Government?**

For questions or more information on the COVID-19 Vaccine Program, email COVID19VacEnroll@dshs.texas.gov or visit the DSHS COVID-19 Vaccine website.

**What type of information will need to be included during the registration process?**

During the registration process, you will be asked to submit information about your organization such as:

- Address
- Vaccine coordinator contact information
- Vaccine delivery times
- Vaccine storage capacity for each unit at the facility
- The patient profile of the population served
- Administering and reporting information
- List of responsible personnel such as the Chief Medical Officer or Chief Executive Officer
- Sign and agree to the conditions in the CDC COVID-19 Vaccination Program Provider Agreement

**Will the information regarding my patient population be made public?**

Patient population information will remain unpublished and private. Identifying patient population is used to understand the communities you serve and to help allocate the COVID-19 vaccine.

**Is an M.D. required to enroll in the COVID-19 Vaccine Program? Who can and who cannot administer the COVID-19 vaccine?**

A licensed signing clinician will be required to enroll in the COVID-19 Vaccine Program. Licensed signing clinicians include Medical Doctors (MD), Doctors of Osteopathic Medicine (DO), Nurse Practitioners (NP)/Advanced Practice Nurses (APN), Physician Assistants (PA), Certified Nurse Midwives (CNM), Dentists (DDS), and Registered Pharmacists (RPh). Any medical professional is eligible to administer the COVID-19 vaccine, including but not limited to licensed nurses, medical assistants, emergency medical services (including paramedic or EMT), or staff members granted authority to vaccinate by a signing clinician.

For additional guidance for PREP Act coverage for qualified technicians and pharmacy interns for COVID-19 vaccines, visit: https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf

**Can medical professionals not included in the list of eligible signing clinicians (Medical Assistants, Licensed Nurses, etc.) administer the vaccine?**

Yes. At this time, additional medical professionals (e.g. RNs, LVNs, EMTs, Certified Medical Assistant) can administer the COVID-19 vaccine as authorized by the signing clinician for the vaccine provider.
Do we have to be enrolled in any additional program, such as the Adult Safety Net (ASN) Program, Texas Vaccines for Children (TVFC) Program, Children’s Health Insurance Program (CHIP)?

No. Any facility who has the personnel to immunize and the capacity to safely store and handle the COVID-19 vaccine is eligible to participate in the COVID-19 Vaccine Program; does not have to be enrolled in any additional vaccine program.

Do I have to be signed up for Texas Immunization Registry, ImmTrac2? If so, how do I sign up?

Yes. All facilities must enroll in ImmTrac2 to become eligible to participate in the COVID-19 Vaccine Program. Enrollment in ImmTrac2 is included in the COVID-19 Vaccine Program Provider Agreement, which can be found at EnrollTexasIZ.dshs.texas.gov

I’m already registered in ImmTrac2. Do I need to re-register to complete my enrollment?

Providers already registered in ImmTrac2 will not need to re-register. However, they will need to provide their ImmTrac2 Organization Code and continue to complete the required fields in order to ensure that DSHS has the most current information for the facility.

Are there any required trainings to complete in order to receive the COVID-19 vaccine? If so, what are the trainings and how do I access them?

All providers who are participating in the COVID-19 Vaccine Program are highly encouraged to complete Module 10 of the CDC's “You Call the Shots” Training. This module can be found in the following website: www.cdc.gov/vaccines/ed/youcalltheshots.

What is the enrollment timeline? When will enrollment open and close?

Enrollment for the COVID-19 Vaccine Program is now open for providers and
can be accessed through EnrollTexasIZ.dshs.texas.gov. There is no close date at this point. Providers are welcome to enroll whenever they feel they are ready to participate in the COVID-19 Vaccine Program.

If I am unable to remember my enrollment login credentials (username/password), how do I log back in?

In order to sign back in and edit the enrollment information, use the following format for the username:

- **firstname.lastname**

If you do not have a password, enter the username and click “Forgot Password.” The password reset information will be sent to the registered email address.

I can log in, but I am unable to edit information. The enrollment is locked. What should I do? How am I able to edit information?

