



(Credit: Orpheus FX/Shutterstock)

COVID-19 Vaccine -Readiness

November 20, 2020



TEXAS
Health and Human
Services

Texas Department of State
Health Services

DISCLAIMER

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

November 20, 2020

Discussion Topics

- Opening Remarks
- Vaccine Updates
- Moderna Vaccine Storage & Handling
- Path to Vaccination
- Critical Population
- Provider Enrollment Update
- Q&A

Vaccine Updates



TEXAS
Health and Human
Services

Texas Department of State
Health Services

COVID-19 Vaccine Landscape

Manufacturer	Platform	Age Group	Doses needed ²	Timing	Storage/Handling
Moderna¹	mRNA	≥18 years	2	0, 28 days	Frozen 30 days refrigerated
Pfizer/BioNTech¹	mRNA	≥ 12 years	2	0, 21 days	Ultra Cold Frozen 5 days refrigerated
AstraZeneca/Oxford ¹	Non-replicating Viral Vector	≥18 years	2	0, 28 days	Refrigerated
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 2: Intramuscular injection



COVID-19 Vaccine Updates

Pfizer Vaccine Candidate

- Pfizer announced this morning they will submit a request today to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of their COVID-19 vaccine candidate.
- Their Phase 3 COVID-19 vaccine study has reached the primary endpoint of 170 confirmed cases of COVID-19.
 - The vaccine demonstrated 95% effectiveness (162 cases in placebo versus 8 cases in vaccine group).
 - Observed efficacy in adults over 65 years of age was over 94%.
 - Efficacy was consistent across age, gender, race and ethnicity demographics.
 - There were 10 severe cases of COVID-19 observed in the trial, (9 case in the placebo versus 1 case in the vaccine group)
- Safety data milestone required by FDA for EUA has been achieved.
 - No serious adverse reported to date.
 - Data demonstrate vaccine was well tolerated across all populations; the only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2.0%.



COVID-19 Vaccine Updates

Moderna Vaccine Candidate

- Moderna announced on Monday this week the results of first interim analysis of their Phase 3 COVID-19 vaccine study.
 - This first interim analysis was based on 95 cases, (90 cases in the placebo group versus 5 cases in vaccine group) resulting in a point estimate of vaccine efficacy of 94.5% ($p < 0.0001$).
 - The 95 COVID-19 cases included 15 older adults (ages 65+) and 20 participants identifying as being from diverse communities (including 12 Hispanic or LatinX, 4 Black or African Americans, 3 Asian Americans and 1 multiracial).
 - A secondary endpoint analyzed severe cases of COVID-19 and included 11 severe cases in this first interim analysis. All 11 cases occurred in the placebo group and none vaccine group.
- A review of solicited adverse events indicated that the vaccine was generally well tolerated.
 - The majority of adverse events were mild or moderate in severity.
 - Grade 3 (severe) events greater than or equal to 2% in frequency after the first dose included injection site pain (2.7%), and after the second dose included fatigue (9.7%), myalgia (8.9%), arthralgia (5.2%), headache (4.5%), pain (4.1%) and erythema/redness at the injection site (2.0%).
 - Majority of the adverse events were mild or moderate in severity, up till this point.



COVID-19 Vaccine Updates

Moderna Vaccine Candidate

- Moderna intends to submit for an Emergency Use Authorization (EUA) with the FDA in the coming weeks and expects the EUA to be based on the final analysis of 151 cases and a median follow-up of more than 2 months.
- Vaccine candidate now expected to remain stable at standard refrigerator temperatures of 2° to 8°C (36° to 46°F) for **30 days**, up from previous estimate of 7 days



Moderna Vaccine Candidate

Storage & Handling



mRNA-1273 from manufacturing to distribution

Pre-conditioned
-25 to -15°C/-13-5°F shipper

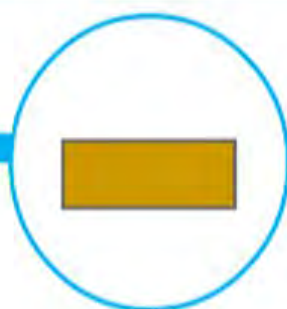


-25 to -15°C Temp controlled truck for full loads



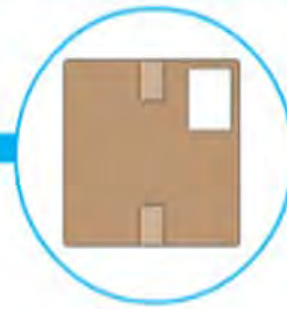
Multi-dose vial

(10 preservative free,
0.5 mL doses per vial)



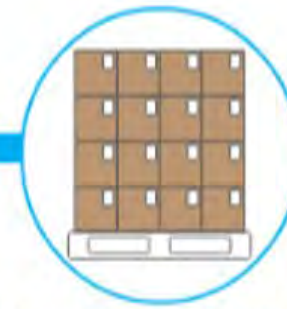
10-vial cartons

(100 doses)



