

### TEXAS Health and Human Services

# The Vaccines are **HERE** !



PAUL REVERE'S RIDE-APRIL 19, 1773 .- DRAWN BY CHARLES G. BUSH -- [SEE THE PORM,

### **Discussion Topics**

- Welcome & Opening Remarks
- Texas COVID-19 Vaccine Allocation
- Moderna COVID-19 Vaccine Review
- What to Expect this Week?
- Closing Remarks



# DISCLAIMER

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

December 20, 2020

# Welcome

#### December 20, 2020

Imelda Garcia, MPH

Associate Commissioner | Laboratory & Infectious Disease Services Division

### **COVID-19 Vaccines**

- Last week, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 vaccine for ages 16 years and older.
- On Friday, December 18, 2020, the FDA issued an EUA to second COVID-19 vaccine, MODERNA's COVID-19 vaccine.
  - Yesterday, Advisory Committee on Immunization Practices (ACIP) met to finalize the recommendations.
  - Earlier today, ACIP released the MMWR with interim recommendations.
  - The Moderna COVID-19 Vaccine Prescribing Information and the corresponding Fact Sheet for vaccine recipient were sent to you earlier today.



### **COVID-19 Vaccines**

- Vaccines authorized for use under an EUA cannot be mandated. Every person has the right to refuse the vaccine.
- Texas will not require written consent from vaccine recipients.



# Texas COVID-19 Vaccine Allocation



### **COVID-19 Expert Vaccination Allocation Panel (EVAP)**

- Texas has convened a team of appointed external and internal subject-matter experts (SME) into the COVID-19 Expert Vaccine Allocation Panel (EVAP) to develop vaccine allocation strategies as recommendations to the Texas Commissioner of Health.
- The panel has developed guiding principles and applies these in their recommendations.
- The recommendations from the EVAP are sent to the Texas Commissioner of Health for final approval.
- EVAP voting members

https://www.dshs.texas.gov/coronavirus/immunize/evap.aspx



### **Texas Guiding Principles**

- **Protecting health care workers** who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the health care infrastructure for all who need it.
- **Protecting front-line workers** who are at greater risk of contracting COVID-19 due to the nature of their work providing critical services and preserving the economy.
- **Protecting vulnerable populations** who are at greater risk of severe disease and death if they contract COVID-19.
- **Mitigating health inequities** due to factors such as demographics, poverty, insurance status and geography.
- **Data-driven allocations** using the best available scientific evidence and epidemiology at the time, allowing for flexibility for local conditions.
- **Geographic diversity** through a balanced approach that considers access in urban and rural communities and in affected ZIP codes.
- **Transparency** through sharing allocations with the public and seeking public feedback.

https://gov.texas.gov/news/post/governor-abbott-dshs-announce-covid-19-vaccine-distribution-plan



### **COVID-19 Critical Population Updated** Phase 1A Healthcare Workers Definition – First Tier

- Paid and unpaid workers in hospital settings working directly with patients who are positive or at high risk for COVID-19. Such as but not limited to:
  - Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.)
  - Additional clinical staff providing supporting laboratory, pharmacy, diagnostic and/or rehabilitation services
  - Others having direct contact with patients or infectious materials
- 2. Long-term care staff working directly with vulnerable residents. Includes:
  - a. Direct care providers at nursing homes, assisted living facilities, and state supported living centers
  - b. Physicians, nurses, personal care assistants, custodial, food service staff
- EMS providers who engage in 9-1-1 emergency services like pre-hospital care and transport
- Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients
  - Residents of long-term care facilities



### **COVID-19 Critical Population Updated** Phase 1A Healthcare Workers Definition – Second Tier

- Staff in outpatient care settings who interact with symptomatic patients. Such as but not limited to:
  - Physicians, nurses, respiratory therapists and other support staff (custodial staff, etc.).
  - Clinical staff providing diagnostic, laboratory, and/or rehabilitation services
  - Non 9-1-1 transportation for routine care
  - Healthcare workers in corrections and detention facilities
- Direct care staff in freestanding emergency medical care facilities and urgent care clinics.
- Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individuals who may have COVID.
- Public health and emergency response staff directly involved in administration of COVID testing and vaccinations.
- Last responders who provide mortuary or death services to decedents with COVID-19. Includes:
  - Embalmers and funeral home workers who have direct contact with decedents
  - Medical examiners and other medical certifiers who have direct contact with decedents.
- School nurses who provide health care to students and teachers.