Once forms are sent off for signatures, the enrollment becomes locked until the review process is complete. Once this review process is completed, the DSHS Immunization Unit can unlock this enrollment if needed.

We are a fire department/EMS station wanting to participate in the COVID-19 Vaccine Program. Are we able to sign up for ImmTrac2? Fire and EMS departments can enroll in the Texas Immunization Registry, ImmTrac2, as long as:

1. There is a signing clinician/medical authority who is directly associated with the first responder organization
2. The department meets the requirements to safely store and handle vaccines.

Are Long Term Care Facilities required to register for the COVID19 Vaccine Program? What are the options for registration?

Long Term Care (LTC) facilities have two options to choose from to receive the COVID-19 vaccine.

- **Option 1:** Pharmacy partnership: Current information from CDC indicates that large chain pharmacies (example: CVS, Walgreens) will be able to enroll directly with CDC and receive COVID-19 vaccine at multiple locations across the state. In turn, pharmacies who enroll will
be available to partner with local LTC facilities and set up COVID-19 vaccination clinics within the LTC facility.

- **Option 2:** Enroll and become a provider with the Texas Department of State Health Services (DSHS): LTC facilities are welcome to enroll as a COVID-19 provider with DSHS (see FAQs on provider enrollment, release date October 7, 2020). Once a LTC facility is enrolled, DSHS will be able to direct ship COVID-19 vaccine to the LTC facility to be stored and used at that individual site.

**How can I receive a copy of my CDC COVID-19 Provider Agreement?**

After signature requests have been sent to the listed email addresses, there will be an option to preview the CDC COVID-19 Provider Agreement and print from your own computer. Email requests for signatures will also include a link to preview the agreement before electronically signing.

**VACCINE ORDERING & DISTRIBUTION**

**What is the COVID vaccine distribution plan?**

The Centers for Disease Control and Prevention (CDC) will fulfill orders for most vaccine products and associated ancillary supplies. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer to the vaccination provider site. Because of cold chain requirements, ancillary supply kits (and diluent, if applicable) will ship separately from the vaccine but should arrive before or on the same day as the vaccine.

Vaccine allocations will be made available in three phases.

1. During the first phase, DSHS anticipates limited supply of the COVID-19 vaccine. Initial efforts will be made to immunize:
   a. Healthcare personnel
   b. Texans at increased risk such as underlying medical conditions and people 65 years of age and older
   c. Other essential workers
2. During the second phase, there will be a large number of vaccine doses available. The focus will be to vaccinate those critical populations who were not vaccinated during phase one as well as the general public.
3. During the third phase, DSHS anticipates a sufficient supply of vaccines doses available to the entire population.

**Will the vaccine be provided by the state or will we have to purchase them as private stock?**

The Federal Government will be providing the COVID-19 vaccine through the state.

**Do we need to order COVID-19 vaccines separately for pediatrics and adults?**

The COVID-19 vaccine will initially be an adult vaccine; however, once the COVID-19 vaccine is approved for pediatric use more information will be provided.

**Who has been identified as critical populations?**

- Healthcare personnel
- Texans at increased risk for severe COVID-19 illness such as:
  - Residents at nursing homes, assisted living centers, or independent living facilities
  - People with underlying medical conditions
  - People 65 years of age and older
- Texans at increased risk of acquiring or transmitting COVID-19 such as:
  - People from racial and ethnic minority groups
  - People from tribal communities
  - People who are incarcerated/detained in correctional facilities
  - People experiencing homelessness or living in shelters
  - People attending colleges/universities
  - People who work in educational settings
  - People living and working in other congregate settings
- Texans with limited access to routine vaccination services such as:
  - People living in rural communities
  - People with disabilities
  - People who are underinsured or uninsured

**What do I do if the vaccine doesn’t arrive?**

Please contact us at COVID19VacEnroll@dshs.texas.gov and we will investigate for shipping information and shipping status.
What is the timeline of deliveries between enrollment and receiving doses?

There is currently no timeline between the completion of an enrollment and receiving the COVID-19 vaccine until it becomes available.

Are providers able to charge an administration fee for the COVID19 vaccine?