Full cases

(1,200 doses)



Full or partial pallets

(up to 230,400
doses)

mRNA-1273 Temperature Stability

Storage Conditions for a non-punctured vial



Freezer: -25 to -15°C / -13 to 5°F for 6 months

+



Refrigerator: 2-8°C / ~36-46°F for up to **30 Days** Do not refreeze

+



Room temperature: up to 12 hours

ing

Each vial of mRNA-1273 has 10, 0.5 mL doses

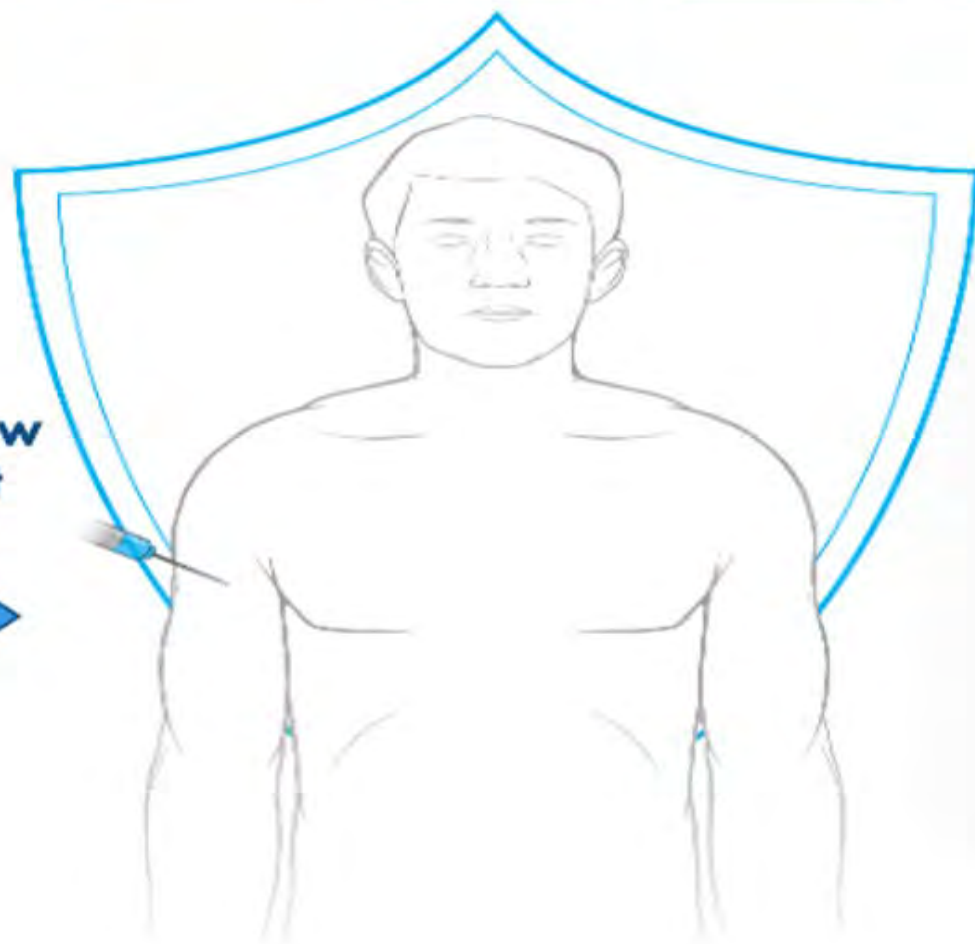
Standard needles
& syringes

No dilution
required



10 dose vials

Ready to use, draw
0.5mL and inject
intramuscularly



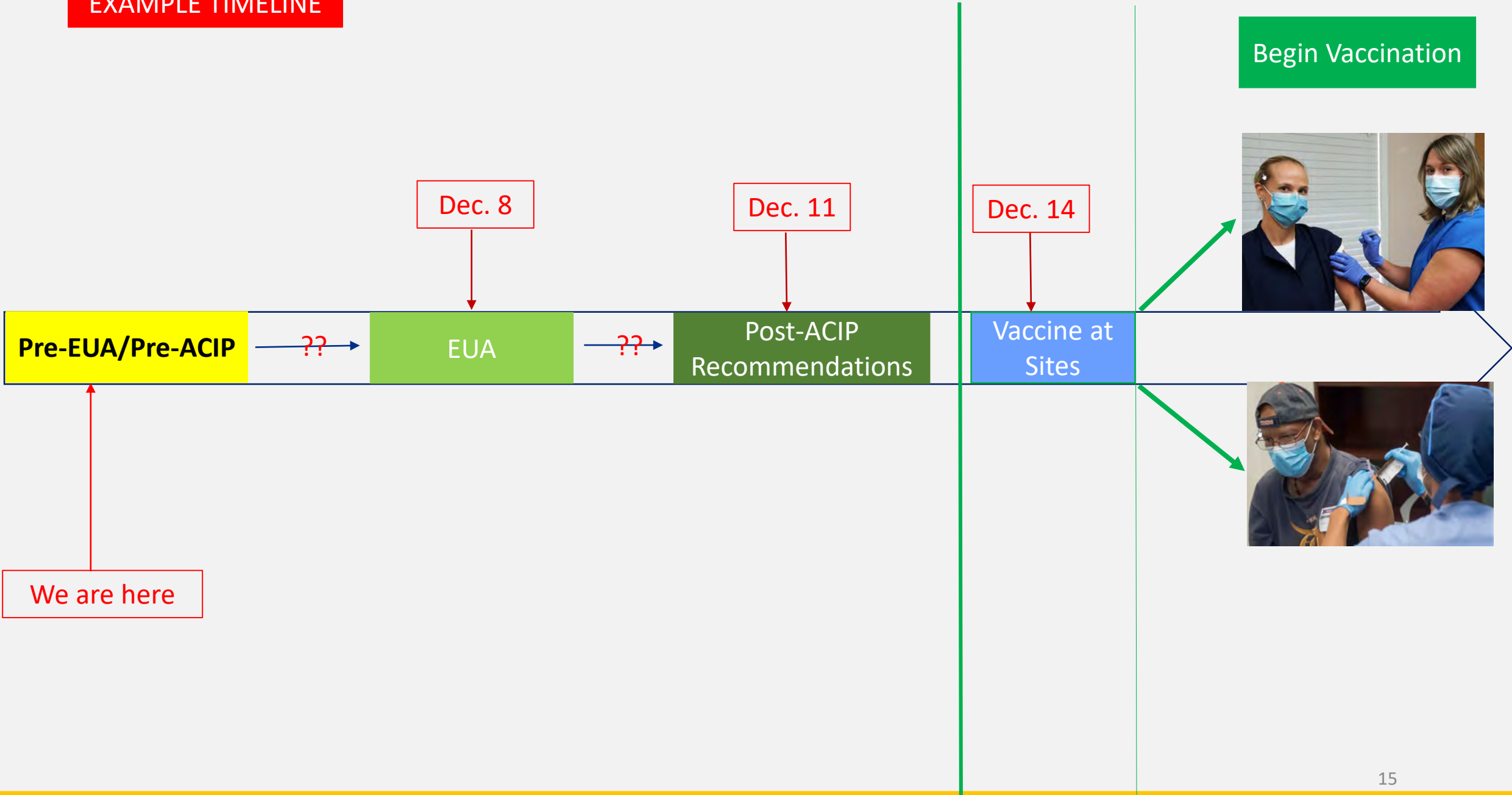
Path to Vaccination



TEXAS
Health and Human
Services

Texas Department of State
Health Services

EXAMPLE TIMELINE



COVID-19 Critical Populations

Healthcare Workers

Other Essential Workers

People at High Risk



CDC Critical Populations for COVID-19 Vaccination

Groups and individuals may fall into multiple categories. Definitions, and recommendations to prioritize among and within groups are in development.

<p>Essential workers</p>	<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)
<p>People at increased risk for severe COVID-19 illness</p>	<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
<p>People at increased risk of acquiring or transmitting COVID-19</p>	<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
<p>People with limited access to routine vaccination services</p>	<ul style="list-style-type: none"> • People living in rural communities • People with disabilities • People who are under- or un-insured



