

COVID-19 Vaccination Plan

TEXAS

Texas Department of State Health Services
OCTOBER 16, 2020 | 1.0

TEXAS COVID-19 VACCINATION PLAN

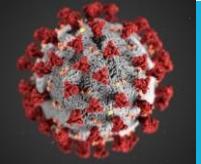
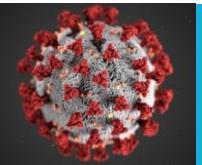


Table of Contents

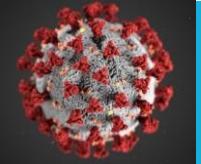
Record of Changes	2
Section 1: COVID-19 Vaccination Preparedness Planning	3
Section 2: COVID-19 Organizational Structure and Partner Involvement	6
Section 3: Phased Approach to COVID-19 Vaccination.....	9
Phase 1: Potentially Limited COVID-19 Vaccine Doses Available	9
Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand.....	9
Phase 3: Likely Sufficient Supply	10
Phase 4: Sufficient supply	11
Section 4: Vulnerable and Frontline Populations	12
Section 5: COVID-19 Provider Recruitment and Enrollment	15
Section 6: COVID-19 Vaccine Administration Capacity.....	18
Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management.....	19
Vaccine Allocation.....	19
Assuring Vaccine Viability	20
Vaccine Ordering & Distribution	21
Section 8: COVID-19 Vaccine Storage and Handling.....	24
Section 9: COVID-19 Vaccine Administration Documentation and Reporting	25
Section 10: COVID-19 Vaccination Second-Dose Reminders.....	26
Section 11: COVID-19 Requirements for IISs or Other External Systems	27
Section 12: COVID-19 Vaccination Program Communication.....	28
Section 13: Regulatory Considerations for COVID-19 Vaccination	29
Section 14: COVID-19 Vaccine Safety Monitoring	30
Section 15: COVID-19 Vaccination Program Monitoring	32
Appendices.....	34
Appendix 1: DSHS Organizational Charts	34
Appendix 2: DSHS Key Staff	36
Appendix 3: Countermeasures Injury Compensation Program	37

TEXAS COVID-19 VACCINATION PLAN



Record of Changes

Date of original version:



Section 1: COVID-9 Vaccination Preparedness Planning

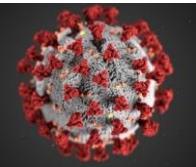
- A. The Centers for Disease Control and Prevention (CDC) recommend that state health departments be responsible for distribution of COVID-19 vaccine within their boundaries. In Texas, the Department of State Health Services (DSHS) will serve as the state's lead agency in COVID-19 vaccine distribution. DSHS will partner with other state agencies and key stakeholders to ensure that voluntary and equitable distribution of the COVID-19 vaccine occurs in a timely and efficient manner.

As part of the COVID-19 vaccine planning, DSHS has reviewed lessons learned from the H1N1 pandemic. DSHS referred to its comprehensive H1N1 after-action evaluation, which captured the history of the H1N1 pandemic response and summarized the successes, challenges, and lessons learned from response partners at the local, regional, and state levels.

For H1N1, much of the planning for pandemic influenza was based on a worst-case scenario (i.e., projections concerning H5N1 avian influenza), but public health officials, emergency responders, and other response partners adapted quickly to this event as it was presented. These efforts led to the major successes specific to vaccine distribution and overall communication, which are highlighted below.

- *Public-Private Partnership for Distribution of the Novel H1N1 Vaccine:* The CDC announced in spring 2009 that it would be responsible for purchasing and distributing the novel H1N1 vaccine to each state. In Texas, DSHS was responsible establishing and overseeing a system to allocate and distribute the vaccine to individual providers using a system. DSHS successfully created a public/private partnership to allocate and distribute vaccine to local health departments, hospitals, physicians, pharmacies, and other providers. A vaccine management system was designed and implemented in a matter of months. By August 2010, DSHS completed the registration of over 11,000 Texas providers registered and distribution of more than nine million H1N1 vaccine doses.
- *Multi-Faceted Communication Strategy:* DSHS implemented a multi-faceted communication strategy to inform and educate both providers and the public regarding the H1N1 influenza pandemic. This included a comprehensive web site (TexasFlu.org), ongoing media relations, a statewide public awareness campaign, conference calls with stakeholders, and use of the Texas Information Referral Network to provide flu information. Response partners identified two particularly beneficial activities: (1) the Texas Division of Emergency Management State Operation Center conference calls intended for local elected officials and response partners; and (2) the partnership between DSHS and the Texas Information Referral Network to

TEXAS COVID-19 VACCINATION PLAN



enhance communication with the public and providers regarding novel H1N1 by using the Texas 211 system.

The novel H1N1 pandemic presented the following major challenges to the state's public health and emergency response systems.

- *Emerging Science about the Virus:* In April 2009, information about the novel H1N1 influenza virus was limited, and a vaccine was not available. However, guidance was needed for medical providers, local public health partners, laboratory submitters, schools, and the public. The CDC and DSHS developed initial guidance documents based on information known at the time, and documents were modified as more definitive information about the virus became available. Keeping response partners and the public informed during a multi-month response was challenging and included management of rumors and misinformation.
- *Availability of the H1N1 Vaccine:* A major challenge during the response was the availability of H1N1 vaccine. At the time the H1N1 virus was identified the production of the 2009 seasonal flu virus was already in progress. As such, the vaccine for the H1N1 strain could not be included with the seasonal flu vaccine, resulting in two separate vaccines being produced.

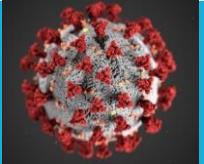
After reviewing H1N1 lessons learned, DSHS determined that the public/private partnership approach was the best COVID-19 vaccine distribution model. This approach harnesses more resources and improves the state's ability to target certain populations based on regional and local assessments. Under the public/private partnership model, providers will indicate the number of vaccines needed, the demographics and sizes of their patient populations; and in turn, DSHS will coordinate and allocate the vaccine while communicating with established vaccine distribution centers.

Additionally, DSHS has established a multi-faceted communication strategy for COVID-19. DSHS will leverage the existing website, communication, and social media strategies to augment and expand upon COVID-19 vaccine communications. Similarly, DSHS has been actively coordinating with the Texas Division of Emergency Management (TDEM) and other state agency partners for further support and assistance for the vaccine distribution.

Based on earlier challenges with COVID-19 testing capacity and personal protective equipment (PPE) shortages, DSHS made some key vaccine planning assumptions:

- Initial vaccine availability will not keep pace with demand.
- Prioritization decisions will occur in stages as supply increases.
- Guidance from CDC and the Advisory Committee on Immunization Practices (ACIP) will change, likely over a relatively short time (weeks and months).

TEXAS COVID-19 VACCINATION PLAN

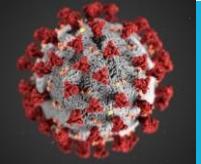


- There will be times when supply is insufficient even for the most vulnerable populations, and DSHS will need to carefully consider how to distribute the limited supply.
- Prioritization will be based on some combination of job functions, exposure potential (i.e., hospital patient care workers, EMS, nursing homes), and individual risk factors for severe illness or poor outcomes.
- Provider participation in administering the vaccine is voluntary. Individuals are not required by the state to receive the vaccine.

Additional insights for planning purposes were gained through review of areas and populations with low seasonal flu vaccination coverage. These are routine activities conducted through ongoing program effectiveness activities performed under the CDC immunization program grant. These areas are being considered for heightened provider recruitment and enrollment. DSHS has also begun assessing county level access for vaccination services to identify potential gaps in availability of COVID-19 vaccine administration.

Planning activities are ongoing as the timelines and planning assumptions from CDC continue to evolve. DSHS will continue to coordinate and communicate with partners to strengthen local, county, and regional plans in anticipation of federal approval of a COVID-19 vaccine. Texas is committed to maintaining situational awareness across the state to quickly identify opportunities to pivot and address emerging situations related to vaccine distribution.

TEXAS COVID-19 VACCINATION PLAN



Section 2: COVID-19 Organizational Structure and Partner Involvement

- A.** The Texas Department of State Health Services (DSHS) will utilize an internal COVID-19 vaccine planning and coordination team gathered from across the agency, including the Immunization Program. This team will be composed of executive staff, existing immunizations staff, other DSHS staff temporarily assigned to immunizations, and temporary/contract employees. Please see Appendix 1 for COVID-19 Organizational Chart.

The DSHS COVID-19 Vaccination Program planning and coordination team will include personnel with a broad range of expertise in vaccine programs, aligned with existing program groups.

