COVID-19 Pandemic Response and Vaccine Update

March 10, 2021

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Texas Department of State Health Services
Overview

• COVID-19 Timeline & Statistics
• Pandemic Response
• Vaccine Rollout
• Vaccine Communication
• Therapeutics Research
COVID-19 Timeline & Statistics
COVID-19 Timeline

• **December 31, 2019**: Municipal Health Commission reported cases of pneumonia with an unknown cause in Wuhan City, Hubei Province, China

• **January 7, 2020**: Chinese authorities identified a new (novel) type of coronavirus

• **January 21**: Centers for Disease Control and Prevention (CDC) confirmed first case of novel coronavirus in the U.S. in Washington state

• **January 23**: DSHS launched the [dshs.texas.gov/coronavirus/](http://dshs.texas.gov/coronavirus/) website and prepared #TexasDSHS social media campaigns

• **January 31**: DSHS activated the State Medical Operations Center (SMOC)
COVID-19 Timeline

• March 4: DSHS announced the first positive test result for COVID-19
• March 17: DSHS announced the first lab-confirmed COVID-19 death
• March 19: DSHS Commissioner Hellerstedt declared a Public Health Disaster for Texas
• October: DSHS assembled the Expert Vaccine Allocation Panel (EVAP)
• November 10: DSHS launched a COVID-19 Vaccine Information Website
• December 14: DSHS distributed the first COVID-19 vaccine doses
• February 12, 2021: 1 million people fully vaccinated in Texas
• March 9, 2021: 2,326,885 confirmed COVID-19 cases reported in all 254 Texas counties with 44,650 fatalities
New Confirmed Texas Cases by Day

New Texas Fatalities by Day

These preliminary data are current as of 2/22/2021.

Note: As of July 27, DSHS is reporting COVID-19 fatality data based on death certificates. The metric used in these charts reports total newly reported fatalities (as opposed to the date of death).

Note: During the week of Feb. 14-Feb. 21, 2021, case and fatality reporting was significantly impacted across the majority of Texas counties due to weather-related issues.
Hospitalizations Over Time
Total Texas Proportion of Lab-Confirmed COVID-19 Occupancy of General and ICU Beds out of Total Hospital Beds as of:

Sunday, February 21, 2021, Totals

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab-Confirmed COVID-19 in General</td>
<td>4,762</td>
</tr>
<tr>
<td>Lab-Confirmed COVID-19 in ICU</td>
<td>2,114</td>
</tr>
<tr>
<td>Total Lab-Confirmed COVID-19 Gen + ICU</td>
<td>6,876</td>
</tr>
</tbody>
</table>

Notes:
- The most recent hospital data is reported for the day prior.
- After 7/24/2021, DSHS reported incomplete hospitalization numbers due to a transition in reporting to comply with new federal requirements.

These preliminary data are current as of 1:00pm on 2/22/2021.
*as of March 8, 2021
Texas COVID-19 Trends: A Full Picture

Total Texas Covid-19 Confirmed Cases, Confirmed New Cases, and Current Confirmed Hospitalizations

Legend
- Blue: State Cases
- Orange: New State Confirmed Cases
- Brown: Currently Hospitalized

These preliminary data are current as of 1:00pm on 2/22/2021.

Notes:
- Mar 22, 2020: DHHS reported incomplete hospitalization numbers due to a transition in reporting to comply with new federal requirements. As of 8/19/2020, 99% of hospitals were reporting.

Total Texas Covid-19 Fatalities

Notes:
- As of July 27, 2020, DHHS is reporting COVID-19 fatality data based on death certificates. The metric used in these charts reports total newly reported fatalities (as opposed to the date of death).
- Notes: During the week of Feb 14-Feb 21, 2021, case and fatality reporting was significantly impacted across the majority of Texas counties due to weather-related issues.
Demographics