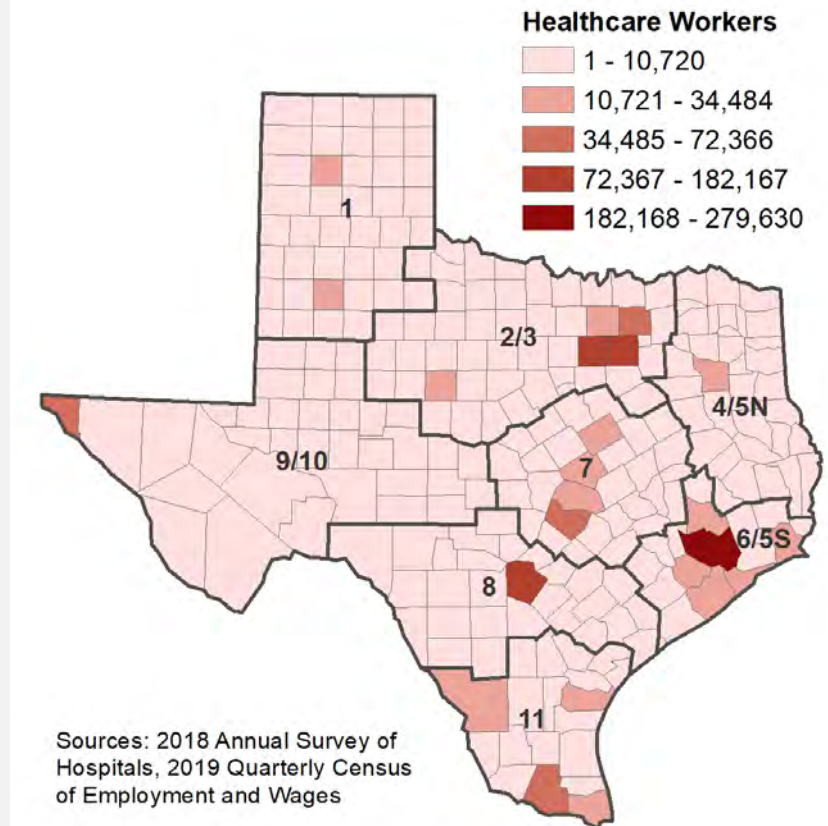
Texas Population Estimates

	Group	Population
ACIP/CDC Draft Recommendations		
	Adults 18+	22,162,539
Phase 1A	Healthcare Workers	1,593,174
Phase 1B	Total Law Enforcement	114,502
Phase 1B	Total Fire, paid and volunteer	68,276
Phase 1B	Education Workers	970,856
Phase 1B	Long-term Care Residents	275,541
Phase 1B	Adults 65+	3,912,028
Phase 1B	Total Medical Conditions	9,499,038
	Incarcerated	158,057
	Total Homeless Adults	22,706
	Colleges and Universities	1,455,533
	Black/African-American, Hispanic, and American Indian/Alaska Native	10,889,530
	Adults with Disabilities	2,855,529
	Un and Under Insured	8,526,320



Healthcare Worker Estimates By Region

Public Health Region	Hospital Workers	Other Healthcare
1	14,295	36,950
2/3	94,642	384,010
4/5N	17,984	72,247
6/5S	99,088	302,692
7	32,195	136,188
8	31,229	140,706
9/10	16,771	58,137
11	20,824	135,216
Total	327,028	1,266,146



Essential Workers (non-healthcare)

Below are **examples** included for **planning purposes**. Will be defined by the Expert Vaccine Advisory Panel (EVAP).

First Responders

- Law Enforcement (police, jails and prisons)
- Fire Service (Paid and Unpaid)

Workers who are essential to maintain services and functions Texans depend on daily

- Education
- Social Services
- Transportation
- Food and Agriculture
- Energy
- Water and Wastewater
- Housing and Construction

Workers who cannot perform their duties remotely and must work near others should be prioritized



Impact of Vaccinating Essential Workers – Direct and Indirect

- COVID-19 outbreaks in nursing homes
 - Statistical modeling shows vaccinating nursing home **personnel** would likely result in the greatest reductions in both infections and deaths among **residents**
- Outbreaks in **meat and poultry processing** plants where workers are often in close quarters
 - Estimated population 40,227 in Texas
- Corrections and Detention Facilities
 - **56%** of outbreaks identified **first case among staff** members
 - Indirect protection of people living in these settings

