

John Hellerstedt, M.D.

Commissioner

Oct. 7, 2020

Dear Colleague,

The State of Texas continues to see the spread of COVID-19 in our communities. While precautions like mask-wearing and physical distancing reduce transmission, COVID-19 vaccinations will be a crucial component in combatting this disease and ending the pandemic in Texas. I am confident you understand the enormous potential benefit that effective COVID-19 vaccines can provide.

Initially, vaccine supplies will be limited, and vaccine will be distributed through the federal government and the states. Therefore, it is critical that Texas healthcare providers register to provide vaccines with the Department of State Health Services (DSHS). This is an essential first step for you to be able to receive and provide vaccine to your patients in the coming months. You will not be able to receive vaccine without registering.

I urge Texas providers, including clinics, healthcare facilities and pharmacies, to enroll to become COVID-19 vaccine providers. The following information provides a high-level overview of how COVID-19 vaccination distribution will take place, and how you can participate in alleviating the effects of the pandemic.

How Providers Register to Become COVID-19 Vaccinators

Texas providers wishing to administer COVID-19 vaccine must register through the registration portal at EnrollTexasIZ.dshs.texas.gov. This website will enroll providers to receive and administer vaccines for the duration of the program. Only providers registered through this site are eligible to receive COVID-19 vaccines within Texas. Vaccines and supplies like needles, syringes and alcohol prep pads will be distributed directly by McKesson Corporation to provider offices.

Provider Requirements

Per federal requirements, providers must agree to administer vaccine regardless of a recipient's ability to pay, provide a vaccination record to each recipient, store doses of vaccine under the proper conditions, and report the number of doses received and used. COVID-19 vaccine providers must track their COVID-19 vaccine activities and submit that information through DSHS online portals.

Timeline of Vaccine Availability

Texas will employ a tiered system for vaccine administration, per federal guidelines to manage the initially lower vaccine supplies. The anticipated phases are:

- November-December 2020: During this phase, Texas will identify providers and/or employers servicing targeted and prioritized populations, such as healthcare workers and other essential workers. DSHS will also conduct outreach and/or recruitment of employers to those target populations.
- Starting January 2021: During this phase, vaccines may still be limited to prioritized populations; however, the larger volumes of vaccines available should reduce the need for highly targeted allocations. Once vaccine supply is adequate, providers will be able to regularly place orders for COVID-19 vaccines.

The CDC continues to update states and stakeholders about its requirements for the anticipated vaccine distribution. The situation continues to evolve as trials for double- and single-dose COVID-19 vaccines continue. Accordingly, DSHS will provide registrants with updated information on an ongoing basis as we learn more about the process. Details will be maintained at www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx.

If you have any questions or concerns, 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. Thank you for doing your part to ensure Texans are kept safe and reduce the spread of COVID-19 in our state.

Sincerely,

John Hellerstedt, M.D. DSHS Commissioner

 Watch a <u>joint video message</u> from TMA President Dr. Fite and DSHS Commissioner Dr. Hellerstedt on COVID-19 vaccine provider enrollment.

COVID-19 Vaccine Provider Questions

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

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 time frame.

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 I require an M.D. to administer the COVID-19 vaccine? Who can and who cannot administer the COVID-19 vaccine?

A licensed professional will be required to administer the COVID-19 vaccine. Licensed professionals include, but are not limited to Medical Doctors (MD), Doctors of Osteopathic Medicine (DO), Nurse Practitioners (NP)/Advanced Practice Nurses (APN), Physician Assistants (PA), Certified Nurse Midwives (CNM), and Registered Pharmacists (RPh).

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

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.

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

Enrollment is now open. There is no close date at this point, but we encourage providers to enroll as early as possible to aid in vaccine planning and ensure providers are able to report vaccine data.

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

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- 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
 - o 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
 - o 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
 - o 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.

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:

- 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

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.

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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. 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.

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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

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.

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What are the contraindications and precautions of the COVID-19 vaccine?

For contraindications and precautions of specific COVID-19 vaccine presentations, contact the appropriate manufacturer.

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/InqWY7lldQw

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/InqWY7lldQw

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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, ImmTac2.

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).

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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/lnqWY7lldQw

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/.

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