### **Phase 1A Healthcare Workers in Texas**

Healthcare Workers	Estimated Population	Healthcare Workers
Hospital Personnel	327,028	10,721 - 34,484
EMS Personnel	66,033	34,485 - 72,366 72,367 - 182,167 182,168 - 279,63
LTC Personnel Total	202,070	
Home Health Workers	257,922	4/5N
Ambulatory/Outpatient	490,000	9/10 7 7
Pharmacy Personnel	231,987	8
Last Responders	10,416	
School Nurses	6,106	Sources: 2018 Annual Survey of Hospitals, 2019 Quarterly Census
Total	1,591,562	of Employment and Wages



### Week 1 Allocations

- Only Pfizer-BioNTech COVID-19 vaccine available
  - Minimum order 975 doses
  - Ultra-low frozen temperature storage
- Allocated to hospitals with minimum 1,000 healthcare workers



### Week 2 Allocations

- 159,900 doses Pfizer-BioNTech COVID-19 vaccine available for allocation
  - 124,800 reserved for federal pharmacy partnership for Long-Term Care (LTC) Program
    - LTC start date December 28, 2020
- 460,500 doses of Moderna COVID-19 vaccine available for allocation
  - Minimum order 100 doses
  - Stored frozen (6 months), refrigerated 30 days
  - Allocated to diverse provider types







### Week 2 Vaccination

- Accept vaccine doses VAOS—acknowledging inventory
- Vaccinate with **URGENCY**
- Vaccinate Phase 1a population meeting the definition of Healthcare Workers
  - Check ID badge for confirmation to a healthcare setting
- Minimize dosage wasted
- Report in ImmTrac2 within 24 hours of administration
- Encourage newly vaccinated people to enroll in V-Safe



## MODERNA COVID-19 Vaccine Review

Saroj Rai, PhD, MPH



### Moderna COVID-19 Vaccine Authorized Use

 Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 1 (SARS-CoV-2) in individuals 18 years of age and older.



### Moderna COVID-19 Vaccine Ingredients

- The Moderna COVID-19 Vaccine contains the following ingredients:
  - messenger ribonucleic acid (mRNA)
  - Lipids
    - SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], Cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]
  - Tromethamine
  - Tromethamine hydrochloride
  - Acetic acid
  - Sodium acetate
  - Sucrose

![](_page_19_Picture_10.jpeg)

### mRNA-1273 Shipping, Storage and Administration

![](_page_20_Figure_1.jpeg)

Able to ship a single carton (100 doses)

![](_page_20_Figure_3.jpeg)

Local transportation under controlled condition at 2 to 8°C **Administration** 

![](_page_20_Figure_6.jpeg)

Multiple-dose vial

Use within 6 hours after first entry

No dilution required

### Moderna COVID-19 Vaccine Storage

#### **Storage Prior to Use**

- The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light.
- Do not store on dry ice or below -40°C (-40°F).
- Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
- Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.
   Do not refreeze once thawed.

#### **Storage After First Puncture of the Vaccine Vial**

- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to77°F).
- Discard vial after 6 hours. Do not refreeze.

![](_page_21_Picture_9.jpeg)

### **Moderna COVID-19 Vaccine** Dose Preparation & Administration

- The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
- Remove the required number of vial(s) from storage and thaw each vial before use.
- Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
- Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
- After thawing, do not refreeze.
- Swirl vial gently after thawing and between each withdrawal. **Do not shake**. Do not dilute the vaccine.
- Each dose is 0.5 mL.
- After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on D-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.
- Administer the Moderna COVID-19 vaccine intramuscularly.