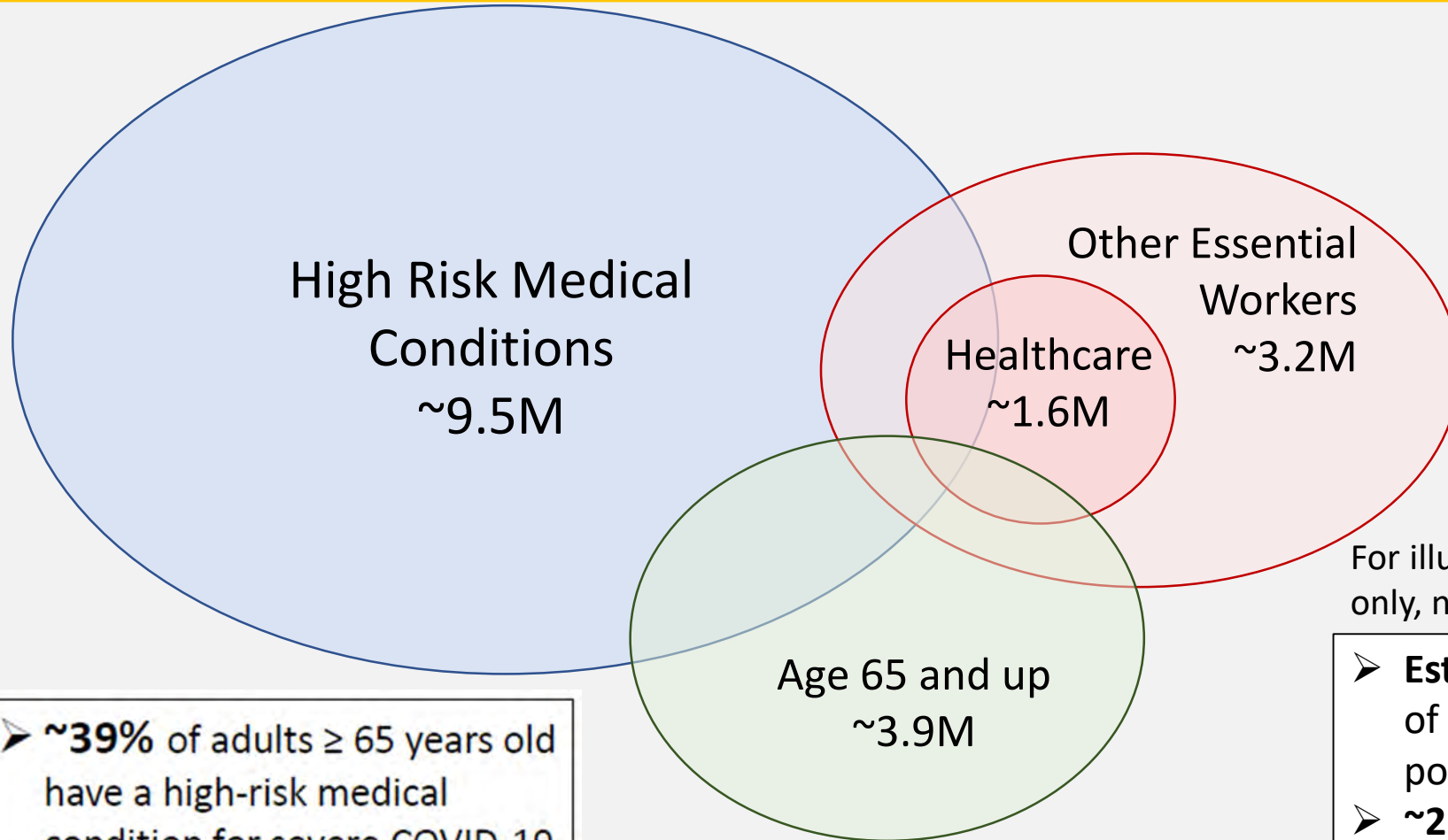


Racial and Ethnic Disparities

- People of Black race and Hispanic ethnicity are more likely to work in essential industries, including healthcare
- Racial and ethnic minority groups are disproportionately affected by workplace-related COVID-19 outbreaks
 - Meat processing plants in Texas



Overlap of Population Estimates in Texas



For illustration purposes only, not to scale

➤ **~39%** of adults ≥ 65 years old have a high-risk medical condition for severe COVID-19

➤ **Estimated overlap** of all these populations

➤ **~21.8%** (Harvard Allocation Tool)

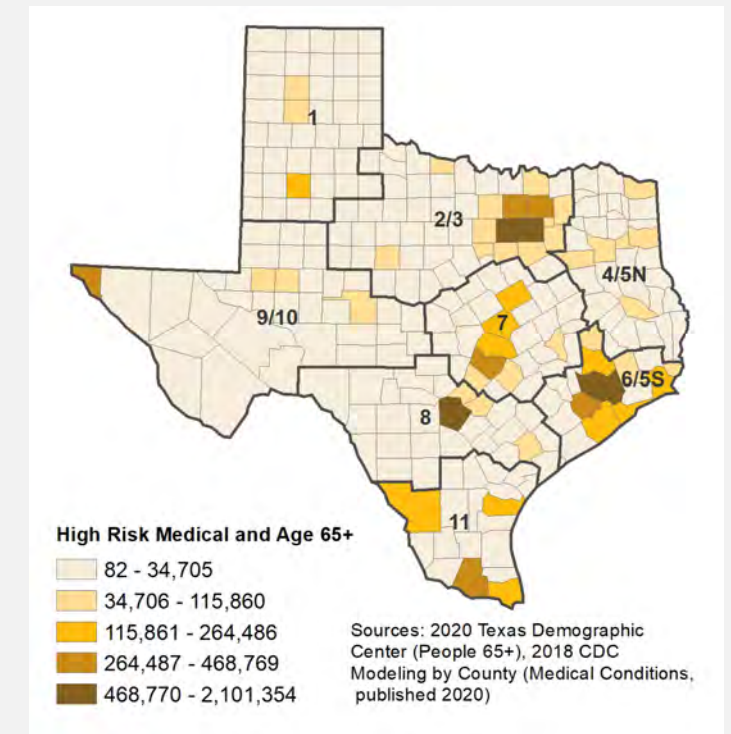


Texas Department of State Health Services

High Risk Populations By Region

Public Health Region	At least one High Risk Medical Condition*	Adults 65+	Nursing Home Residents
1	290,135	134,264	6,598
2/3	2,671,602	1,103,089	42,431
4/5N	592,868	295,987	15,305
6/5S	2,476,882	949,259	23,848
7	1,067,255	462,672	17,702
8	1,058,860	450,704	16,651
9/10	513,205	211,456	6,281
11	828,231	304,597	9,035
Total	9,499,038	3,912,028	137,851