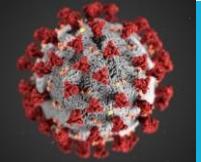
- Immunization Unit Office (Unit)
- Immunization Operations Group
- Texas Immunization Registry (ImmTrac2)
- Vaccine Data and Finance (VDF)
- Vaccine Operations Group (VOG)
- Assessment, Compliance and Evaluation (ACE)
- Public Information and Education Team (PIET)
- CDC Advisor(s)

- B.** Reaching intended vaccine recipients is essential to achieving desired levels of COVID-19 vaccination coverage. DSHS is collaborating with the Texas Division of Emergency Management (TDEM) and the Texas Emergency Management Council (TEMC) to identify targeted populations and logistical requirements for providing them COVID-19 vaccine. TDEM serves the State of Texas by managing the all-hazards emergency management plan for the state. TDEM works closely with local jurisdictions, state agencies, and federal partners to ensure Texas becomes more resilient for future disasters. The TEMC includes 39 state agencies and nonprofit emergency assistance organizations.

Through this partnership, DSHS hopes to enhance the development of risk/crisis response communication messaging and delivery of communication plans needed to reach vulnerable and frontline populations throughout Texas so that individuals can make an informed decision about whether to get vaccinated.

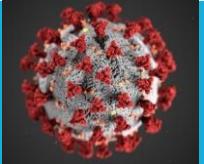
- C.** Texas will leverage partnerships to ensure planning activities are comprehensive.
- DSHS serves as the lead agency for distribution of COVID-19 vaccines. Key DSHS staff are listed in Appendix 2.
 - Through the TEMC, all state agencies involved in emergency response will coordinate and actively participate in the planning of the Texas distribution plan.
 - DSHS will engage key stakeholders through an Expert Vaccine Allocation Panel, established by the Texas Commissioner of Health.

TEXAS COVID-19 VACCINATION PLAN



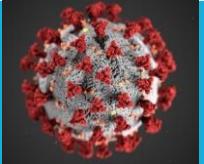
- DSHS will receive public input through the Task Force on Infectious Disease Preparedness and Response.
- D.** Texas will coordinate efforts between state, regional and local leaders through a series of meetings, calls and webinars. Texas has defined the planning phase as Phase 0, which is currently underway with many coordination calls and meetings already having occurred. Coordination activities include:
- Routine planning meetings between DSHS, TDEM, and external stakeholders like the Texas Hospital Association, Texas Medical Association, Pharmacy Board, and regional and local entities.
 - Routine update calls with all state agencies through TEMC.
- E.** Texas will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban tribal organizations through briefings with tribal leadership, conference calls to solicit input and ensure vaccine is available and accessible to tribes and established regional points of contact with for each tribe to facilitate vaccination services. DSHS will offer support to all recognized tribes. Tribal entities included in this effort are:
- **Federally-recognized tribes**
 - a) Alabama-Coushatta Tribe of Texas <https://www.alabama-coushatta.com/>
 - b) Kickapoo Traditional Tribe of Texas <https://kickapootexas.org/services-administration/chs/>
 - c) Ysleta Del Sur Pueblo <https://www.ysletadelsurpueblo.org/tribal-services/department-of-health-services/health-care-division>
 - **State-recognized tribes**
 - a) Texas Lipan Apache: <http://www.lipanapache.org/>
 - b) Texas Band of Yaqui: <https://yaquitribetexas.com/>
 - Urban Inter-Tribal Center of Texas (Dallas)
- F.** Texas has identified the following key partners for vulnerable and frontline populations. These partners have in many cases already provided data on vulnerable and frontline populations and Texas will continue to engage these partners throughout Phase 0 (planning phase).
- Texas Pharmacy Association
 - Texas Pharmacy Board
 - Texas Medical Association
 - Texas Medical Board
 - Texas Nurses Association
 - Texas Nursing Board
 - Texas Hospital Association
 - Health and Human Services Commission

TEXAS COVID-19 VACCINATION PLAN



- State EMS Coordinator
- Texas Department of Criminal Justice
- Public Utilities Commission
- Texas Commission on Law Enforcement
- Texas A&M Forest Service (Statewide Fire Services)
- Texas Higher Education Coordinating Board
- Federally Qualified Health Centers and Rural Health Centers

TEXAS COVID-19 VACCINATION PLAN



Section 3: Phased Approach to COVID-19 Vaccination

COVID-19 vaccination will be voluntary and left up to the individual to decide if and when to receive the vaccine. Due to changing vaccine supply levels at various points during the COVID-19 Vaccination Program, planning needs to be flexible but as specific as possible to accommodate a variety of scenarios. A key point to consider is that vaccine supply will be limited at the beginning of the program, so initial allocations must focus on providers and settings that can vaccinate and conduct outreach to limited vulnerable and frontline populations. The vaccine supply is projected to increase quickly over the following months, allowing vaccination efforts to expand to additional populations and the public. Recommendations on the various population groups receiving initial doses of vaccine could change after vaccine is available, depending on each vaccine's characteristics, vaccine supply, disease epidemiology, and local community factors.

Final decisions are being made about use of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials, but populations of focus for initial COVID-19 vaccination may include:

- Healthcare personnel likely to be exposed to or treat people with COVID-19.
- People at increased risk for severe illness from COVID-19, including those with underlying medical conditions and people 65 years of age and older
- Other vulnerable, frontline workers

Phase 1: Potentially Limited COVID-19 Vaccine Doses Available

In the initial phase, or Phase 1, of the COVID-19 Vaccination Program, doses of vaccine will likely be distributed in a limited manner, with the goal of maximizing vaccine acceptance and public health protection while minimizing waste and inefficiency. Key considerations in planning for this phase are:

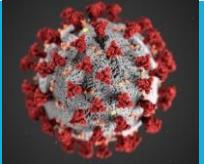
- COVID-19 vaccine supply may be limited.
- COVID-19 vaccine administration efforts must concentrate on the vulnerable and frontline populations to achieve vaccination coverage in those groups.
- Inventory, distribution, and any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses.

Texas will prioritize enrollment activities for vaccination providers and settings who will administer COVID-19 vaccine to vulnerable and frontline populations of focus for Phase 1, and considering those who live in remote, rural areas and who may have difficulty accessing vaccination services. Allocations will be equitable among geography and facility types. Simultaneously, Texas will develop operational procedures for any temporary or mobile clinics planned for Phase 2.

Phase 2: Large Number of Doses Available; Supply Likely to Meet Demand

As the supply of available vaccine increases, distribution will expand, increasing access to vaccination services for a larger population. When larger quantities of vaccine become available, there will be two simultaneous objectives:

TEXAS COVID-19 VACCINATION PLAN



- Provide equitable access to COVID-19 vaccination for all vulnerable and frontline populations to achieve high COVID-19 vaccination coverage in these populations.
- Ensure high uptake in specific populations, particularly in groups that are at [higher risk for severe outcomes from COVID-19](#).

The key considerations in planning for Phase 2 are:

- COVID-19 vaccine supply will likely be sufficient to meet demand for vulnerable and frontline populations as well as the public.
- Additional COVID-19 vaccine doses available will permit an increase in vaccination providers and locations.
- A surge in COVID-19 vaccine demand is possible, so a broad vaccine administration network for surge capacity will be necessary.
- Low COVID-19 vaccine demand is also a possibility, so jurisdictions should monitor supply and adjust strategies to minimize vaccine waste.

Texas will adapt to the increase in COVID-19 vaccine supply levels by:

- Expanding vaccination efforts beyond initial population groups in Phase 1 with emphasis on equitable access for all populations.

During Phase 2, Texas expects to administer vaccine through:

- Commercial and private sector partners (pharmacies, doctors' offices, clinics).
- Public health sites (mobile clinics, Federally Qualified Health Centers [FQHCs], RHCs, public health clinics, temporary/off-site clinics).
- Specialized vaccine teams to target areas with limited access in coordination with local and regional leadership.

Phase 3: Likely Sufficient Supply

Ultimately, COVID-19 vaccine will be widely available and integrated into routine vaccination programs, run by both public and private partners.

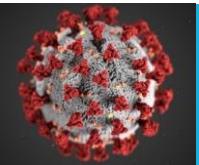
The key considerations in planning for Phase 3 are:

- The COVID-19 vaccine supply will likely be sufficient, and supply might exceed demand.
- A broad vaccine administration network will become available for increased access.

Strategies that Texas will consider:

- Continuing to focus on equitable vaccination access to vaccination services.
- Monitoring COVID-19 vaccine uptake and coverage in vulnerable and frontline populations and enhancing strategies to reach populations with low vaccination uptake or coverage.
- Partnering with commercial and private entities to ensure COVID-19 vaccine and vaccination services are widely available.
- Monitoring supply and repositioning refrigerated vaccine products to minimize vaccine waste.

TEXAS COVID-19 VACCINATION PLAN



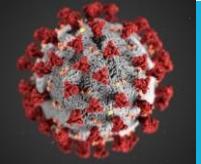
Phase 4: Sufficient supply

COVID-19 vaccine will be at a decreased need due to most of the population being vaccinated previously. May include boosters or annual vaccines if required.

Strategies that Texas will consider:

- Vaccine availability open throughout private providers. Population able to visit provider of choice.
- Monitoring COVID-19 vaccine uptake and coverage in vulnerable and frontline populations and enhancing strategies to reach populations with low vaccination uptake or coverage.
- Partnering with commercial and private entities to ensure COVID-19 vaccine and vaccination services are widely available.
- Monitoring supply and repositioning refrigerated vaccine products to minimize vaccine waste.

TEXAS COVID-19 VACCINATION PLAN

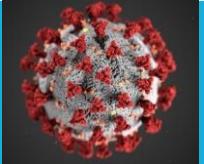


Section 4: Vulnerable and Frontline Populations

- A. Texas will use a combination of publicly available datasets, data provided by CDC, and data from other state agencies, state regulatory boards and private partners to: identify, estimate numbers of, and locate vulnerable and frontline populations via mapping. Mapping of vulnerable and frontline populations and vaccine providers will be accomplished using Tableau and/or ArcGIS and shared with key decision-makers using an internal data dashboard. Vulnerable and frontline population groups may include:

<i>Vulnerable and Frontline Population as defined by CDC</i>	<i>Texas Data Sources (subject to change)</i>
Healthcare personnel Acute Care Hospital EMS Long-term care Pharmacy All other healthcare	Annual Hospital Survey, 2018 Texas Workforce Commission (TWC) Quarterly Census of Employment and Wages by county Office of State EMS Director Health and Human Services Commission Texas Pharmacy Board
Other frontline workers	Texas Commission on Law Enforcement Texas Forest Service (Fire service) Texas Education Agency
Long-term care facility residents	HHSC, bed capacity by facility and county
People with underlying medical conditions	CDC Estimates by County (MMWR Morb Mortal Wkly Rep 2020;69:945-950.)
People 65 years of age and older	Texas Demographic Center 2020 Estimates
People from racial and ethnic minority populations	Texas Demographic Center 2020
People from tribal communities	US Census Bureau; ACS 2018 5-year estimates https://www.census.gov/programs-surveys/acs/data/race-aian.html Estimates from all state and federally-recognized tribal communities in Texas
People who are incarcerated/detained	Texas Department of Criminal Justice
People experiencing homelessness/living in shelters	HUD Point-in-time estimates, by county/Community of Care
People attending colleges and universities	Texas Higher Education Coordinating Board
People living and working in other congregate settings	HHSC (State-supported Living Centers and State Hospitals)
People living in rural communities	Texas Demographic Center 2020 Estimates, for counties not designated CBSA Metropolitan
People with disabilities	ACS 2018 5-year estimates
People who are uninsured or underinsured	Small Area Health Insurance Estimates (SAHIE), by County

TEXAS COVID-19 VACCINATION PLAN



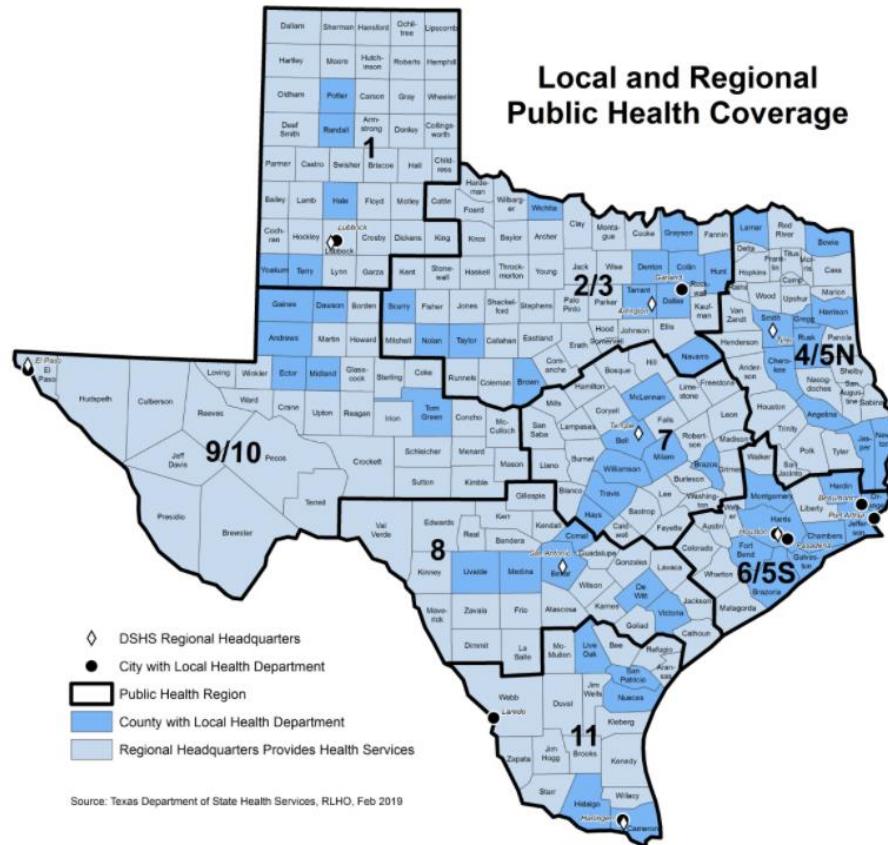
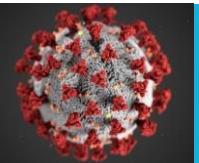
- B. Non-healthcare frontline infrastructure groups will be defined by the Expert Vaccine Allocation Panel (EVAP). Frontline workers may include public safety, firefighting, education, food and agriculture, and other sectors as defined by the EVAP. Number of persons in each workforce group will be estimated by county using data from the Texas Workforce Commission's Quarterly Census of Employment and Wages, except where other more accurate data sources are available (i.e. Texas Commission on Law Enforcement, Public Utility Commission of Texas). Texas will work with stakeholder groups to identify subsets of workers within larger sectors who 1) perform critical functions and 2) are not easily able to perform those functions while maintaining social distance.
- C. The EVAP will recommend additional population subsets to prioritize if there is insufficient vaccine supply, considering the most current recommendations from the Advisory Committee on Immunization Practices (ACIP). The recommendation will be reviewed and finally approved by the Texas Commissioner of Health.
- D. Texas will utilize existing communication networks such as the Texas Immunization Stakeholder Working Group (TISWG), already-established points of contact with other state agencies and regulatory authorities such as the Texas Medical Board and Texas State Board of Pharmacy, and the Texas Emergency Management Council to identify, estimate and locate vulnerable and frontline population groups.

Some population group sizes are provided by Public Health Region in the graphics below.

Estimated Number of Adults by Vulnerable and Frontline Population, by Public Health Region (PHR)

PHR	Healthcare Personnel	EMS	Acute Care Hospital Employees	Nursing Home Residents	Adults 65+ ^c
1	24,380	2,775	14,295	6,598	134,264
2/3	188,431	18,421	94,642	42,431	1,103,089
4/5N	42,154	4,125	17,984	15,305	295,987
6/5S	163,834	16,509	99,088	23,848	949,259
7	74,212	9,156	32,195	17,702	462,672
8	72,370	6,969	31,483	16,651	450,704
9/10	30,443	3,381	16,771	6,281	211,456
11	42,700	4,697	20,824	9,035	304,597
Texas	638,524	66,033	327,282	137,851	3,912,028

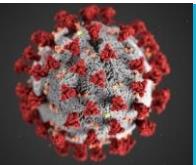
TEXAS COVID-19 VACCINATION PLAN



Estimated Number of Adults Aged ≥18 Years with Selected Underlying Medical Conditions that May Increase Risk for Severe COVID-19–Associated Illness

PHR	Any Condition	Obesity	Heart Disease	COPD*	Diabetes	Chronic Kidney Disease
1	290,135	226,660	47,582	46,624	80,737	20,327
2/3	2,671,602	2,130,162	397,243	393,643	709,204	178,230
4/5N	592,868	442,302	107,230	108,232	168,835	42,681
6/5S	2,476,882	1,985,110	352,006	339,249	714,730	163,269
7	1,067,255	855,198	165,001	158,013	278,784	72,829
8	1,058,860	837,714	158,110	139,929	304,143	71,777
9/10	513,205	419,784	74,622	66,810	52,75	36,184
11	828,231	660,067	126,936	108,811	63,844	61,294
Total	9,499,038	7,556,997	1,428,730	1,361,311	2,673,033	646,591

*Chronic obstructive pulmonary disease (COPD)



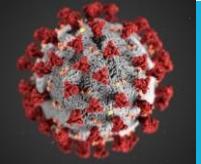
Section 5: COVID-19 Provider Recruitment and Enrollment

DSHS has initiated an outreach campaign to potential COVID-19 vaccine providers. To enable providers to register and receive COVID-19 vaccine, DSHS developed a web portal, EnrollTexasIZ.dshs.texas.gov, for providers to enter their enrollment information. In addition to providing enrollment information, the CDC requires interested providers to sign a CDC Provider Agreement Form. This form will be completed digitally during the registration process.

The purpose of the registration phase is to estimate vaccine needs of the public by collecting information from interested providers. The registration process will gather providers' logistics, the number of patients served, 2019-2020 flu vaccinations, licensure information, and other required elements to complete the CDC provider agreement, as listed below:

1. Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).
2. Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine-Administration Data) for reporting can be found on CDC's website. Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements. Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3. Organization must 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.
4. Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.
5. Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6. 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.
7. Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following:
 - a) Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine

TEXAS COVID-19 VACCINATION PLAN



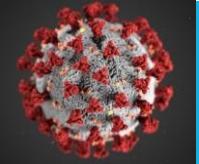
- Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 Vaccine;
- b) Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit;
 - c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;
 - d) Organization must monitor and comply with COVID-19 Vaccine expiration dates; and
 - e) Organization must preserve all records related to COVID-19 Vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
8. Organization must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.
 9. Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.
 10. Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).
 11. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.
 12. Organization must:
 - a) 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.
 - b) must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

The CDC Provider Agreement form will be completed using EnrollTexasIZ.dshs.texas.gov. Each registered provider is required to digitally sign a CDC Provider Agreement. This registration process gathers a provider's name, license number, phone number, and verification that the provider agrees to the Provider Agreement. The process also gathers information on a signing clinician and two clinic contacts (primary and backup) for each site. Providers will be assigned a six-digit registration ID number, which will be the provider's username. Data reporting to CDC will be subject to state reporting laws.

Each registering COVID-19 provider is highly recommended to complete the CDC online training entitled "You Call the Shots-Module 10-Storage and Handling" located at:

<https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>. Should providers choose to complete the highly recommended CDC training, providers are required to keep all training certificates on hand in accordance with the 3-year record retention policy for COVID-19 vaccine.

TEXAS COVID-19 VACCINATION PLAN



DSHS will conduct a webinar on how to enroll and order COVID-19 vaccine, including suggested ordering amounts. The webinar will be recorded and posted on <https://www.dshs.texas.gov/immunize/>.

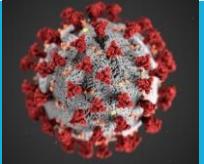
DSHS will conduct quality assurance (QA) activities on completed registrations from providers. QA activities include, but are not limited to:

- Verify the provider's ImmTrac2 Organization Code is listed and verified with the ImmTrac2 group
- Verify all necessary documents are received
- Verify all required signatures
- Verify medical licenses of all prescribing authorities
- Verify biological order for vaccine choice and maximum stock levels
- Verify that clinic has appropriate operational hours to receive vaccine and that data has been entered correctly for shipping
- Verify all data entered into vaccine ordering system was spelled correctly and in correct fields of system
- Verify accuracy of shipping address
- Verify accuracy of site contacts to include phone numbers and email addresses
- Verify correct provider type is selected

There may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites. In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed to redistribute vaccine, if approved by the jurisdiction's immunization program and if validated cold-chain procedures are in place in accordance with the manufacturer's instructions and CDC's guidance on COVID-19 vaccine storage and handling. There must be a signed *CDC COVID-19 Vaccine Redistribution Agreement* for the facility/organization conducting redistribution and a fully completed *CDC COVID-19 Vaccination Provider Profile Information* form (Section B of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location.

Vaccine service reports will be generated on a regular basis to include:

- Doses allocated by provider/county/region
- Doses ordered by provider/county/region
- Regional analysis for allocation, including the percentage of vaccine allocated to each region
- Vaccine distributor distribution
- Allocation by type and doses

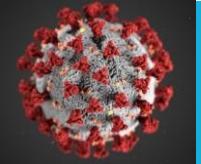


Section 6: COVID-19 Vaccine Administration Capacity

During the registration process, providers will identify the populations they serve per the CDC's required registration categories. One aspect of this is to also note the volume of each population they serve.

Additionally, providers note how many flu doses they administered during the peak week of the 2019-20 flu season. This data point allows DSHS to plan for how many doses should be shipped simultaneously to a provider about their vaccination capacity in a one week's time. This will assist during allocations; however, special arrangements may need to occur for specific vaccination events which may be required to accommodate the 1,000-minimum shipment for the ultra-cold frozen product.

Texas will target provider recruitment efforts in relation to the populations they serve and the size of the populations they serve.



Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

Vaccine Allocation

Allocation Advisory Panel

Texas has convened a team of appointed external and internal subject-matter experts (SME) into the Expert Vaccine Advisory Panel (EVAP) to develop vaccine allocation strategies as recommendations to the Texas Commissioner of Health. The panel will develop and apply guiding principles in their recommendations. Some of these principles may include equitable distribution across urban and rural communities, and considerations of application of ACIP guidance for vulnerable populations. The guiding principles are under development and will be finalized by the EVAP. The recommendations from the EVAP will be sent to the Texas Commissioner of Health for final approval.

CDC Vaccine Allocation Management System (VAMS)

DSHS is considering use of VAMS during Phase 1, if the newly developed Texas Vaccine Allocation and Ordering System (VAOS) is not ready when the vaccine arrives. Completion of VAOS is on target for November 2020.

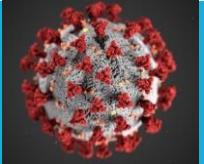
COVID-19 Vaccine Registration

Allocation methods will be based off data collected through vaccine provider registration. The vaccine provider registration process will help DSHS estimate vaccine needs by collecting information from interested providers. The registration process will gather providers' logistics, the number of patients served, 2019-2020 flu vaccinations, licensure information, and other required elements to complete the CDC provider agreement.

- Registration gathers a provider's name, license number, phone number, and verification that the provider agrees to the Provider Agreement in addition to a signing clinician for each site and two clinic contacts (primary and backup).
- Providers will be assigned a six-digit registration ID number, which will be the provider's user name.

The vaccine registration tool helps to create weighted calculations for targeted populations. The weighted calculations will align with ACIP and CDC recommendations. Below is an example of how the data would be viewed at the county level with healthcare workers as an example population of focus.

TEXAS COVID-19 VACCINATION PLAN



COUNTY	Healthcare Workers	Previous Doses Shipped	Weight	Doses Allocated
1	1361		0.2%	100
2	362		0.1%	0
3	3259		0.5%	100
4	306		0.0%	0
5	94		0.0%	0
6	32		0.0%	0
7	764		0.1%	100
8	322		0.1%	0
9	133		0.0%	0
10	242		0.0%	0

The weighted calculations will be created for each PIN in a county. Proper allocation will include disseminating the doses to the PINs with the largest populations of focus. Below is an example of provider level data driven recommendations.

COUNTY	Facility	Healthcare Workers	Previous Doses Shipped	Weight	Doses Allocated
1	100	1361		0.2%	100
2	101	362		0.1%	0
3	102	3259		0.5%	100
4	103	306		0.0%	0
5	104	94		0.0%	0
6	105	32		0.0%	0
7	106	764		0.1%	100
8	107	322		0.1%	0
9	108	133		0.0%	0
10	109	242		0.0%	0

The recommendations will be adjusted depending on the data collected through the vaccine registration in conjunction with increases in vaccine availability.

Providers must report their refrigeration capabilities and storage capacity and current inventory. This data will inform allocations to ensure that amounts are appropriate to a provider's storage capabilities and capacity. The provider must sign the provider agreement which accepts certain responsibilities relating to cold storage. These requirements are in accordance with DSHS rules and the manufacturer's specifications. State-supplied vaccines will only be held at the facility listed in the agreement and will not be transferred to another facility without DSHS approval. To receive vaccine, providers must have equipment appropriate for vaccine storage, including the ability to maintain and monitor appropriate temperatures.

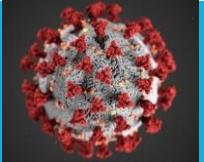
Assuring Vaccine Viability

Each registering COVID-19 provider is highly recommended to complete the CDC online training entitled "You Call the Shots-Module 10-Storage and Handling" located at:

<https://www2a.cdc.gov/nip/isd/ycts/mod1/courses/sh/ce.asp>.

Should providers choose to complete the highly recommended CDC training, providers are required to keep all training certificates on hand in accordance with the 3-year record retention policy for COVID-19

TEXAS COVID-19 VACCINATION PLAN



vaccine. You Call the Shots consists of a series of modules that discuss vaccine-preventable diseases and the latest recommendations for vaccine storage, administration, cold storage, and use.

In addition, providers must assure they have appropriate storage units (refrigerator, freezer), and data logger equipment and a back-up for each unit that will store vaccine. If the data logger fails, the back-up is available to provide temperature monitoring of the vaccine. Storage capacity at each provider site (fridge, freezer, ultra-cold) capabilities are reported during the provider enrollment process, which will be scrutinized by DSHS enrollment approval staff. To remove barriers for providers who may not have data logger equipment purchased, DSHS has planned on purchasing additional data loggers to have available to providers.

Vaccine Ordering & Distribution

Vaccine Allocation and Ordering System (VAOS)

Texas will use VAOS to allocate vaccines and allow providers to order and receive COVID-19 vaccine. Providers registered through EnrollTexasIZ.dshs.texas.gov will be registered to receive vaccines and provide vaccinations. Once providers complete their registration, they will be eligible to receive vaccines directly from the distributor. The minimum shipped quantity totals 100 doses. While vaccines are in limited supply, Texas DSHS will continue the allocation process and ship vaccines to providers serving prioritized populations. During this phase:

- Providers will be notified via email they will be receiving vaccines.
- Providers must receive their shipment digitally within VAOS which will update their on-hand inventory. This must be completed within 24 hours of receiving the shipment.

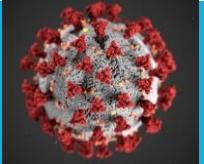
Providers must report doses used in ImmTrac2 and complete the reporting process within the VAOS system to keep information on their inventory up to date. This includes reporting doses wasted and transferred. Reporting must be completed within 24 hours of usage, waste, or transfer.

Once allocations have been completed and supply is able to meet demand, providers will be able to order COVID-19 vaccine through VAOS at their discretion.

Vaccine Ordering Process

- The CDC provides a forecast of vaccine anticipated to be available by week, which will be tracked and reported by the DSHS Vaccine Allocation Team (VAT) team.
- The DSHS Assessment, Compliance, and Evaluation (ACE) team prepares data on vulnerable and frontline populations for EVAP consideration.
- The Vaccine Data and Finance (VDF) team prepares reports of inventory on hand, doses used as notated in VAOS, and additional doses required due to series completion requirements.
- EVAP recommends how vaccine is to be directed to vulnerable and frontline populations (e.g., high-risk children) and provider types (e.g., private practice) based on the quantity of each

TEXAS COVID-19 VACCINATION PLAN



vaccine formulation available and, upon its completion, in accordance with the EVAP Guiding Principles.

- Texas Commissioner of Health approves allocation with advice from the EVAP.
- The CDC provides actual numbers of vaccine available to Texas.
- VAT implements the approved allocation across selected providers.
- VAT posts allocations online in VAOS. Selected providers' accounts show the quantity of vaccine available to each provider.
- VAT sends an email notification to providers who were allocated vaccine.
- Providers accept their order in VAOS. They may order up to the maximum amount of vaccine allocated to them (i.e., if they have refrigeration constraints they may order less than their allocation).
- VAT places the order within the federal ordering system, which then direct-ships from the CDC warehouse to the designated clinic address.

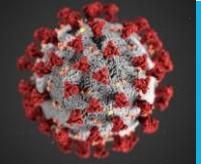
Any repositioning of vaccine will be closely monitored through reporting to ensure end-to-end visibility of vaccine doses. In later phases, strike teams may be procured and deployed to accommodate vulnerable and frontline populations that do not have access to the vaccine (e.g. Long-Term Care facilities). Monitoring and repositioning refrigerated vaccine products to minimize wastage will be a strategy to increase sufficiency in supply. This is essential during Phase 1 due to limited doses of availability. Additional doses needing repositioning will be allocated back to the initial populations of focus.

Providers must receive their shipment digitally within the VAOS, which will update their on-hand inventory. This must be completed within 24 hours of receiving the shipment. Providers must report doses used in ImmTrac2 and complete the reporting process within the VAOS system to maintain accurate and up-to-date inventory information. This includes reporting doses wasted and transferred. Reporting must be completed within 24 hours of usage, waste, or transfer. The provider must report to DSHS the number of doses of vaccine which were not used because the vaccine expired, or the vaccine was wasted for other reasons. These doses must be disposed of in accordance with state regulations for biological waste.

Reporting and Monitoring

- A. *Data Tracking:* The Vaccine Data & Finance team will disseminate the reports below to track COVID-19 vaccine brands and presentations. The inventory spreadsheet will include the following:
- Weekly
 - i. Amount of vaccine allocated to Texas from the CDC (vaccine at McKesson).
 - ii. Provider orders sent to McKesson.

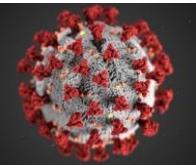
TEXAS COVID-19 VACCINATION PLAN



- Daily
 - i. Doses reported as administered by providers from VAOS
 - ii. McKesson's shipped list.
 - iii. Doses reported as administered by providers from ImmTrac2

Daily inventory data is critical to ensure that appropriate amounts and presentations of vaccines are available at the two distributors. The inventory data provides immediate responses to requests for information on orders from internal and external sources.

- B. *Quality Assurance:* Texas will use ImmTrac2 as the official repository of data because this will be the basis for the data reported to the CDC and used for their analysis. DSHS will ensure that all the necessary protections are in place for the data in transit and at rest. Due to Texas's laws governing the Texas Immunization Registry, no individual data will be shared via the CDC Immunization Gateway. Instead DSHS will directly provide CDC with aggregate data regarding vaccine doses administered, and will not provide personally identifiable data, per state law.



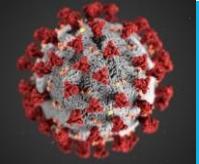
Section 8: COVID-19 Vaccine Storage and Handling

To ensure that all providers are educated in CDC storage and handling best practices, DSHS highly encourages all COVID-19 vaccine providers to complete CDC's You Call the Shots Module 10 with their enrollment process. Should providers choose to complete the highly recommended CDC training, providers are required to keep all training certificates on hand in accordance with the 3-year record retention policy for COVID-19 vaccine.

Upon enrollment, providers are required to enter storage equipment details such as fridge/freezer make and model as well as certificates of calibration for data loggers. DSHS will assess the provider's ability to store and maintain Ultra-Cold vaccine storage units. Based on CDC's guidance, DSHS is not recommending the purchasing of these special storage units for Ultra-Cold storage.

DSHS will conduct Vaccine Storage and Handling webinars and possibly record trainings for providers to view. DSHS has also created access to additional resources for providers that include CDC Storage and Handling Toolkit. DSHS team members are trained in vaccine storage and handling and are available via a call center line to answer provider questions Monday through Friday, 8 am to 5 pm.

- A. DSHS will review provider registrations to assess if the facility has sufficient and appropriate capacity for the types of vaccine they will receive.
- B. Redistribution of COVID-19 vaccine will require both parties to sign the CDC COVID-19 Vaccine Redistribution Agreement for the facilities that are sending/receiving the COVID-19 vaccine. Receiving locations/facilities will also need to provide evidence to DSHS of their ability to safely store the vaccine and to maintain cold chain integrity. For proper vaccine tracking, the site(s) involved will all need to have provider identification numbers (PIN) registered with DSHS. Completed forms will be submitted to COVID19VacEnroll@dshs.texas.gov for review. Providers will need to note on the form the amount, presentation, lot number and expiration of the vaccine to be redistributed to another site. Submitted information will be scrutinized by DSHS staff and once approved by DSHS staff, the Redistribution Agreement will remain on file in the pandemic prep enrollment module located at <https://enrolltexasiz.dshs.texas.gov/login.asp>.



Section 9: COVID-19 Vaccine Administration Documentation and Reporting

Texas will use the Texas Immunization Registry, known as ImmTrac2, to collect data from providers on COVID-19 vaccine doses administered. Additionally, Texas will receive COVID-19 vaccine doses administered data from providers through the CDC Immunization (IZ) Gateway interface from chain pharmacies directly enrolled by CDC. Security of the systems maintaining doses administered data will comply with all federal and state laws governing confidentiality and privacy issues. DSHS will ensure that all the necessary protections are in place for the data in transit and at rest.