- We are currently awaiting an amount to be determined by the CDC for an administration fee. Once we have that information available, you will be notified.

VACCINE STORAGE & HANDLING

What are the requirements for storage and handling of the COVID-19 vaccine?

COVID-19 vaccine products are temperature-sensitive and must be stored and handled correctly to ensure efficacy and maximize shelf life. For information on proper vaccine storage and handling, visit the CDC Vaccine Storage and Handling Toolkit at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

Will shipments include ancillary supplies?

COVID-19 vaccine shipments will contain the following ancillary supplies:
  - Ancillary supplies – we don’t know how the shipment will look, but we know what it will contain.
  - Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
  - Syringes, 105 per kit
  - Alcohol prep pads, 210 per kit
  - 4 surgical masks and 2 face shields for vaccinators, per kit
  - COVID-19 vaccination record cards for vaccine recipients, 100 per kit

What is the size of the boxes for doses being shipped?

Currently, we do not know the size of the boxes for COVID-19 vaccine doses when shipped, however the minimum vaccine order quantity will be 100 doses.
Will appropriate equipment for storage be provided? E.g. freezers, data loggers, etc.

COVID-19 Vaccine Program providers are responsible for providing the required vaccine storage units as listed in the CDC Vaccine Storage and Handling Toolkit.

Do I need to purchase a data logger for my refrigerator/freezer?

Facilities are required to have a digital data logger (DDL) to continuously monitor the temperature of the vaccine. Listed below are recommendations that should be considered before purchasing one:

- 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 that shows the current temperature, as well as minimum and maximum temperatures.
- 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.

Will providers be responsible for purchasing an ultra-cold storage unit?

At this time, it is the choice of the COVID-19 Vaccine Program providers to purchase an ultra-cold storage unit if needed. The Texas Department of State Health Services does not recommend that providers purchase a separate ultra-cold storage unit at this time until further guidance is provided by CDC.

What are the emergency transport procedures?

Emergency transport procedures can be found in the CDC Vaccine Storage
and Handling Toolkit on pages 21 through 26. For information on proper vaccine storage and handling, visit the CDC Vaccine Storage and Handling Toolkit at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

**How do I update my facility’s shipping information?**

Providers may update their shipping information in the registration portal, EnrollTexasIZ.dshs.texas.gov. However, once signature requests have been emailed, the enrollment will automatically lock and remain locked until the review process is complete. Providers must update their shipping information **BEFORE** accepting a COVID-19 vaccine allocation to prevent issues with delivery.

**If one of my clinic’s vaccine coordinators no longer works here, how do I update my facility’s contact information?**

Providers may update their contact information on the registration portal, EnrollTexasIZ.dshs.texas.gov. As a reminder, providers must have a primary and back-up vaccine coordinator to receive COVID-19 vaccines.

**What happens if the diluent or the cold chain is not maintained?**

Providers should call the manufacturer listed on the box for viability determination. If the dose is deemed non-viable, then the doses should be reported as wasted.

**VACCINE INFORMATION & PRESENTATION**

**When will the COVID-19 vaccine become available?**

DSHS anticipates the vaccine to become available in fall 2020. For the most up-to-date information, please visit www.ImmunizeTexas.com.

**How much will it cost to receive COVID-19 vaccine?**

COVID-19 vaccines and ancillary supplies will be distributed by the federal government at no cost to enrolled COVID-19 vaccination providers.
How many doses come in each kit?
Each kit contains 100 doses for refrigerated and frozen COVID-19 vaccines. There will be a 1000 dose minimum order for the ultra-cold COVID-19 vaccine.

Is the COVID-19 vaccine a one-dose or a two-dose series? What is the timeframe between doses if it is a series?
There will be multiple presentations of the COVID-19 vaccine which may include both one-dose and two-dose series. Each COVID-19 vaccine presentation will have its own timeframe between the first and second dose, if applicable. For more information about each COVID-19 vaccine presentation and the interval between doses, contact the appropriate manufacturer.

Will the COVID-19 vaccines be single-dose or multi-dose vials?
There will be multiple presentations of the COVID-19 vaccine which may include single-dose vials, multi-dose vials, or pre-filled syringe. For more information about each COVID-19 vaccine presentation, contact the appropriate manufacturer.