With 39% overlap between adults 65+ and high-risk medical conditions, total **~7,912,529**



*Heart disease, asthma, COPD, bronchitis, emphysema, chronic kidney disease, diabetes, obesity (BMI>30)



Texas Department of State Health Services

Overlap in Possible Phase 1 Population Estimates – for illustration purposes

Population Group	Size
Healthcare Workers	1,593,174
Other Essential Workers	3,170,717
High Risk due to age ≥ 65 years or high-risk medical condition	7,912,529
Sum of Possible Phase 1 Populations	12,676,420
Total Estimate Phase 1, Factoring in Estimated Overlap	9,912,960
Adult Population of Texas	22,162,539



Provider Enrollment

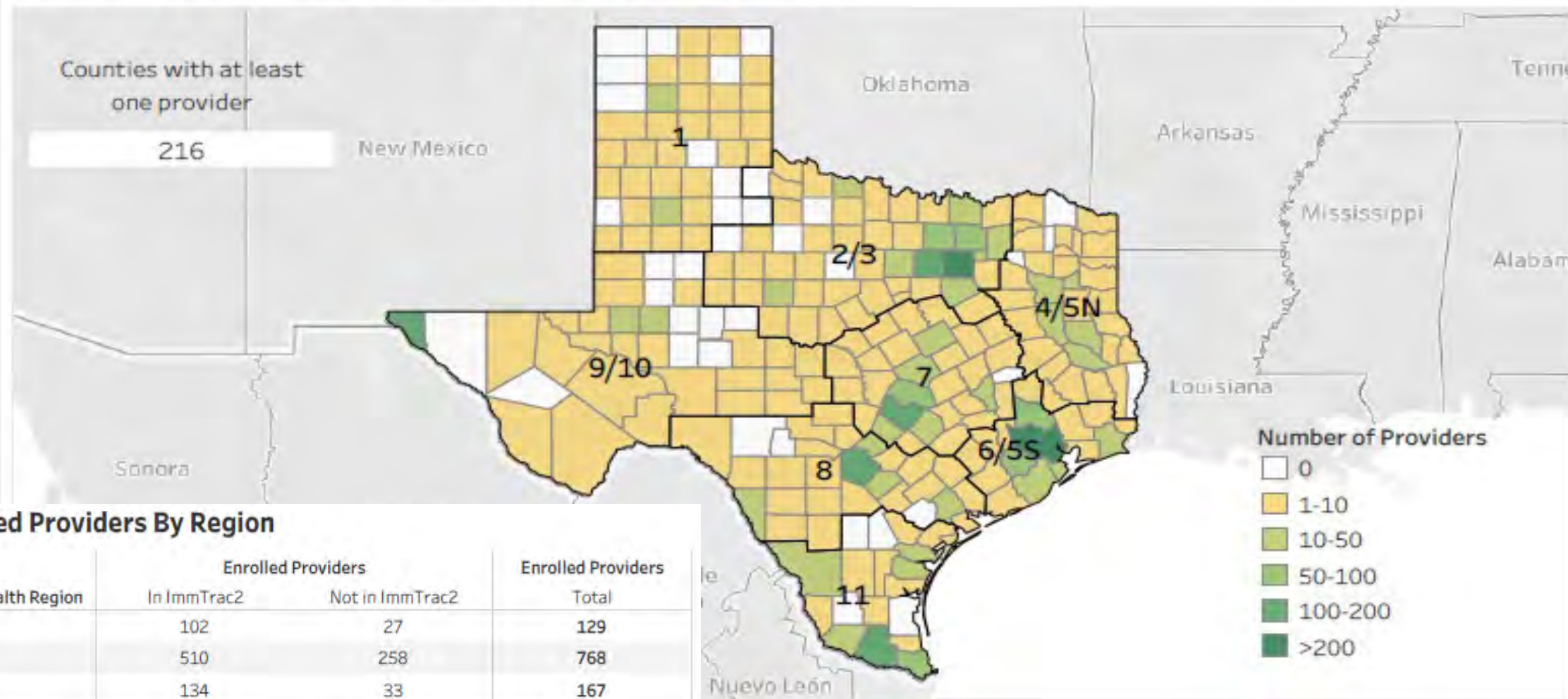
Update on Storage, Handling & Administration



TEXAS
Health and Human
Services

Texas Department of State
Health Services

COVID-19 Enrolled Vaccine Providers by County

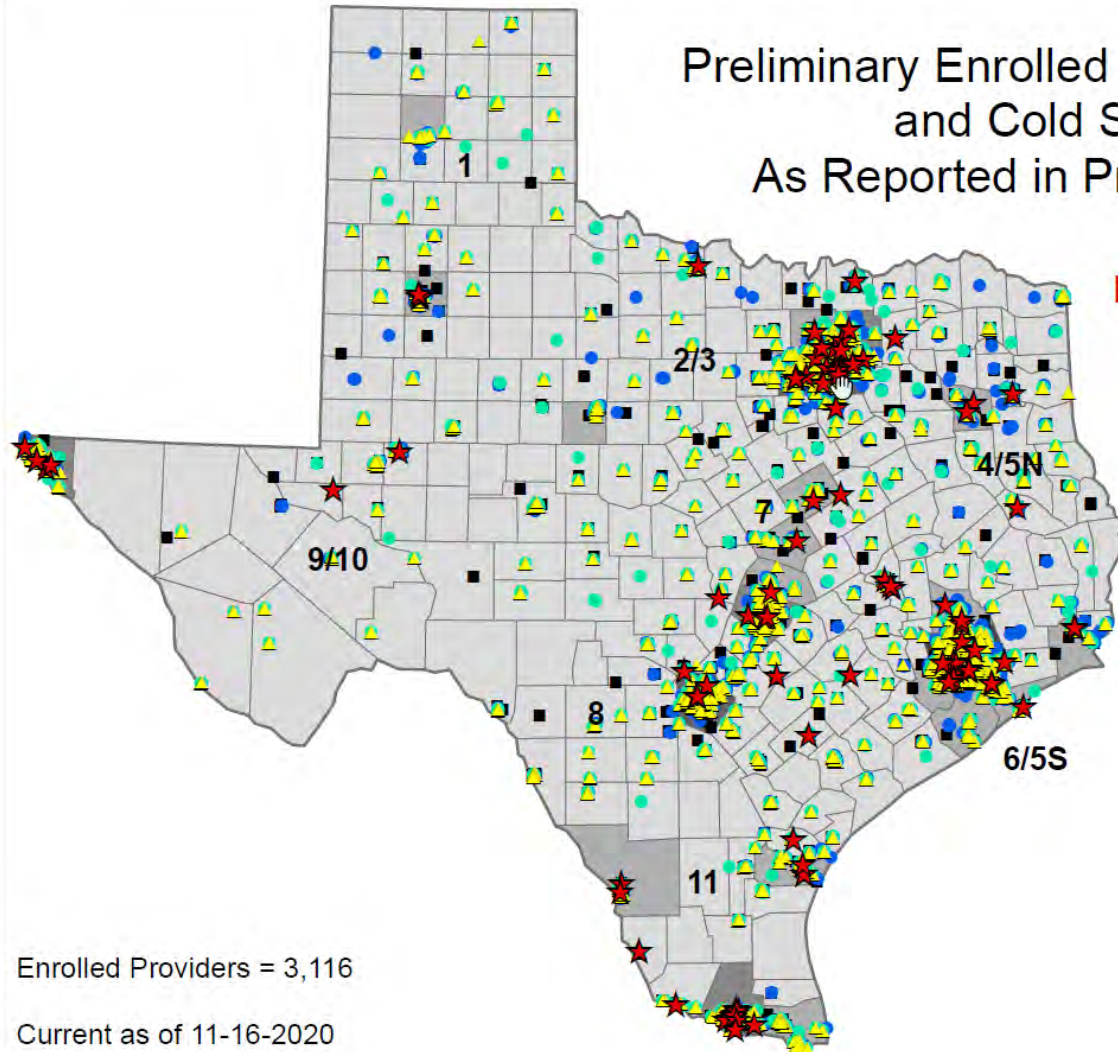


Enrolled Providers By Region

Public Health Region	Enrolled Providers		Enrolled Providers Total
	In ImmTrac2	Not in ImmTrac2	
1	102	27	129
2/3	510	258	768
4/5N	134	33	167
6/5S	659	199	858
7	306	89	395
8	286	80	366
9/10	179	55	234
11	346	46	392
Texas	2,522	787	3,309

Preliminary Enrolled COVID-19 Vaccine Providers and Cold Storage Capabilities As Reported in Provider Registration Portal

FOR PLANNING PURPOSES ONLY



- ★ Ultracold (n=107)
- ▲ Frozen (n=1,393)
- Refrigerated (n=1,950)
- Federal Pharmacy Partners (n=2,757)
- No Cold Storage Specified (n=1,086)

Phase 1A Population

- Healthcare Workers**
- 1 - 10,720
 - 10,721 - 34,484
 - 34,485 - 72,365
 - 72,366 - 182,167
 - 182,168 - 279,630

Federal Pharmacy Partners all report refrigerated storage

Enrolled Providers = 3,116

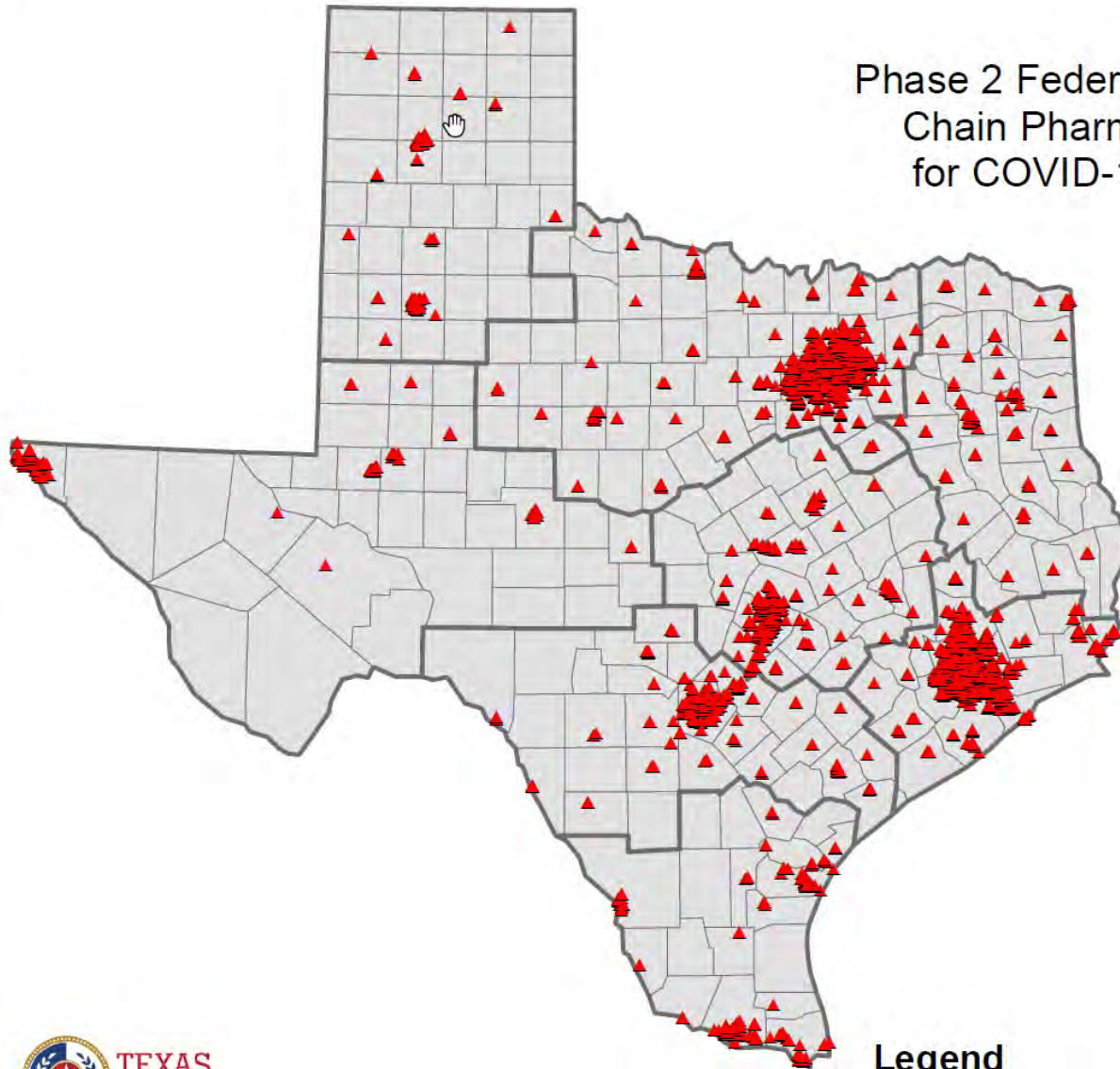
Current as of 11-16-2020

Data is preliminary based on providers enrolling in the COVID-19 vaccine program and does not indicate approval by DSHS of these sites. Site reviews are in progress to ensure each site can meet the requirements for storage, handling and reporting.
Note: Numbers of each storage capability do not sum to total because they are independent questions.



Texas Department of State Health Services

Phase 2 Federal (CDC) Partner Chain Pharmacy Locations for COVID-19 Vaccination



TEXAS

Health and Human
Services

Texas Department of
State Health Services

Legend

▲ Pharmacies CDC Partners, n=2,757

Current as of last provided by CDC November 4, 2020

Q&A



TEXAS
Health and Human
Services

Texas Department of State
Health Services

Resources

Slides/Recordings from Weekly Forums

<https://www.dshs.texas.gov/immunize/covid19/Public-Health-Entity-Forums/>

Website for Providers:

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

FAQ for Providers

<https://www.dshs.texas.gov/immunize/covid19/COVIDproviderfaq.pdf>

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