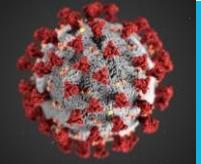
Due to Texas's laws governing the Texas Immunization Registry under Health and Safety Code Section 161.0073, no individualized data will be shared via the CDC Immunization Gateway. Instead DSHS will directly provide CDC with aggregate anonymized data regarding vaccine doses administered, and will not provide personally identifiable data, per state law.

Texas will ensure COVID-19 vaccine providers have received all needed ImmTrac2 guidance and resources, including training on COVID-19 vaccine reporting requirements specific to whether the provider intends to report to the registry online or electronically. During onboarding of the COVID-19 vaccine provider, DSHS staff will record that the provider has received training or is aware of all training materials made available on public-facing website.

Texas will conduct remote trainings with participating COVID-19 vaccine providers to inform them of federal and state reporting requirements. Data received to the registry will be closely monitored to ensure complete, accurate, and timely reporting. Organizations will be provided access to enter immunization data online to ensure real-time reporting of COVID-19 administration data.

Texas will run daily queries for all COVID-19 vaccine administrations by provider. DSHS will review these reports to analyze timeliness of reporting from date of administration. DSHS will notify providers that exceed the 24-hour required time period of the importance of reporting vaccine within the specified 24-hour time period. Additional data quality queries will be run against all COVID-19 submitting providers to ensure that all data fields required are correct and complete.

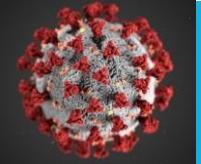
COVID-19 vaccination coverage reports will be run on a regularly scheduled basis and results will be made available on an internal Tableau server for review. Aggregate vaccine administration and coverage data will also be posted regularly to a public-facing Tableau dashboard.



Section 10: COVID-19 Vaccination Second-Dose Reminders

The Texas Immunization Registry, ImmTrac2, will provide regular extracts of clients coming due for the second COVID-19 dose. Local Health Departments (LHD) and provider organizations will be encouraged to develop procedures to perform reminder/recall outreach based on data received from ImmTrac2 or available through their respective Electronic Health Record (EHR) systems. Regularly scheduled file extracts will contain all necessary data elements needed to complete outreach efforts. Files would be made available to those provider organizations through existing Secure File Transfer Protocol (SFTP). Additional options for reminders are being considered at this time.

Trainings will be conducted with LHDs and provider organizations on the steps to retrieve and review the data files. Technical support will be provided on an as needed basis. These requests can be emailed to ImmTracMU@dshs.texas.gov.



Section 11: COVID-19 Requirements for IISs or Other External Systems

In addition to vaccination event data (e.g. date, vaccine administered, dose number), Texas will capture date of birth, age at vaccination, series completion, and address of recipient and race/ethnicity.

Texas is currently migrating the registry platform to an updated environment that will ensure that the system has capacity for the increased volume of data and users. The registry application will also undergo a performance test to ensure that expected load in the coming months will be manageable without any significant production issues. If performance-related issues are identified, the registry maintenance vendor will make necessary adjustments to mitigate any risks associated with increased traffic and processing of files.

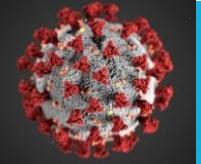
DSHS contracted for development of the Immunization Portal. This portal will be used to register organizations and allow them to request the COVID-19 vaccine in a centralized system. Additionally, a new Vaccine Allocation and Ordering System (VAOS) is currently in development.

Texas is currently in the process of establishing an interface with the CDC's IZ Gateway Connect.

Below are all the activities currently being conducted related to data exchange:

1. *Data use agreement with the Association of Public Health Laboratories to participate in the IZ Gateway:* Texas is currently reviewing the DUA with APHL.
2. *Data use agreement with CDC for national coverage analyses:* Texas is currently in process of reviewing the DUA with APHL.
3. *Memorandum of Understanding to share data with other jurisdictions via the IZ Gateway Share component:* Texas law authorizes the sharing of statistical data only.
4. Security of the systems maintaining doses administered data will comply with all federal and state laws governing confidentiality and privacy issues. DSHS will ensure that all the necessary protections are in place for the data in transit and at rest.

Texas will run regular queries against all incoming data to closely monitor if providers are conforming to data standards. Any provider that does not meet the standards will be informed of their issue(s) and registry staff will provide technical assistance to mitigate and correct subsequent immunization files.



Section 12: COVID-19 Vaccination Program Communication

Texas will implement a statewide integrated communications/outreach/engagement plan. The plan is tiered for providers (recruitment, vaccine administration), the public (information, call to action) and stakeholders (outreach, support and feedback).

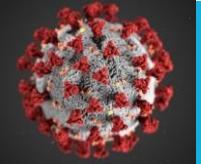
Key audiences are as follows: healthcare providers; community-based public health partners and coalitions; local and regional health entities; city, regional and statewide elected officials and administrators; municipal departments/agencies; vulnerable and frontline audiences identified by the CDC; and the public. An emphasis will be placed on targeting media outlets favored by the following audiences: vulnerable and frontline workers; people at increased risk for severe illness or death; people at increased risk of acquiring or transmitting COVID-19; and people with limited access to vaccination services.

Creative messaging will come in the following forms: TV, radio, digital/online/out-of-home/social media advertising. Creative media assets will focus on the following topics: vaccine safety/vaccine hesitancy; vaccine importance; location of providers; and dosage schedule/reminder. The media buy will include the following metropolitan markets: Dallas/Fort Worth, Houston, Austin, San Antonio, Rio Grande Valley and El Paso. Digital and out-of-home media buys will include rural areas. Breakdown of each phase, relating to the scheduled media buy strategy is detailed below.

- *Phase 1:* Statewide media campaign's message: what to expect, why vaccine is important; continued provider outreach (targeted and aided by stakeholder mobilization)
- *Phase 2:* Statewide media campaign's message: vaccine safety, dose requirements and provider locations
- *Phase 3:* Statewide media campaign's message: vaccine safety, dose reminder

When preparing and finalizing informational materials, DSHS will adhere to CDC Crisis and Emergency Risk Communication principles. All materials, including media assets, will be reviewed by subject matter experts before distribution. DSHS will also employ its partners during strategy implementation.

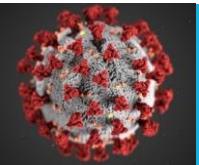
Feedback garnered from these groups will identify potential alterations during the campaign. When possible, focus groups will be used to test public messaging. Communication channels will be chosen based on the ability to provide information in the best manner possible, both timely and accurate. As much as possible, templates will be created and approved, offering more efficient means of creating materials in quick succession.



Section 13: Regulatory Considerations for COVID-19 Vaccination

As part of the provider enrollment process, each enrollee will receive instruction of the CDC-mandated Emergency Use Authorization (EUA) facts sheets as well as Vaccine Information Statements (VIS). Instruction will come in both written and electronic modes. Any EUA/VIS documents will be available via the DSHS web site (immunizetexas.com) as well as featured in mass-distributed communications (newsletters, memos, webinars). The documents will also be shared with immunization stakeholders and relevant state agencies that regulate providers with instructions to distribute to their targeted demographics.

Produced webinars will include instruction on the need to provide EUA/VIS documents to vaccine recipients prior to vaccine administration. A notice will also be placed where documents are available for download or ordering. All created instruction materials will be shared with immunization stakeholders with guidance on how to distribute to their targeted audiences.



Section 14: COVID-19 Vaccine Safety Monitoring

Ensuring the public that vaccines are safe and effective is essential to the success of any vaccination program, and COVID-19 will be no different. Although vaccine development timelines have been accelerated through investments in technology and manufacturing capacity, safeguards remain in place at all stages of vaccine development and licensure to monitor safety. Part of the U.S. vaccine safety post-licensure monitoring system is the Vaccine Adverse Event Reporting System (VAERS), which was established by the CDC and the U.S. Food and Drug Administration (FDA) in 1990 in response to the National Childhood Vaccine Injury Act passed by Congress in 1986. Healthcare providers are required by federal law to report [certain adverse events](#) to VAERS. [Additional reporting requirements](#) for adverse events may apply for COVID-19 vaccines in the early stages of their use in the US.