Will the COVID-19 vaccine need to be reconstituted?
There will be multiple presentations of the COVID-19 vaccine which may or may not need to be reconstituted. For more information about each COVID-19 vaccine presentation, contact the appropriate manufacturer.

What are the contraindications and precautions of the COVID-19 vaccine?
The FDA will determine the contraindications and precautions once the COVID-19 vaccines receive authorization and approval.

What’s the COVID-19 Vaccine Provider hotline?
If you have any questions or concerns, please call the DSHS COVID-19
Vaccine Provider hotline at 877-835-7750. The COVID-19 hotline hours of operation are 8 a.m. to 5 p.m., Monday through Friday. You may also email COVID19VacEnroll@dshs.texas.gov.

VACCINE REPORTING

What are the reporting requirements?

Texas Health and Safety Code Sec. 161.00705 states that any Antiviral, Immunization, or Medication administrations in response to a declared disaster or emergency must be entered into the Texas Immunization Registry (ImmTrac2) at https://immtrac.dshs.texas.gov/

The Texas Health and Safety Code can be found at: https://statutes.capitol.texas.gov/Docs/HS/htm/HS.161.htm

ImmTrac2 disaster reporting training video can be found at: https://youtu.be/lnqWY7lldQw

Where do I report COVID-19 administration data?

All COVID-19 vaccine administration data must be reported to the Texas Immunization Registry (ImmTrac2). Requests for ImmTrac2 access can be emailed to ImmTrac2@dshs.texas.gov.

ImmTrac2 disaster reporting training video can be found at: https://youtu.be/lnqWY7lldQw

What reporting requirements must be met for the COVID-19 Vaccine Program? How often must they be submitted?

The CDC and DSHS require that organizations enrolled in the COVID-19 Vaccination Program report data elements for each dose administered within 24 hours of administration to the Texas Immunization Registry, ImmTrac2.

Additional Requirements for COVID-19 Vaccine Administration:

Organizations must:

- Administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC’s Advisory Committee on Immunization Practices (ACIP).
- Administer COVID-19 Vaccine regardless of the vaccine recipient’s
ability to pay COVID-19 Vaccine administration fees.

- Report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by DSHS.
- Preserve the record for at least 3 years as required by DSHS. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
- 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 the Organization.
- Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.
- Organization’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.

How quickly does COVID-19 vaccine administration data need to be reported to ImmTrac2?

CDC requires that vaccination providers enrolled in the COVID-19 Vaccination Program report each dose administered within 24 hours of administration to the Texas Immunization Registry (ImmTrac2).

Do I have to submit COVID-19 administration data to ImmTrac2 through data exchange?

No. COVID-19 vaccine administration data can be entered online in the ImmTrac2 application.

Can I fax DSHS the immunization histories?

No. Providers enrolled in the COVID-19 Vaccination Program are required to report these data elements to the Texas Immunization Registry (ImmTrac2).

ImmTrac2 disaster reporting training video can be found at: https://youtu.be/lnqWY7IlOw

Where do we report adverse reactions/effects to the COVID-19 vaccine?
The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the Food and Drug Administration (FDA) and the CDC. The purpose of VAERS is to detect possible signals of adverse events associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of U.S. licensed vaccines.

Reports of adverse events are welcome from all concerned individuals, including the following:

- Patients
- Parents
- Health care professional,
- Pharmacist
- Vaccine manufacturers

Requirement: Organizations must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/. Additional reporting mechanisms and requirements may be implemented by the CDC. DSHS will update this information as it becomes available.

**What is v-safe?**

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after someone receives a COVID-19 vaccination. Through v-safe, vaccine recipients can quickly tell CDC if they have any side effects after getting the COVID-19 vaccine. Depending on their responses, CDC may follow up with them by phone to get more information. V-safe will also remind them to get their second COVID-19 vaccine dose, if needed.

At the time of vaccination, providers should patients a v-safe information sheet and encourage them to enroll and fill out the surveys when prompted.

More information is available:


The Spanish site: