



TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

COVID-19 Vaccine Distribution Plan

October 19, 2020

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DISCLAIMER

The information presented today is based on CDC's recent guidance and MAY change.

October 19, 2020

Discussion Topics

- COVID-19 Vaccine Landscape
- Frontline and Vulnerable Populations
- Vaccine Allocation Guiding Principles & Framework
- Phased Approach to Allocation & Ordering
- Provider Enrollment
- Vaccine Communication
- Provider Reporting Requirements



Evolving Landscape for COVID-19 Vaccine

Key Assumptions for COVID-19 Vaccine



Limited doses may be available by early November 2020, but **supply will increase substantially** in 2021



Initial supply will either be **approved as a licensed vaccine** or **authorized for use under an EUA** issued by the FDA



Cold chain storage and handling requirements are likely to vary from **refrigerated to ultra-cold frozen**



Two doses, separated by ≥ 21 or 28 days, will be **needed for immunity** for most COVID-19 vaccines



COVID-19 Vaccine Candidates

Manufacturer	Platform	Age Group	Doses needed ²	Timing	Storage/Handling
Moderna ¹	mRNA	≥18 years	2	0, 28 days	Frozen ~ 7 days refrigerated
Pfizer/BioNTech ¹	mRNA	≥ 16 years	2	0, 21 days	Ultra Cold Frozen ~ 5 days refrigerated
AstraZeneca/Oxford ^{1*}	Non-replicating Viral Vector	TBD	2	4 weeks apart	TBD
Janssen/Johnson & Johnson ^{1*}	Non-replicating Viral Vector	≥18 years	1	N/A	Frozen ~ 3 months refrigerated
Novavax	Recombinant Protein Subunit	≥18 years	2	0, 21 days	Refrigerated
Sanofi/GSK	Recombinant Protein Subunit	TBD	2	TBD	Refrigerated

1. Phase 3

1*: On hold

2: Intramuscular injection



Phased Approach to Vaccination

(Specific dates are subject to change)

- ***Phase 0 (October 2020):***
 - Provider recruitment and registration into ImmTrac2 and new web-based portal.
- ***Phase 1 (November 2020 – December 2020): Limited supply of COVID-19 vaccine doses available.***
 - McKesson will direct ship vaccines to registered providers serving healthcare workers and other select populations based upon the DSHS Commissioner's approval in accordance with CDC and ACIP recommendations.
 - Occupational healthcare settings, existing vaccinators serving closed settings will be the primary administrators of vaccines.
 - Some large chains enrolled directly by CDC to serve some targeted populations (long-term care facilities).
 - Continue ongoing provider recruitment and registration to ensure access to vaccination.



Phased Approach to Vaccination

(Specific dates are subject to change)

- **Phase 2 (January 2021-July 2021): Increased number of vaccine doses available.**
 - Emphasis on ensuring access to vaccine for members of Phase 1 critical populations who were not yet vaccinated as well as for the additional populations; expand provider network.
 - Texas will use specialized vaccine teams, as needed, to vaccinate identified critical groups lacking access to the vaccine (e.g., Long-term care facilities, rural communities, etc).
- **Phase 3 (July 2021 -October 2021): Sufficient supply of vaccine dose for entire population.**
 - DSHS will focus on ensuring equitable vaccination access across the entire population. Monitor vaccine uptake and coverage; reassess strategy to increase uptake in populations or communities with low coverage.
 - May consider extending the use of vaccine teams depending on the uptake and coverage received so far, especially to ensure second doses are administered from the end of Phase 2.
- **Phase 4 (October 2021 and forward) Sufficient supply of vaccine with a decreased need due to most of the population being vaccinated previously.**
 - May include boosters or annual vaccines if required.
 - Vaccine availability open throughout private providers. Population able to visit provider of choice.



CDC Critical Populations for COVID-19

Groups and individuals may fall into multiple categories.
 Prioritization recommendations among and within groups are in development.

Category	Includes:
Essential Workers	<ul style="list-style-type: none"> Healthcare personnel (i.e. EMS, hospital staff, vaccinators, pharmacy and long-term care staff) Other essential workers (i.e. first responders, education, others with critical roles who cannot easily socially distance)
People at increased risk for severe COVID-19 illness	<ul style="list-style-type: none"> People 65 years of age and older LTCF residents (i.e., nursing home, assisted living, others) People with underlying medical conditions that are risk factors for severe COVID-19 illness
People at increased risk of acquiring or transmitting COVID-19	<ul style="list-style-type: none"> People from racial and ethnic minority groups People from tribal communities People who are incarcerated/detained in correctional facilities People experiencing homelessness/living in shelters People attending colleges/universities People living in other congregate settings
People with limited access to routine vaccination services	<ul style="list-style-type: none"> People living in rural communities People with disabilities People who are under- or un-insured



H1N1 Key Lessons Learned

- Decisions about how to prioritize groups for vaccine allocation may have negatively impacted **vaccine uptake (the long-term goal)**
 - Changes in priority groups were confusing to the public and healthcare providers, and communication was challenging
 - Some products had contraindications among priority groups (i.e. could not be given safely to that group)
 - Feelings of alienation in early phases may have contributed later to low uptake among some groups of people
- Many patients and health care providers expressed safety concerns
 - Clear **risk communication** is important
- **Logistical limitations** such as minimum order sizes were a barrier to access for some smaller localities

(National Academy of Medicine, 2020)



Foundational principles for allocation

Ethical Principles

- **Maximum benefit** encompasses the obligation to protect and promote the public's health and socioeconomic well-being in the short and long term.
- **Equal concern** requires that every person be considered and treated as having equal dignity, worth, and value.
- **Mitigation of health inequities** includes the obligation to explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and health inequities.