The main goals of VAERS are to:

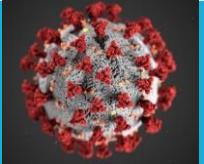
- Detect new, unusual, or rare adverse events that happen after vaccination
- Monitor for increases in known side effects
- Identify potential patient risk factors for particular types of health problems related to vaccines
- Assess the safety of newly licensed vaccines
- Detect unexpected or unusual patterns in adverse event reports

Anyone can file a VAERS report, including healthcare providers, manufacturers, and vaccine recipients. Information included in the VAERS data does **not** mean that the vaccine caused the adverse event. Once VAERS receives a report, VAERS staff analyze data for trends and conduct follow-up as needed to determine if there is reason for concern related to the vaccine. Data received on a weekly basis for COVID-19 vaccine will be preliminary and subject to further CDC investigation. Vaccine safety is also continuously monitored through the [Vaccine Safety Datalink \(VSD\)](#) system, using sentinel sites throughout the U.S.

The preferred reporting method is online through the [VAERS website](#), but reports can also be submitted via writable PDF from the same website.

- A. Texas will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) by:
- Providing instructions to COVID-19 providers on reporting significant adverse events after COVID-19 vaccination, to include what adverse events must be reported and how to report.
 - Posting an online provider tool kit, including a webinar on safe administration of vaccine and links to the CDC's [Clinical Immunization Safety Assessment Project](#) for providers to request a consultation for a complex vaccine safety issue with an individual patient.
 - Collaborating via the Texas Hospital Association with hospital staff to encourage timely submission of VAERS reports on clinically significant adverse events after COVID-19 vaccination.

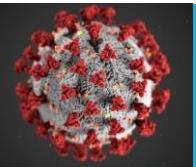
TEXAS COVID-19 VACCINATION PLAN



- Collaborating with the 2-1-1 Texas Call Center to provide accurate vaccine safety information and VAERS reporting resources.
 - Assisting the DSHS COVID-19 Vaccine Call Center with questions from medical providers and the public on vaccine safety and VAERS reporting.
 - Participating in CDC VAERS communication and data gathering, when requested.
 - Coordinating with the Texas Poison Control Network (TPCN) on messaging and reporting.
- B. Upon approval and distribution of COVID-19 vaccines, federal VAERS will provide each state with weekly data on all VAERS reports related to COVID-19 vaccine within their jurisdiction. Information will include patient identifiable information, details on the vaccine given, and information about the adverse event. Patient data privacy and confidentiality will be carefully maintained and conform to all state and federal privacy laws.

Based on lessons learned from H1N1, Texas will utilize a Vaccine Safety Clinical Team to respond to any vaccine safety concerns. The team will consist of the DSHS Infectious Disease Medical Officer, the DSHS Vaccinologist, DSHS Immunizations Nurse Consultant, DSHS Medical Research Specialist, and the DSHS VAERS Coordinator, who is the lead immunization epidemiologist in the DSHS Immunization Unit and the main point of contact with the federal VAERS program. The VAERS Clinical Team will serve as the primary liaison between the State and VAERS. The team will assist in the following activities:

- Notify the CDC of reports of clusters of serious or unusual adverse events
- Answer questions about VAERS and vaccine safety
- Provide current, relevant vaccine safety information via the DSHS website and other means
- Assist with the reporting of vaccine adverse events to VAERS
- Analyze VAERS data
- Monitor VAERS data for new adverse events or trends
- Participate in special studies to assess adverse events



Section 15: COVID-19 Vaccination Program Monitoring

- A. DSHS plans to continuously monitor resources such as budget, staffing and other operational needs through weekly meetings with the immunization leadership team and executive leadership to ensure needs are being met. These meetings will serve as a mechanism to escalate items throughout the grant period.

Texas will use a variety of analytic tools to assist in the active monitoring of vaccine distribution. These tools will include, but not be limited to SAS, SQL, ArcGIS, and Tableau. These tools will be used to establish internal and external dashboards for state leadership and public reporting.

- B. DSHS will leverage the internal communications team within the agency and partner with other state agencies' communications teams to monitor public messages regarding COVID-19 vaccine. Additionally, below are a few examples of internal communication monitoring activities.

- *Message delivery:*
 - Stakeholders/providers: Tracking recipient reports for each mass GovDelivery distribution.
 - General public: Conducting evaluation on media campaigns, reporting on demographic reached, message saturation and acceptance.
- *Communication effectiveness among target audiences:*
 - Testing messaging via focus groups and audience interviews.
 - Conducting evaluation and analysis of all COVID vaccine messaging.

- C. Communication and coordination with local jurisdictions and tribal organizations are important in all phases of the COVID-19 Vaccination Program. DSHS will monitor and maintain awareness of local level strategies, activities and provide technical assistance as needed. This visibility can help ensure local jurisdictions and providers adhere to recommendations and guidance from CDC and state and local authorities.

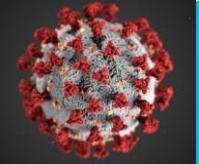
DSHS will gather, organize, verify, and share aggregate information to help leaders and responders make science-based decisions and actionable recommendations.

- Collect and analyze data from many sources
- Provide secure and adaptable systems for gathering and sharing data
- Check the data and our analyses to be sure they are as accurate as possible
- Provide recommendations on the process and systems used to collect, analyze and validate this information

DSHS will turn data and analyses into accessible, easy-to-use tools by:

- Creating reports, charts, maps, and databases
- Ensuring that information is clear and accessible

TEXAS COVID-19 VACCINATION PLAN



- Using processes, tools, and information to predict future circumstances

DSHS will work with partners such as TDEM and regional and local entities to develop and maintain resources that support information-sharing.

DSHS will share this information with partners by:

- Collaborating with the TDEM and the Emergency Management Council
- Developing open-sourced, interactive, web-based tools for information sharing
- Developing standard operating procedures (SOP), memorandums of understanding (MOUs), and trainings to support information/knowledge management

D. The following metrics will be used to track and monitor progress throughout Texas's COVID vaccination response efforts.

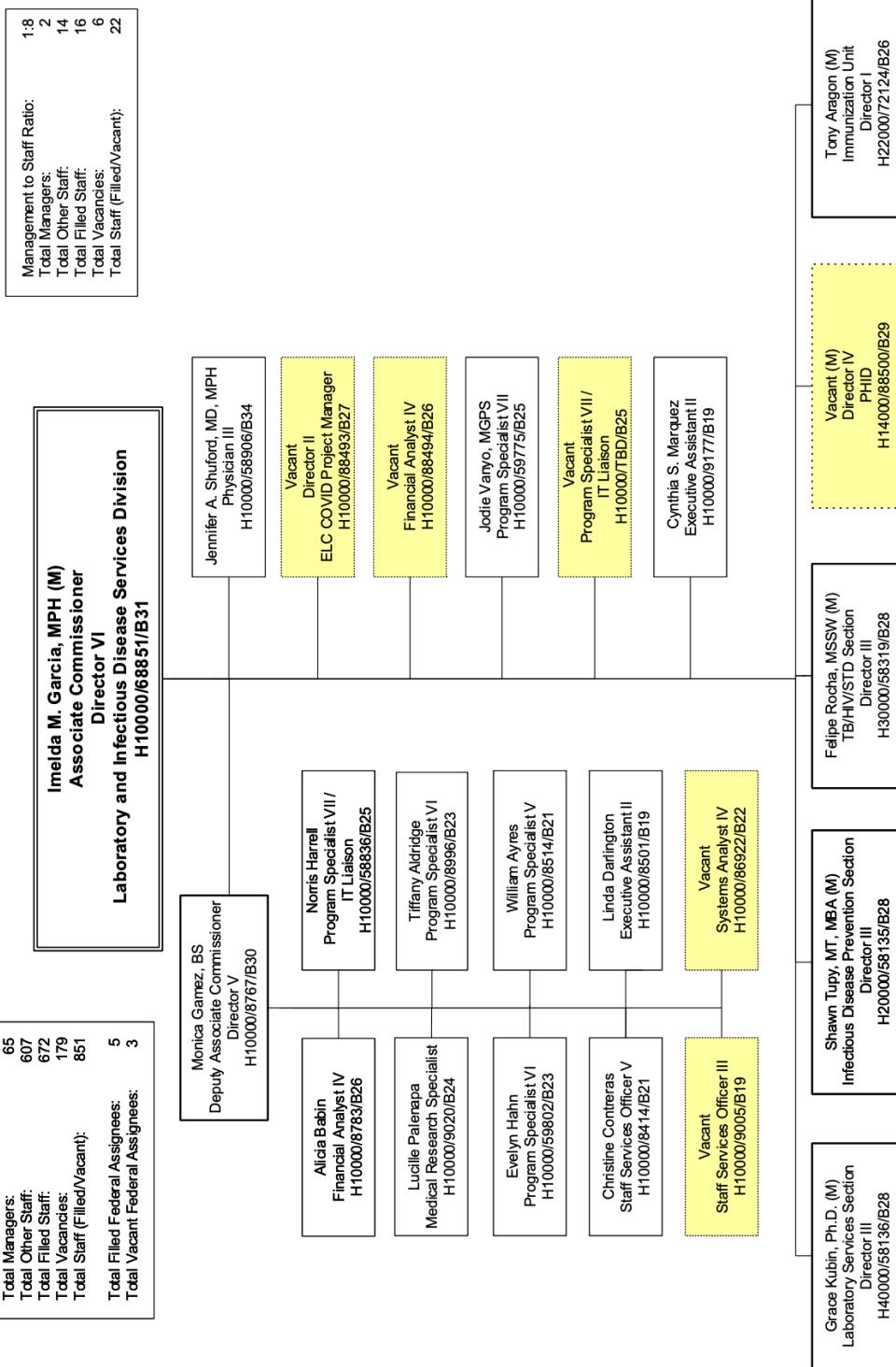
- *Providers*
 - Provider enrollment will be monitored and reported to the CDC twice weekly as required.
 - Provider enrollment will be reported to DSHS leadership, local health departments and public health regions, and other key stakeholders. Data will be broken down by provider type and provider county, to assist in identifying gaps in access to COVID-19 vaccine.
 - Pre-book amounts reported by providers will be compared against populations identified. This process will assist with the identification of gaps in provider coverage throughout Texas.
- *Vaccine ordering and distribution*
 - Allocations by county, region, and facility type.
 - Doses shipped by county, region, and facility type.
 - Monitoring inventory through inventory aging reports as well as inventory turnover reports.
- *Vaccination Coverage, county-level from ImmTrac2*
 - Dashboard accessible to the public through the DSHS website.
 - Tracking and monitoring second dose completion rates, if applicable.