![](_page_22_Picture_10.jpeg)

#### Moderna COVID-19 Vaccine

#### Storage & Handling

#### **EMERGENCY USE AUTHORIZATION**

12

hours

Cool storage up to

8º to 25ºC (46º to 77ºF)

room temperature

The Moderna COVID-19 Vaccine has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA), to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 18 years of age and older. There is no FDA-approved vaccine to prevent COVID-19.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the declaration is terminated or the authorization is revoked sooner.

![](_page_23_Figure_5.jpeg)

![](_page_23_Figure_6.jpeg)

**NEVER** refreeze thawed vaccine

Vial should be held between

2° to 25°C (36° to 77°F). Record the date

and time of first use on the vial label.

Discard punctured vial after 6 hours.

### Moderna COVID-19 Vaccine Dosing & Schedule

- The Moderna COVID-19 Vaccine is administered as a series of two doses (0.5 mL each) 1 month apart.
- Per the guidance from the FDA and the CDC, use every available dose per vial. DO NOT mix partial doses from different vials.
  - Further guidance coming from the CDC on ordering additional ancillary supplies.
- There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series.
- Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

![](_page_24_Picture_6.jpeg)

### **Moderna COVID-19 Vaccine** Warning - Management of Acute Allergic Reactions

- Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.
- Monitor Moderna COVID-19 vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines.
  - All vaccine recipients be observed for 15 minutes after vaccination.
  - Person with a history of anaphylaxis, due to any cause, be observed for 30 minutes after vaccination.

![](_page_25_Picture_5.jpeg)

### Moderna COVID-19 Vaccine Pregnancy

#### **Pregnancy Exposure Registry**

 There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866- MODERNA (1-866-663-3762).

![](_page_26_Picture_3.jpeg)

### **Moderna COVID-19 Vaccine** Mandatory Provider Requirements for Administration under EUA

- Provider must provide to the individual receiving the vaccine the "Fact Sheet for Recipients and Caregivers" prior to vaccination.
- Must report doses administered in ImmTrac2 within 24 hours post vaccination
  - Report complete information including race/ethnicity
- Provider must report the following to the Vaccine Adverse Event Reporting System (VAERS): <u>https://vaers.hhs.gov/reportevent.html</u>
  - Vaccine administration errors whether or not associated with an adverse event,
  - Serious adverse events\* (irrespective of attribution to vaccination),
  - Cases of Multisystem Inflammatory Syndrome (MIS) in adults, and
  - Cases of COVID-19 that result in hospitalization or death.

![](_page_27_Picture_9.jpeg)

### **Additional Vaccine Safety Monitoring** *v-safe* | after vaccination health checker

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V-safe is a smartphone-based tool that uses text messaging and web surveys to provide **personalized health check-ins** after someone receives a COVID-19 vaccination.

![](_page_28_Picture_3.jpeg)

Vaccine recipients can quickly tell the CDC if they have any side effects. The CDC may follow up with them by phone to get more information.

![](_page_28_Picture_5.jpeg)

**V-safe** will also remind them to get their second COVID-19 vaccine dose, if needed.

![](_page_28_Picture_7.jpeg)

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

![](_page_28_Picture_9.jpeg)

### **V-Safe** | after vaccination health checker

#### How long do v-safe check-ins last?

- During the first week after you get your vaccine, *v-safe* will send you a text message each day to ask how you are doing.
- Then you will get check-in messages once a week for up to 5 weeks.
- The questions *v-safe* asks should take less than 5 minutes to answer.
- If you need a second dose of vaccine, *v-safe* will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well.
- You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

![](_page_29_Picture_7.jpeg)

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

![](_page_29_Picture_9.jpeg)

### **v-safe** | your role as a provider

- Give patients a v-safe information sheet at the time of vaccination
- Encourage them to enroll and fill out the surveys when prompted

https://vsafe.cdc.gov/

V-safe now available in Spanish https://espanol.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe.html

![](_page_30_Picture_5.jpeg)

# What to Expect this Week?

![](_page_31_Picture_1.jpeg)

### This week

- Moderna COVID-19 Vaccine shipment to the 23 sites scheduled to be delivered on Monday/Tuesday (12/21/2020 -12/22/2020).
  - Please check VAOS for your shipping tracking number.
  - Ancillary supplies have been shipped.
- All other sites expected to receive vaccine shipments Tuesday Thursday
  - Please check in VAOS for your shipping tracking number.
  - Ancillary supplies will either arrive the day of the vaccine shipment or one day prior.