Cases & Mortality by Age

Cases & Mortality by Race/Ethnicity

*as of March 7, 2021*
Pandemic Response
DSHS Roles during the Pandemic

• Coordination of local and state public health efforts
• Statewide management and provision of lab testing and capacity
• Data collection, analysis, and reporting
• Health care system support and deployment of medical staffing to hospitals and nursing facilities
• Statewide public education and awareness
• Public health guidance for individuals and businesses, and consultation with local elected leaders
• Sourcing and allocating therapeutics and medications, medical supplies, and personal protective equipment
• Utilizing the established infrastructure and expanding it further to safely and appropriately disseminate vaccine
<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days of emergency response activation</td>
<td>401</td>
</tr>
<tr>
<td>DSHS staff working on COVID response</td>
<td>1,567</td>
</tr>
<tr>
<td>COVID data points collected and processed daily</td>
<td>193,000</td>
</tr>
<tr>
<td>Vaccinators fully registered to administer COVID vaccine</td>
<td>7,332</td>
</tr>
<tr>
<td>Maximum medical surge staff deployed</td>
<td>13,737</td>
</tr>
<tr>
<td>Hospitals supported with medical surge staff</td>
<td>229</td>
</tr>
<tr>
<td>Calls or emails to DSHS Call Center staff</td>
<td>82,781</td>
</tr>
<tr>
<td>Doses administered</td>
<td>6,970,799</td>
</tr>
<tr>
<td>Public health follow up staff supporting local health departments</td>
<td>3,561</td>
</tr>
<tr>
<td>COVID tests performed by the state public health laboratory</td>
<td>75,385</td>
</tr>
<tr>
<td>Patient courses of monoclonal antibodies allocated to treat COVID patients</td>
<td>81,701</td>
</tr>
<tr>
<td>Persons fully vaccinated</td>
<td>2,463,006</td>
</tr>
<tr>
<td>Alternate Care Beds</td>
<td>1,340</td>
</tr>
<tr>
<td>Isolation and Quarantine Sites</td>
<td>140</td>
</tr>
<tr>
<td>State of Texas Assistance Request related to the pandemic</td>
<td>2,965</td>
</tr>
</tbody>
</table>

*as of March 9, 2021*
Pandemic Hurdles Addressed

• Expanding initial testing capacity & managing PPE scarcity
• Expanding and standardizing testing, hospital, and mortality reporting
• Scaling public health follow up
• Addressing COVID-19 hospitalizations
• Adapting prevention messaging as new scientific data emerges
• Scaling vaccine effort to meet statewide need and demand
Pandemic Response Overview

- Rapidly modernized the lab result reporting system—National Electronic Disease Surveillance System (NEDSS)
  - Increasing daily lab result ingestion by 9,990% (from 2,000 to 200,000 per day)
- Processed 89,040 hospitalizations data points from Texas healthcare facilities on daily basis
  - Over 20 million COVID-19 data points collected from hospitals to date
- Developed a functioning statewide public health follow up system in less than three weeks
  - Mature system within five months with significant participation by local health jurisdictions
  - Grew DSHS-supported public health follow up staff from 115 to 2,400
- Supported responses to more than 600 facility outbreaks
- DSHS given “A” grade from The COVID Tracking Project for data transparency
  - Based on consistent, reliable, and complete reporting including patient outcomes and demographics
## COVID-19 Pandemic Expenditures (Estimated)

<table>
<thead>
<tr>
<th>Category</th>
<th>How much we spent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Surge Staffing</td>
<td>$4.5 Billion</td>
</tr>
<tr>
<td>Local Response</td>
<td>$261.3 Million</td>
</tr>
<tr>
<td>Disease Surveillance</td>
<td>$160.8 Million</td>
</tr>
<tr>
<td>Local Contracts</td>
<td>$67.3 Million</td>
</tr>
<tr>
<td>Lab Costs</td>
<td>$27.7 Million</td>
</tr>
<tr>
<td>Repatriation</td>
<td>$5.5 Million</td>
</tr>
<tr>
<td>Other Costs</td>
<td>$0.5 Million</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$5.0 Billion</strong></td>
</tr>
</tbody>
</table>

*as of March 9, 2021*
Current Staff Deployed: 11,702
(staff demobilization continues)

Maximum Staff Deployed: 13,737
Medical Surge Staff Working
July 2020-March 5, 2021
# Federal Grants to Support COVID-19 Expenses

<table>
<thead>
<tr>
<th>Grantor</th>
<th>Description</th>
<th>Total in Millions</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FEMA</strong></td>
<td>Public Assistance - FEMA Category B</td>
<td>$2,399.6</td>
<td>General disaster public assistance. The funds require a 25% state match. Additional funds can be requested.</td>
</tr>
<tr>
<td>Dept of Treasury</td>
<td>Coronavirus Relief Fund (CRF)- CARES Act</td>
<td>$2,009.5</td>
<td>Various uses, funds allocated to DSHS for direct care medical staffing needs.</td>
</tr>
<tr>
<td><strong>CDC</strong></td>
<td>Coronavirus Response and Relief Supplemental Appropriations Act/Epi &amp; Lab Capacity (ELC) Enhancing Detection Expansion</td>
<td>$1,535.4</td>
<td>Develop, purchase, administer, process, and analyze COVID-19 tests, conduct surveillance, and related activities.</td>
</tr>
<tr>
<td>CDC</td>
<td>Paycheck Protection Program and Health Care Enhancement Act/Epi &amp; Lab Capacity for Testing (PPPHEA-ELC)</td>
<td>$473.6</td>
<td>Develop, purchase, administer, process, and analyze COVID-19 tests, conduct surveillance, and related activities.</td>
</tr>
<tr>
<td>CDC</td>
<td>Coronavirus Response and Relief Supplemental Appropriations Act/Implementation and Expansion of the Vaccine Program</td>
<td>$227.1</td>
<td>Vaccine distribution and administration</td>
</tr>
<tr>
<td>CDC</td>
<td>Coronavirus Preparedness and Response Supplemental Appropriations (Crisis CoAg)</td>
<td>$55.1</td>
<td>Crisis response and recovery, information and surge management, surveillance</td>
</tr>
<tr>
<td>CDC</td>
<td>CARES Act/Epi &amp; Lab Capacity to Reopen America. (ELC)</td>
<td>$39.1</td>
<td>Surveillance, epidemiology, lab capacity, data surveillance and analytics infrastructure, disseminating information about testing, and workforce support necessary to expand and improve COVID–19 testing.</td>
</tr>
<tr>
<td>CDC</td>
<td>COVID-19 Supplemental via 2020 CARES ACT Round 1</td>
<td>$14.4</td>
<td>Plan and implement COVID-19 vaccination services</td>
</tr>
<tr>
<td>CDC</td>
<td>PPPHEA National Center for Immunization and Respiratory Diseases</td>
<td>$10.1</td>
<td>Enhanced Influenza-COVID19 response for staffing, communication, preparedness and vaccination, with emphasis on enrolling new vaccinators. Funds may not be used to purchase vaccines.</td>
</tr>
<tr>
<td>CDC</td>
<td>COVID-19 Supplemental via 2020 CARES ACT Round 2</td>
<td>$10.1</td>
<td>Plan and implement COVID-19 vaccination services</td>
</tr>
</tbody>
</table>
### Federal Grants to Support COVID-19 Expenses

<table>
<thead>
<tr>
<th>Grantor</th>
<th>Description</th>
<th>Total in Millions</th>
<th>Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASPR</td>
<td>CARES Act - Hospital Preparedness Program Supplemental Award for COVID-19 (CARES HPP)</td>
<td>$8.7</td>
<td>Urgent preparedness and response needs of hospitals, health systems, and health care workers on the front lines.</td>
</tr>
<tr>
<td>CDC</td>
<td>Paycheck Protection Program and Health Care Enhancement Act Epi &amp; Lab Capacity</td>
<td>$5.4</td>
<td>focus on genetic testing lab preparedness; and ensuring safe travel through optimized data sharing and communication with international travelers</td>
</tr>
<tr>
<td>CDC</td>
<td>ELC /Healthcare-associated Infections/ Antimicrobial Resistance Program (ELC-HAI)</td>
<td>$3.7</td>
<td>Funds support Project Firstline, a CDC training collaborative for health care infection prevention and control.</td>
</tr>
<tr>
<td>HRSA</td>
<td>CARES Act - Ryan White HIVAIDS</td>
<td>$1.5</td>
<td>Infrastructure and practice improvement needed to prevent, prepare, and respond to COVID-19 for Texans living with HIV.</td>
</tr>
<tr>
<td>HUD</td>
<td>CARES Act - Housing Opportunities for Persons With AIDS COVID-19 Supplemental (CARES HOPWA)</td>
<td>$0.7</td>
<td>Allowable activities authorized by the AIDS Housing Opportunity Act to maintain housing for low-income persons living with HIV (PLWH) and their households.</td>
</tr>
<tr>
<td>ASPR</td>
<td>Paycheck Protection Program and Health Care Enhancement Act (PPPHEA) (PPP HPP Ebola)</td>
<td>$0.4</td>
<td>Funds dedicated for Special Pathogen Hospital to increase the capability of health care systems to safely manage individuals with suspected and confirmed COVID-19.</td>
</tr>
<tr>
<td>ASPR</td>
<td>CARES Act - Hospital Preparedness Program Ebola (CARES HPP Ebola)</td>
<td>$0.3</td>
<td>Funds dedicated for Special Pathogen Hospital to increase the capability of health care systems to safely manage individuals with suspected and confirmed COVID-19.</td>
</tr>
<tr>
<td>CDC</td>
<td>Rape Prevention &amp; Education: Using the Best Available Evidence for Sexual Violence Prevention - COVID-19</td>
<td>$0.3</td>
<td>The OAG will interagency cooperation contracts with Texas Association Against Sexual Violence and Texas A&amp;M University Health Science Center to enhance existing activities that address the most pressing COVID-19 related violence issues including Intimate Partner Violence</td>
</tr>
<tr>
<td>HHS</td>
<td>ATSDR’s Partnership to Promote Local Efforts to Reduce Environmental Exposure – COVID-19</td>
<td>$0.2</td>
<td>Development of a training and educational module on safe ways to disinfect for COVID-19 at home-based child care facilities.</td>
</tr>
<tr>
<td>USDA</td>
<td>Cooperative State Meat and Poultry Inspection – COVID-19</td>
<td>$0.01</td>
<td>COVID-19 specific prevention and safety activities.</td>
</tr>
</tbody>
</table>
Vaccine Rollout
Phased Approach

- **Phase 0 (Oct.-Nov. 2020)**: Planning and provider recruitment
- **Phase 1 (Dec. 2020-Present)**: Limited supply of COVID-19 vaccine doses available
- **Phase 2 (Mar.-July 2021)**: Increased number of vaccine doses available
- **Phase 3 (July - Oct. 2021)**: Sufficient supply of vaccine doses for entire population
- **Phase 4 (Oct. 2021 forward)**: Sufficient supply of vaccine with decreased need due to most of population being vaccinated previously
Vaccine Distribution Process

1. CDC Recommendation & Vaccine Allocations
2. DSHS – Monitors Allocations & Models Options
3. EVAP Reviews Options and Issues Recommendations
4. DSHS Commissioner – Makes Final Allocation Decision
5. DSHS Loads Orders Into System – CDC Facilitates Direct Shipment
COVID-19 Expert Vaccination Allocation Panel (EVAP)

• Texas has convened a team of appointed external and internal subject-matter experts into the COVID-19 Expert Vaccine Allocation Panel to develop vaccine allocation strategies as recommendations to the Texas Commissioner of Health.

• The panel has developed guiding principles and utilizes in their recommendations.

• The recommendations from the Expert Vaccine Allocation Panel will be sent to the Texas Commissioner of Health for final approval.

• EVAP voting members
Texas will allocate COVID-19 vaccines that are in limited supply based on:

• **Protecting healthcare workers** who fill a critical role in caring for and preserving the lives of COVID-19 patients and maintaining the healthcare 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.
### Texas Phase 1A and 1B Definitions

<table>
<thead>
<tr>
<th>Phase 1A, Tier 1</th>
<th>Phase 1A, Tier 2</th>
<th>Phase 1B</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Paid &amp; unpaid workers in hospital settings working directly with patients who are positive or at high risk for COVID-19</td>
<td>• Staff in outpatient care settings who interact with symptomatic patients</td>
<td>• People 65 years of age and older</td>
</tr>
<tr>
<td>• Long-term care staff working directly with vulnerable residents</td>
<td>• Direct care staff in freestanding emergency medical care facilities and urgent care clinics</td>
<td>• People 16 years of age and older with at least one chronic medical condition that puts them at increased risk for severe illness from the virus that causes COVID-19</td>
</tr>
<tr>
<td>• EMS providers who engage in 911 emergency services like pre-hospital care and transport</td>
<td>• Community pharmacy staff who may provide direct services to clients, including vaccination or testing for individual who may have COVID-19</td>
<td></td>
</tr>
<tr>
<td>• Home health care workers, including hospice care, who directly interface with vulnerable and high-risk patients</td>
<td>• Public health and emergency response staff directly involved in administration of COVID-19 testing and vaccinations</td>
<td></td>
</tr>
<tr>
<td>• Residents of long-term care facilities</td>
<td>• Last responders who provide mortuary or death services to decedents with COVID-19</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• School nurses who provide health care to students and teachers</td>
<td></td>
</tr>
</tbody>
</table>

~13.5 million Texans in Phase 1A and 1B
Federal Directive: School/Daycare Settings

• **Tuesday, March 5th:** DSHS notified by US Health and Human Services that all COVID-19 providers should include school and daycare staff on list of people eligible to be vaccinated

• **Includes:**
  • "those who work in pre-primary, primary, and secondary schools, as well as Head Start and Early Head Start programs (including teachers, staff, and bus drivers)"
  • "those who work as or for licensed child care providers, including center based and family care providers."

• **Effect in Texas:** Texas 1A & 1B populations, and persons meeting school/daycare staff criteria outlined above are eligible to receive vaccine
COVID-19 Vaccine: Texas Milestones

- December 14, 2020: First doses of COVID-19 Vaccine arrive in Texas
- December 21, 2020: DSHS announces Phase 1B population definition
- December 23, 2020: DSHS announced vaccinating Phase 1A & 1B population.
- January 14, 2021: 1 Million doses of COVID-19 vaccine administered in Texas
  - 1M Dose administered reported in ImmTrac2 retrospectively by January 9, 2021
- January 28, 2021: 2 Million doses of COVID-19 vaccine administered in Texas
  - 2M Dose administered reported in ImmTrac2 retrospectively by January 24, 2021
- February 6, 2021: 3 Million doses of COVID-19 vaccine administered in Texas
  - 3M Dose administered reported in ImmTrac2 retrospectively by February 5, 2021
- February 12, 2021: 1 Million Texans fully vaccinated
  - 1M fully vaccinated reported in ImmTrac2 retrospectively by February 11, 2021
- February 13, 2021: 4 Million doses of COVID-19 vaccine administered in Texas
  - 4M Dose administered reported in ImmTrac2 retrospectively by February 11, 2021
- February 26, 2021: 5 Million doses of COVID-19 vaccine administered in Texas
  - 5M Doses administered reported in ImmTrac2 retrospectively by February 25, 2021
- March 3, 2021: 2 Million Texans fully vaccinated
  - 2M fully vaccinated reported in ImmTrac2 retrospectively by February 27, 2021
- March 4, 2021: 6 Million doses of COVID-19 vaccine administered in Texas
  - 6M Doses administered reported in ImmTrac2 retrospectively by March 2, 2021
Vaccine Distribution – Provider Enrollment

• All interested providers required to register with DSHS
• Must meet ordering, handling, administration, and reporting requirements
• Common registered COVID-19 provider types:
  • Hospitals
  • Health departments
  • Federally qualified health centers (FQHCs)
  • Rural health clinics
  • Long term care facilities
  • Fire departments
  • Medical practices
• Fully-enrolled providers: 7,332
# Vaccine Distribution Strategies - State

## Community Based Providers
- Ensure that rural communities and underserved areas have access to vaccine
- Register with individual provider

## Vaccine Hubs
- Mass efforts to quickly vaccinate 1,000s of Phase 1A and 1B individuals each week
- Must use all doses and report doses administered to DSHS and Texas Division of Emergency Management
- Register online or by phone

## Other State Programs
- Mobile Vaccine Pilot Program: Vaccination Texas National Guard deployed to certain rural counties
- Save Our Seniors: Texas National Guard deployed to vaccinate homebound seniors

## DSHS Regions
- DSHS Region offices hold local clinics
- Facilitate open enrollment for providers to serve in hard-to-reach areas

## Other State Initiatives
- Federal Qualified Health Centers to reach medically underserved
- Long Term Care/Intellectual or Developmental Disability - partnering with pharmacies not served by Federal Long Term Care program
Vaccine Distribution Strategies - Federal

**Pharmacy Program for Long-Term Care Facilities**
- Federal program to vaccinate staff and residents of nursing homes and long-term care
- Partnership with DSHS, HHS, Walgreens and CVS

**Federal Retail Pharmacy Program**
- Vaccines sent to pharmacies nationwide
- Doses shipped directly to Texas pharmacies will not be deducted from Texas allocations

**Federal Emergency Management Agency (FEMA)**
- Administering doses in Harris, Dallas, and Tarrant Counties
- Doses are on top of state's normal allotment
- EVAP redistributing allocations with excess doses to address needs in other counties to maintain geographic equity

**Federally Qualified Health Centers (FQHC)**
- Receiving direct allocations from the Federal Government
- 38 Texas facilities have been announced to receive allotments

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Getting Vaccines to all Texans
Vaccine Allocations Per Week

Week 1 - 13 Vaccine Allocations

First Doses  Second Doses

<table>
<thead>
<tr>
<th>Week</th>
<th>First Doses</th>
<th>Second Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>224,250</td>
<td>100,000</td>
</tr>
<tr>
<td>2</td>
<td>620,400</td>
<td>200,000</td>
</tr>
<tr>
<td>3</td>
<td>325,000</td>
<td>300,000</td>
</tr>
<tr>
<td>4</td>
<td>325,000</td>
<td>400,000</td>
</tr>
<tr>
<td>5</td>
<td>319,000</td>
<td>500,000</td>
</tr>
<tr>
<td>6</td>
<td>333,650</td>
<td>500,000</td>
</tr>
<tr>
<td>7</td>
<td>332,750</td>
<td>520,425</td>
</tr>
<tr>
<td>8</td>
<td>216,350</td>
<td>401,750</td>
</tr>
<tr>
<td>9</td>
<td>188,225</td>
<td>407,650</td>
</tr>
<tr>
<td>10</td>
<td>330,925</td>
<td>433,650</td>
</tr>
<tr>
<td>11</td>
<td>591,920</td>
<td>516,830</td>
</tr>
<tr>
<td>12</td>
<td>676,280</td>
<td>429,600</td>
</tr>
<tr>
<td>13</td>
<td>929,320</td>
<td>457,000</td>
</tr>
</tbody>
</table>
Vaccine Use Breakdown

First Dose Administered, 3,911,642
Second Dose Administered, 2,177,635
Vaccine Pending Administration, 1,277,380
Vaccine Waste, 2,029

*as of March 5, 2021

Improved Race/Ethnicity Reporting

Proportion of first doses reported administered with unknown race/ethnicity

2/4 - 3/7 First Doses Reported Administered by Race/Ethnicity

12/14 - 2/3 First Doses Reported Administered by Race/Ethnicity
Therapeutics Research

Updated Food and Drug Administration Guidelines for Certain Monoclonal Antibodies
Monoclonal Antibodies Overview

- FDA issued Emergency Use Authorizations for three COVID-19 Monoclonal Antibody regimens

- Products intended for Outpatients with:
  - Mild to moderate COVID-19
  - High risk for progressing to severe disease and/or hospitalizations

- Federal government purchased doses of both monoclonal antibody regimens and is providing free of charge to qualified facilities
  - Previously, state health departments (DSHS) directed allocation process
  - In February 2021, allocation process shifted to direct ordering by facilities to the product distributor
  - If supplies run scarce, process will revert to state-directed allocation
Monoclonal Antibodies EUAs

- **November 2020:** Food and Drug Administration (FDA) issues Emergency Use Authorizations (EUA):
  - **Products:** bamlanivimab (Eli Lilly), casirivimab/imdevimab (Regeneron)
  - **Emergency Use Authorization:** based on phase 1 and 2 clinical trial data
  - **National Institutes of Health Guidelines:** insufficient data to recommend for or against the use of these products for their intended purposes under the EUA

- **February 2021:** FDA issues new Emergency Use Authorization for monoclonal antibodies
  - **Products:** bamlanivimab/etesevimab (Eli Lilly)
  - **Emergency Use Authorization:** based on phase 3 clinical trial data – which includes more robust analysis, including hospitalizations and deaths
  - **National Institutes of Health Guidelines:** recommends use of this regimen for outpatient treatment for mild/moderate COVID-19 in outpatients that meet Emergency Use Authorization criteria
Thank you

Presentation to the Senate Committee on Health and Human Services

Dr. John Hellerstedt, Commissioner
Imelda Garcia, Associate Commissioner