Appendices

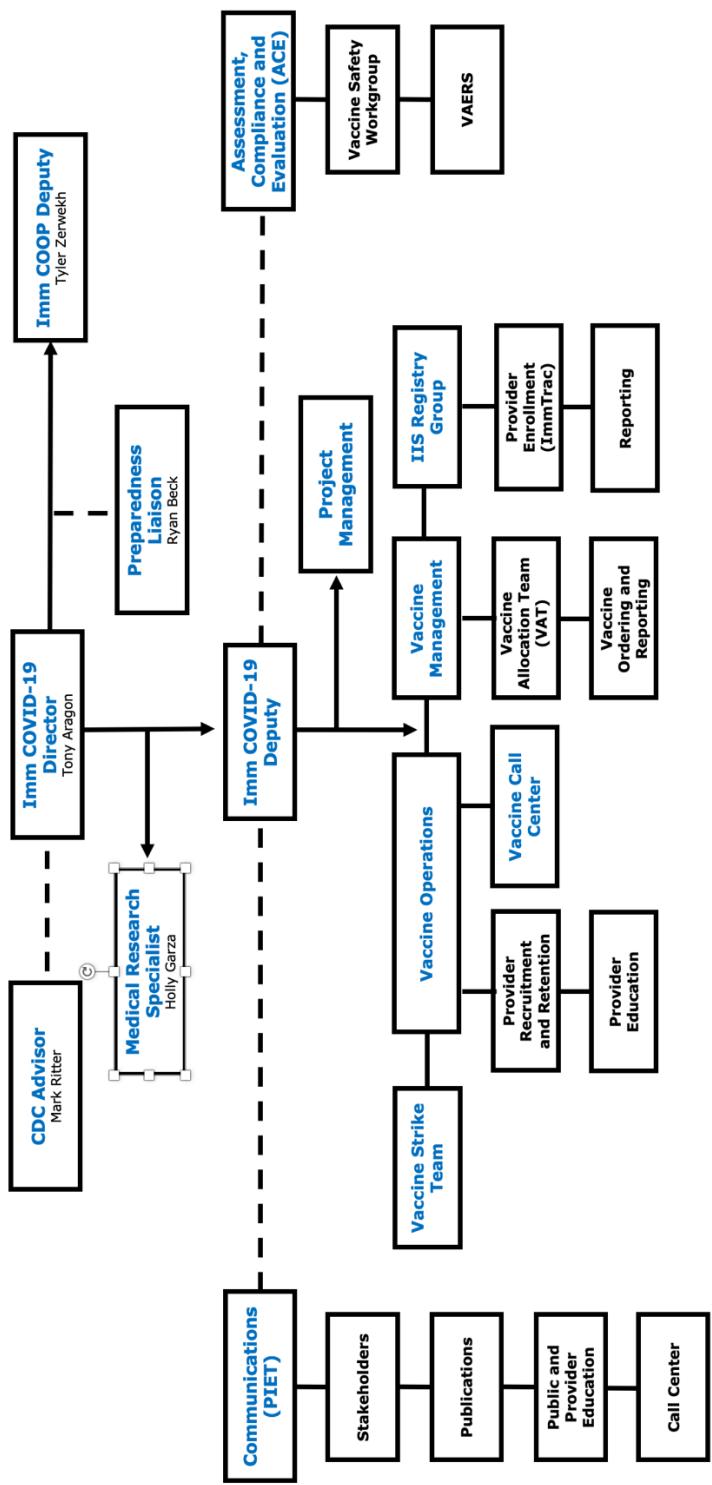
Appendix 1: DSHS Organizational Charts

LABORATORY AND INFECTIOUS DISEASE SERVICES DIVISION October 2020

Overall Section	
Management to Staff Ratio:	1:10
Total Managers:	65
Total Other Staff:	607
Total Filled Staff:	672
Total Vacancies:	179
Total Staff (Filled/Vacant):	851
Total Filled Federal Assignees:	5
Total Vacant Federal Assignees:	3



2020 DSHS Immunizations Unit COVID-19 Vaccine Response Org Chart - Vaccine Management Team (VMT)



Appendix 2: DSHS Key Staff

- Immunization Unit Director: Directs and provide leadership to the Immunization by reaching the goals of the DSHS Immunization Unit in which the main goal is to eliminate the spread of vaccine preventable diseases by increasing vaccine coverage for Texans.
- Vaccine Data & Finance Manager: Oversees and manages vaccine shipments, provider inventory and associated reporting.
- Vaccine Operations Group Manager: Oversees provider enrollment, COVID-19 vaccine call center for providers, storage and handling training, and program policy.
- Immunization Registry Group Manager: Performs highly advanced managerial, consultative, administrative, and technical work in planning, developing, implementing, evaluating, coordinating, and directing immunization registry (ImmTrac2) activities for the Immunization Unit.
- Public Information, Education and Training Manager: Responsible for the coordination of the integrated communications/outreach/engagement plan.
- Vaccinologist: Provides expert scientific/medical consultation by evaluating and reporting on vaccine development and safety for the Immunization Unit.
- Medical Research Specialist: Facilitates a coordinated approach across the Immunization Unit to data quality and data dashboards, evaluates populations and datasets critical to immunization program activities, works closely with Unit epidemiologists, and advises on vaccine safety and medical research information.
- Assessment, Compliance, and Evaluation [ACE] Group Manager: Plans, assigns, and supervises ACE staff in the areas of epidemiology, perinatal hepatitis B program, and school compliance with immunization requirements. The lead epidemiologist in ACE will oversee VAERS reporting. The nurse in the perinatal hepatitis B program will assist with the Vaccine Safety Group.
- Preparedness Liaison: Performs highly advanced consultative, communication, and technical assistance work for the Immunization Unit. Develops or oversees the development of guidelines, policies, documents, and procedures for the Unit.

Appendix 3: Countermeasures Injury Compensation Program

The federal **Public Readiness and Emergency Preparedness Act** (PREP Act) authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of covered countermeasures identified in and administered or used under a PREP Act declaration. The CICP also may provide benefits to certain survivors of individuals who die as a direct result of the administration or use of such covered countermeasures. The PREP Act declaration for medical countermeasures against COVID-19 states that the covered countermeasures are:

- Any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used:
- To treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or
- To limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or
- Any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the Federal Food, Drug, and Cosmetic Act (FD&C Act), and the Public Health Service Act, or a respiratory protective device approved by National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary of the Department of Health and Human

Services determines to be a priority for use during a public health emergency declared under section 319 of the Public Health Service Act.

For more information about the CICP, visit the program's website at www.hrsa.gov/cicp, email cicp@hrsa.gov, or call 1-855-266-CICP (1-855-266-2427).