#### **Provider Name BSA HEALTH SYSTEM** PAMPA REGIONAL MEDICAL CENTER JPS STOP SIX CLINIC JPS NORTHEAST CHC TITUS REGIONAL MEDICAL CENTER WOODLAND HEIGHTS MEDICAL CENTER CHI ST LUKES HLTH MEMORIAL LUFKIN VICTORIA COUNTY PUBLIC HEALTH DEPARTMENT CHRISTUS SANTA ROSA HOSPITAL NEW BRAUNF PECOS COUNTY MEMORIAL HOSPITAL DBA FAMI UNITED MEMORIAL MEDICAL CENTER ODESSA REGIONAL MEDICAL CENTER BSW MEDICAL CENTER MARBLE FALLS SCENIC MOUNTAIN MEDICAL CTR LAREDO REGIONAL MEDICAL CENTER ASCENSION SETON HIGHLAND LAKES MEDICAL CITY WEATHERFORD CHI STLUKES HEALTH BRAZOSPORT CHRISTUS SPOHN HEALTH SYSTEM BEEVILLE MEDICAL CENTER HOSPITAL CHRISTUS SPOHN HEALTH SYSTEM SOUTH MEDICAL CITY DENTON HENDRICK MEDICAL CENTER BROWNWOOD

### **Important Reminders**

- Accept vaccine orders in VAOS.
- Print out Fact Sheet and V-safe documents to give to individuals getting vaccinated.
- Fill out the shot record cards in the ancillary kit supplies.
- Report **daily** all doses administered data to ImmTrac2.

![](_page_33_Picture_5.jpeg)

### Moderna Healthcare Providers Training Webinar

- December 23 at 12:00 PM EST <u>https://zoom.us/webinar/register/WN\_GYOVNrkAS6yNQ5LXgI3</u> <u>mfQ</u>
- December 29 at 3:00 PM EST <u>https://zoom.us/webinar/register/WN\_0ZFGO3UTQ060puKHzZn</u> <u>Elw</u>

![](_page_34_Picture_3.jpeg)

### **Closing Remarks**

- Calls from the Texas Department of Emergency Management
- Media Inquiries
  - There is intense media attention around the arrival of vaccine. If you are getting questions, how you engage is up to you. Some sites are planning to document vaccine arrival and administration with photos and video and release them to the media.
- Vaccinate with URGENCY
- THANK YOU for your partnership

![](_page_35_Picture_6.jpeg)

### Resources

#### Website for Providers:

www.dshs.texas.gov/coronavirus/immunize/provid er-information.aspx

FAQ for Providers https://www.dshs.texas.gov/immunize/covid19/CO VIDproviderfaq.pdf

#### **DSHS COVID-19 Vaccine Provider hotline:**

(877) 835-7750, 8 a.m. to 5 p.m., Monday - Friday Email: <u>COVID19VacEnroll@dshs.texas.gov</u>.

Website to enroll as a COVID-19 provider: EnrollTexasIZ.dshs.texas.gov.

General Questions: Email: <u>COVIDvaccineQs@dshs.texas.gov</u>

Texans Vaccinated for COVID-19 website

ImmTrac2 support Email:

(800) 348-9158, 8 a.m. to 5 p.m., Monday - Friday ImmTrac2@dshs.texas.gov

V-safe https://vsafe.cdc.gov/ https://espanol.cdc.gov/coronavirus/2019ncov/vaccines/safety/vsafe.html

Vaccine Adverse Event Reporting System (VAERS): <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>

Moderna (Pregnancy Registry & MedInfo): medinfo@modernatx.com 1-866- MODERNA (1-866-663-3762) www.modernatx.com/covid19vaccine-eua

CDC McKesson: Phone #: 833-272-6634 SNSSupport@McKesson.com

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![](_page_37_Picture_1.jpeg)

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