Procedural Principles

- **Fairness** requires engagement with the public, particularly those most affected by the pandemic, and impartial decision-making about and evenhanded application of allocation criteria.
- **Transparency** includes the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the allocation framework as it is being developed, deployed, and modified.
- **Evidence-based** expresses the requirement to base the allocation framework on the best available and constantly updated scientific information and data.

(National Academy of Medicine, 2020)

Expert Vaccination Allocation Panel (EVAP)

- Made of external and internal subject matter experts
- Make recommendations to the Commissioner
 - Establish prioritization of critical populations for Phase 1 and Phase 2 distribution
 - Weekly review of the data to guide allocation recommendations



CDC Requirements for COVID-19 Vaccination Providers

- Must have an active NPI/TPI number.
- Must follow ACIP requirements and recommendations.
- Must comply CDC requirements for COVID-19 vaccine management and maintain adequate storage capacities to maintain integrity of the vaccine cold-chain requirements
- Must report dose usage within 24 hours to the state immunization registry, ImmTrac2.
- Must report of all doses received including those administered, lost, wasted, etc.
- Must report of any adverse event related to receiving the vaccine.



Provider Registration Portal

EnrollTexasIZ.dshs.texas.gov



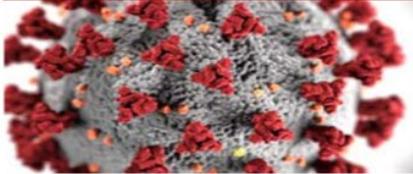
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Home Register Contact Us

Welcome to the Texas DSHS Immunization Program Portal

Here health care providers and pharmacies may register to be considered to receive COVID-19 vaccine.

Pandemic Vaccine Provider Registration



COVID-19

Click to Register

[Learn more about becoming a COVID-19 vaccine provider](#)

Browser Compatibility Notice: For the best results using this application use the latest versions of Google Chrome or Microsoft Edge.

Please allow up to 14 days for processing of enrollment during this busy time.

Returning Users

Username:

Password:

Login Clear

[Forgot Password.](#)



Texas Department of State Health Services

Communication, Outreach, Engagement (COE) Plan

- Provider
 - Recruitment
 - Vaccine Administration logistics/guidance
- Public
 - Statewide media campaign (TV, radio, digital, out-of-home)
 - General information
 - Vaccine availability
 - Vaccine's safety/importance
- Stakeholders
 - Outreach to providers and public
 - Source of feedback



COE Plan – Timeline

(Specific dates are subject to change)

- Phase 0 (Sept. 2020 – Oct. 2020)
 - Presentations to stakeholders; mass emailing (GovDelivery); media briefings (Ex. provider portal); creation of supporting panels
- Phase 1 (Nov. 2020 – Dec. 2020)
 - Statewide media campaign's message: what to expect, why vaccine is important; continued provider outreach (targeted and aided by stakeholder mobilization)
- Phase 2 (Jan. 2021 – July 2021)
 - Statewide media campaign's message: vaccine safety, dose requirements and provider locations
- Phase 3 (July 2021 – Oct. 2021)
 - Statewide media campaign's message: Vaccine safety, dose reminder



Vaccine Reporting Requirements

- CDC Requirements
 - Dose level accountability, connecting the Lot ID to the patient
 - Providers must report dose usage within 24 hours
- Texas DSHS reporting from providers
 - Doses Allocated by County
 - Doses Shipped by County
 - Doses Administered by County
 - Doses Wasted by County



Reporting to Texas Immunization Registry for Disasters and Emergencies

- Health and Safety Code §161.00705
 - Recording Administration of Immunization and Medication for Disasters and Emergencies, any antiviral medication distributed by the state in response to a declared disaster or public health emergency must be entered into the Texas Immunization Registry, known as ImmTrac2.
- Texas Administration Code §100.7
 - The immunization registry shall contain information regarding individuals who receive an immunization, antiviral, or other medication administered.



Existing Safety Monitoring Systems

Vaccine Adverse Event Reporting System (**VAERS**)

- The national system that collects reports from healthcare professionals, vaccine manufacturers, and the public of adverse events that happen after vaccination; reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies.

Vaccine Safety Datalink (**VSD**)

- A network of 9 integrated healthcare organizations across the United States that conducts active surveillance and research; the system is also used to help determine whether possible side effects identified using VAERS are actually related to vaccination.

Biologics Effectiveness and Safety System (**BEST**)

- A system of electronic health record, administrative, and claims-based data for active surveillance and research.

Other systems using electronic data from Medicare, Medicaid, VA



Expanded Safety Monitoring Systems

The following systems build upon the existing safety monitoring to evaluate COVID-19 vaccine in real time and provide additional surveillance.

- CDC **V-SAFE** A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines.
 - V-SAFE will use text messaging and web surveys to check in with vaccine recipients for health problems following COVID-19 vaccination.
 - The system also will provide telephone follow-up to anyone who reports medically significant (important) adverse events.
- CDC National Healthcare Safety Network (**NHSN**)
 - An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS.
- FDA Other large insurer/payer database
 - A system of administrative and claims-based data for surveillance and research.



More Information

Website for Providers:

www.dshs.texas.gov/coronavirus/immunize/provider-information.aspx

DSHS COVID-19 Vaccine Provider hotline:

(877) 835-7750, 8 a.m. to 5 p.m., Monday through Friday or

Email: COVID19VacEnroll@dshs.texas.gov.

Website to enroll as a COVID-19 provider:

EnrollTexasIZ.dshs.texas.gov.

General Questions:

Email: COVIDvaccineQs@dshs.texas.gov

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